

**Directorate General of Foreign Trade**  
**Ministry of Commerce & Industry, Maulana Azad Road, Udyog Bhawan New**  
**Delhi -110011**

-----

**Para 4.7 Decision**

**MEETING NUMBER** : 31/82-ALC4/2007 **MEETING DATE** : 04.12.2007

The Meeting No.31/08 for the licensing year 2007-08 to consider the cases under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2004-09 pertaining to Pharma Products was held on 04.12.2007 under the Chairmanship of Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No.28/08 dated 13.11.2007 were ratified by the Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Case No.B-416                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | M/S Avon Organics Ltd.,        |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | F.No.01/87/50/127/AM06/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | RLA F.No.09/24/40/20/AM06      |
| Adv.Lic. No.0910022755 dated 09.05.2005                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                |
| <p>Committee considered case as per agenda for ratification of norms for export product 5 Aceto Acetyl Amino Benzimidazolone (AABZ) or 5 Aceto Acetyl Amino Benzimidaxolone-2(AABI) under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/100/2005-PI-III dated 30.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>5-Aceto Acetyl Amino Benzimidazolone or<br/>5-Aceto Acetyl Amino Benzimidaxolone-2(AAB)-----1kg.</p> <p>Import items:</p> <p>1. Acetic Acid-----1.43kg/kg<br/>2. Triethyl phosphate (TEP)-----0.0050kg/kg<br/>3. DABCO Crystalline (1,4 diazobicyclo (2,2,2)-Octane---0.0013kg/kg<br/>4. Methanol-----0.70kg/kg<br/>5. 5-amino Benzimidazolone -----0.89kg/kg</p> <p style="text-align: center;"><b>OR</b></p> <p>5a Ortho Phenylene Diamine-----0.95kg/kg<br/>5b Urea-----0.57kg/kg<br/>5c Chlorobenzene-----0.57kg/kg<br/>5d Sodium hydroxide flakes/Caustic Soda flakes-----0.061kg/kg<br/>5e Raney Nickel-----0.100kg/kg<br/>5f Activated Carbon-----0.050kg/kg</p> |                                |

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Case No.B-417                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | M/S Advy Chemical              |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | F.No.01/87/50/313/AM07/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | RLA F.No.03/94/40/310/AM07     |
| Adv.Lic. No.0310387468 dated 29.06.2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                |
| <p>Committee considered case as per agenda for ratification of norms for export product HBs Ag Subtypes ad Reagent (4000mgs) (Hepatitis B Surface antigen-subtypes ad) under para 4.7 of HBP.</p> <p>Committee observed that written comments forwarded by Department of Biotechnology vide their letter No.BT/IL/05/231/06/2006-PID dated 06.08.2007 does not contain unit of measurement of quantity of inputs. Committee, therefore, decided to again refer the case to DBT for their comments. Accordingly, case was deferred for four weeks.</p> |                                |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Case No.B-418                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | M/S Cadila Pharmaceuticals Ltd. |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | F.No.01/82/50/757/AM05/DES-III  |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | RLA F.No.08/24/40/45/AM05       |
| Adv.Lic. No.0810040146 dated 08.07.2004                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                 |
| <p>Committee considered case as per agenda for ratification of norms for export product Carbetapentane Tannate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/258/2004-PI-III dated 04.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Carbetapentane Tannate-----1kg.</p> <p>Import items:<br/>1. Carbetapentane Citrate-----0.86kg/kg<br/>2. Tannic Acid-----0.73kg/kg</p> |                                 |

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                             |                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Case No.B-419                                                                                                                                                                                                                                                                               | M/S Divi's Laboratories Ltd.  |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                            | F.No.01/82/50/56/AM07/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                    | RLA F.No.09/24/40/182/AM01    |
| Adv.Lic. No.0910019924 dated 30.08.2004                                                                                                                                                                                                                                                     |                               |
| <p>Committee considered case as per agenda for revision of norms for export product Capecitabine under para 4.7 of HBP.</p> <p>Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for four weeks.</p> |                               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Case No.B-420                                                                                                                                                                                                                                                                                                                                                                                                                                       | M/S Zandu Chemicals Ltd.                                         |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                                                                                                                                                                                    | F.No.01/83/50/242/AM07/DES-III<br>F.No.01/83/50/428/AM06/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                                                                                                                                                                            | RLA F.No.03/95/40/789/AM06<br>RLA F.No.03/95/40/123/AM07         |
| Adv.Lic. No.0310355085 dated 10.11.2005<br>Adv.Lic. No.0310382709 dated 01.06.2006                                                                                                                                                                                                                                                                                                                                                                  |                                                                  |
| <p>Committee considered case as per agenda for revision of norms for export product Carbamic Acid-[2-Hydroxy-3-(2-methyl propyl) [4-nitrophenyl)sulphonyl]-Amino]-1-(phenyl methyl) propyl-1,1-dimethyl ester (BOC Nitro) purity 99.5% under para 4.7 of HBP.</p> <p>Committee observed that norms were ratified in this case on the basis of written comments of Chemical Division. It was, therefore, decided to transfer the case to DES-IV.</p> |                                                                  |

|                                  |                                  |
|----------------------------------|----------------------------------|
| Case No.B-421                    | M/S Sandoz Pvt. Ltd.             |
| Norms Committee Meeting No.31/08 | F.No.01/82/162/1266/AM01/DES-III |
| Meeting Date: 04.12.2007         |                                  |
| Adv.Lic. No.0310002380 dated     |                                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 27.07.1999                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <p>Committee considered case as per agenda for revision of norms for export product Aminolupetitim under para 4.7 of HBP.</p> <p>Committee observed that a report regarding development of case was called for from concerned RA, but same has not been received. Committee also observed that Advance Authorisation is dated 27.07.99 and it is not possible to revise norms against such an old licence. It was, therefore, decided to close the case.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |  |

|                                                                                                                                                                                                                                                                                                                                                                                                       |                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Case No.C-26                                                                                                                                                                                                                                                                                                                                                                                          | M/S R.L. Fine Chem.            |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                                                                                                                                      | F.No.01/82/162/47/AM08/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                                                                                                                              |                                |
| <p>Committee considered case as per agenda for modification of SION in respect of export product at Sl.No.A-3357.</p> <p>Committee observed that All Industry Data was called for from Pharmexcil, but same has not been received. Committee, therefore, decided a plant visit may be taken by a team and recommend the norms. Accordingly, case was deferred till receipt of report is received.</p> |                                |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Case No.A-882                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | M/S Arch Pharma Labs Ltd.       |
| Norms Committee Meeting No.31/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | F.No.01/82/162/591/AM08/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | RLA F.No.03/94/40/125/AM07      |
| Adv.Lic. No.0310381222 dated 25.05.2006                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                 |
| <p>Committee considered case as per agenda for ratification of norms for export product Clopidogrel Bisulphate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/192/2006-PI-III dated 24.04.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Clopidogrel bisulphate-----1kg.<br/>Import items:<br/>1. DL-2 chloro phenyl glycine-----1.05kg/kg</p> |                                 |

2. Thiophene 2-ethanol-----1.00kg/kg
3. Thionyl chloride-----1.30kg/kg
4. Caustic Soda flakes-----1.00kg/kg
5. L+tartaric acid-----0.70kg/kg
6. Toluene-----0.20kg/kg
7. Para toluene sulphonyl chloride-----1.08kg/kg
8. Acetonitrile-----1.43kg/kg
9. Ethyl acetate-----0.95kg/kg
10. Isopropyl alcohol-----0.23kg/kg
11. Methanol-----4.25kg/kg
12. Methylene dichloride-----1.03kg/kg
13. Acetone-----1.68kg/kg
14. Formic Acid-----0.185kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                              |                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Case No.A-883                                                                                                                                                | M/S Sandoz Pvt. Ltd.           |
| Norms Committee Meeting No.31/08                                                                                                                             | F.No.01/82/50/209/AM08/DES-III |
| Meeting Date: 04.12.2007                                                                                                                                     | RLA F.No.03/95/40/488/AM08     |
| Adv.Lic. No.0310441155 dated 29.08.2007                                                                                                                      |                                |
| Committee considered case as per agenda for ratification of norms for export product Blister (Multi-Bacillary) Child/Adult under para 4.7 of HBP.            |                                |
| Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. |                                |

|   |                                                                                                                                                               |                                     |                                            |                                        |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|----------------------------------------|
| 1 | <b>Case No.:10/20/87-ALC1/2005</b>                                                                                                                            | Party Name:ALKALOIDS CORP           | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:</b><br><b>Case Deferred</b> |
|   | HQ File :<br>01/87/050/00429/AM06/                                                                                                                            | RLA File :<br>02/24/040/00081/AM06/ | Lic.No/Date:021008<br>0076<br>15.07.2005   | Defer<br>Date:<br>01.01.2008           |
|   | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP. |                                     |                                            |                                        |
|   | Representative of MSME present in meeting informed Committee that case is                                                                                     |                                     |                                            |                                        |

under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                    |                                                       |                                            |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------------------------|--------------------------------------------|------------------------------|
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Case No.:31/47/82-ALC1/2005</b> | Party Name:CALYX CHEMICALS & PHARMACEUTICALS PVT.LTD. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | HQ File :<br>01/82/050/01335/AM06/ | RLA File :<br>03/94/040/01210/AM06/                   | Lic.No/Date:031036<br>5692<br>03.02.2006   | Defer<br>Date:<br>15.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Coenzyme Q10 under para 4.7 of HBP.</p> <p>Committee observed that Department of Bio-technology vide their letter No.BT/IL/05//231/06/2006/PID dated 20.07.2007 informed Committee that during the manufacturing process, phytochemicals are converted to bio-chemicals through chemical reactions and there is no bio-process involved. Committee, therefore, decided to refer the case to PI Division for their comments. Accordingly, case was deferred for six weeks.</p> |                                    |                                                       |                                            |                              |

|                                                                                                                                                                                                                                                                                                                                                                                                |                                    |                                     |                                            |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 3                                                                                                                                                                                                                                                                                                                                                                                              | <b>Case No.:8/10/87-ALC1/2006</b>  | Party Name:ALKALOIDS CORP           | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                                                                                                                                                                                                                                                                | HQ File :<br>01/87/050/00096/AM07/ | RLA File :<br>02/24/040/00020/AM07/ | Lic.No/Date:021008<br>8734<br>28.04.2006   | Defer<br>Date:<br>01.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Aescin (Horse Chestnut Extract) under para 4.7 of HBP.</p> <p>Representative of MSME present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.</p> |                                    |                                     |                                            |                              |

|                                                                                                                                                                                                                                    |                                    |                                      |                                            |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------------------------|--------------------------------------------|------------------------------|
| 4                                                                                                                                                                                                                                  | <b>Case No.:1/23/87-ALC1/2006</b>  | Party Name:ALCHEM INTERNATIONAL LTD. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                                                                                                    | HQ File :<br>01/87/050/00336/AM07/ | RLA File :<br>05/24/040/00255/AM07/  | Lic.No/Date:051018<br>5276<br>21.06.2006   | Defer<br>Date:<br>15.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Silymarin Extract under para 4.7 of HBP.</p> <p>Committee observed that Department of MSME vide letter No.5(9)/2005-</p> |                                    |                                      |                                            |                              |

Chem dated 26.11.2007 have called for following information from the firm.

1. Purity of the export product.
2. End use of the export product.
3. Published technical literature of crude cardui mariae extract.
4. Percentage of Silymarine Extract in crude cardui mariae extract.
5. Details of extraction process along with percentage of yield at each step of the extraction.

Committee, accordingly, decided to remind the firm to furnish the above information. It was accordingly, decided to defer the case for six weeks.

|   |                                                                                                                                                                                                                                                                                                                                                                             |                                     |                                            |                              |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 5 | <b>Case No.:16/27/87-ALC1/2006</b>                                                                                                                                                                                                                                                                                                                                          | Party Name:ALKALOIDS CORP           | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|   | HQ File :<br>01/87/050/00419/AM07/                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>02/24/040/00123/AM07/ | Lic.No/Date:021009<br>2125<br>02.08.2006   | Defer<br>Date:<br>01.01.2008 |
|   | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Kola Extract under para 4.7 of HBP.</p> <p>Representative of MSME present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Accordingly, Committee decided to defer case for four weeks.</p> |                                     |                                            |                              |

|   |                                                                                                                                                                                                                                                                                 |                                              |                                            |                                |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------|--------------------------------|
| 6 | <b>Case No.:25/27/87-ALC1/2006</b>                                                                                                                                                                                                                                              | Party Name:ALCON BIOSCIENCES PRIVATE LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Transferred</b> |
|   | HQ File :<br>01/87/050/00446/AM07/                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/01463/AM06/          | Lic.No/Date:031039<br>3946<br>09.08.2006   |                                |
|   | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Benzil Pure 99% under para 4.7 of HBP.</p> <p>Committee in consultation with representative of PI Division present in meeting decided to transfer case to DES-IV.</p> |                                              |                                            |                                |

|   |                                    |                                                   |                                            |                                |
|---|------------------------------------|---------------------------------------------------|--------------------------------------------|--------------------------------|
| 7 | <b>Case No.:13/29/82-ALC1/2006</b> | Party Name:INNOVASSYNTH TECHNOLOGIES (INDIA) LTD. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Transferred</b> |
|   | HQ File :<br>01/82/050/00961/AM07/ | RLA File :<br>03/94/040/00603/AM07/               | Lic.No/Date:031040<br>0077<br>19.09.2006   |                                |

**Decision :** Committee considered case as per agenda for ratification of norms for export product 5-O-Dimethoxytrityl-2-O-tert-butyldimethylsilyl-N2-isobutyryl Guanosine/DMT-rG(ib)-TBMDS under para 4.7 of HBP.

Committee decided to transfer the case to DES-IV as export product pertains to R&D chemicals.

|   |                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                          |                                            |                             |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------------------------------|-----------------------------|
| 8 | <b>Case No.:555/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                           | Party Name:GULF OIL CORPORATION LIMITED. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Rejected</b> |
|   | HQ File :<br>01/82/050/01110/AM07/                                                                                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>09/24/040/00247/AM07/      | Lic.No/Date:0910027792<br>09.10.2006       |                             |
|   | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Amoxycillin Capsules 500mg under para 4.7 of HBP.</p> <p>Committee in consultation with representative of PI Division present in meeting decided to close the case as firm is not entitled to manufacture Amoxycillin Capsules.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                          |                                            |                             |

|   |                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |                                            |                             |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------|-----------------------------|
| 9 | <b>Case No.:35/31/82-ALC1/2006</b>                                                                                                                                                                                                                                                                                                                                                                                        | Party Name:CLARIANT CHEMICALS [INDIA] LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|   | HQ File :<br>01/82/050/01132/AM07/                                                                                                                                                                                                                                                                                                                                                                                        | RLA File :<br>03/94/040/00773/AM07/       | Lic.No/Date:0310403496<br>11.10.2006       | Defer Date:<br>15.01.2008   |
|   | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 5 Fluoro Cyto Sine under para 4.7 of HBP.</p> <p>Committee in consultation with representative of PI Division present in meeting decided to call for end use of export product, percentage yield on molar basis and technical literature in support of yield. Accordingly, case was deferred for six weeks.</p> |                                           |                                            |                             |

|    |                                                                                                |                                     |                                            |                             |
|----|------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 10 | <b>Case No.:2/46/87-ALC1/2006</b>                                                              | Party Name:AVON ORGANICS LTD.,      | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :<br>01/87/050/00663/AM07/                                                             | RLA File :<br>09/24/040/00271/AM07/ | Lic.No/Date:0910027981<br>30.10.2006       |                             |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for</p> |                                     |                                            |                             |



export product 5-Aceto Acetyl Amino Benzimidazolaone (AABZ) (OR) 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/100/2005-PI-III dated 30.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

5-Aceto Acetyl Amino Benzimidazolone or  
5-Aceto Acetyl Amino Benzimidaxolone-2(AAB)-----1kg.

Import items:

1. Acetic Acid-----1.43kg/kg
2. Triethyl phosphate (TEP)-----0.0050kg/kg
3. DABCO Crystalline (1,4 diazobicyclo (2,2,2)-Octane----0.0013kg/kg
4. Methanol-----0.70kg/kg
5. 5-amino Benzimidazolon -----0.89kg/kg

**OR**

- 5a Ortho Phenylene Diamine-----0.95kg/kg
- 5b Urea-----0.57kg/kg
- 5c Chlorobenzene-----0.57kg/kg
- 5d Sodium hydroxide flakes/Caustic Soda flakes-----0.061kg/kg
- 5e Raney Nickel-----0.100kg/kg
- 5f Activated Carbon-----0.050kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                    |                                     |                                            |                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Case No.:12/45/87-ALC1/2006</b> | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | HQ File :<br>01/87/050/00747/AM07/ | RLA File :<br>09/24/040/00128/AM07/ | Lic.No/Date:091002<br>8249<br>17.11.2006   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Sterile Ampicillin Sodium+Salbactam Sodium (2:1) under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/274/2006-PI-III dated 26.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis as per details below or as applied by firm whichever is lower.</p> |                                    |                                     |                                            |                             |

Export product:

Sterile Ampicillin Sodium + Salbactam Sodium (2;1)-----1kg.

Import items:

1. 6 APA-----1.039kg/kg
2. Pivaloyl chloride-----0.283kg/kg
3. Triethylamine-----0.0171kg/kg
4. Methylene chloride-----0.745kg/kg
5. D(-)Alpha Phenyl glycine Base-----0.374kg/kg
6. Ethyl Aceto acetate-----0.358kg/kg
7. Sodium Thiocynate-----0.189kg/kg
8. Acetonitrile-----1.342kg/kg
9. Isopropyl Alcohol-----1.684kg/kg
10. Acetone-----0.501kg/kg
11. 2-Ethyl Hexanoic Acid-----0.016kg/kg
12. Aluminium Canisters-----As per packing policy
13. MIBK-----0.24kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                     |                                            |                              |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 12 | <b>Case No.:2/46/82-ALC1/2006</b>                                                                                                                                                                                                                                                                                                                                                                                               | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/82/050/01441/AM07/                                                                                                                                                                                                                                                                                                                                                                                              | RLA File :<br>09/24/040/00390/AM07/ | Lic.No/Date:091002<br>8634<br>13.12.2006   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product N-Trifluoro Acetyl-N-1 Ysine-Praline (Lysipro (Isolated) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                            |                              |

|    |                                    |                               |                                            |                             |
|----|------------------------------------|-------------------------------|--------------------------------------------|-----------------------------|
| 13 | <b>Case No.:27/48/87-ALC1/2006</b> | Party Name:AROCHEM INDUSTRIES | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :                          | RLA File :                    | Lic.No/Date:031041                         |                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |                    |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--|
| 01/87/050/00958/AM07/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 03/94/040/01134/AM07/ | 6228<br>16.01.2007 |  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Choline Bitartrate-FCC-V/USP (with 1% Silicon dioxide) under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O.35011/271/2006-PI-III dated 04.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Choline Bitartarate USP Coated-----1kg.</p> <p>Import item:<br/>L-tartaric acid-----0.775kg/kg</p> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.</p> |                       |                    |  |

|    |                                                                                                                                                                                                                                                                                                                                        |                                     |                                            |                              |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 14 | <b>Case No.:2/48/83-ALC1/2006</b>                                                                                                                                                                                                                                                                                                      | Party Name:SURYA PHARMACEUTICAL LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/01135/AM07/                                                                                                                                                                                                                                                                                                     | RLA File :<br>22/24/040/00291/AM07/ | Lic.No/Date:221000<br>6400<br>17.01.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Sultamicillin Tosylate under para 4.7 of HBP.</p> <p>Committee decided to hand over the file to representative of PI Division for examination of case and their comments. Accordingly, case was deferred for four weeks.</p> |                                     |                                            |                              |

|    |                                    |                                                              |                                            |                              |
|----|------------------------------------|--------------------------------------------------------------|--------------------------------------------|------------------------------|
| 15 | <b>Case No.:5/9/82-ALC4/2007</b>   | Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/82/050/01646/AM07/ | RLA File :<br>05/24/040/00937/AM07/                          | Lic.No/Date:051019<br>9268<br>09.02.2007   | Defer<br>Date:<br>01.01.2008 |

**Decision :** Committee considered case as per agenda for ratification of norms for export product 3,4 Dihydroxy-4-Oxo-6Acetoxy-7Methoxyquinazole under para 4.7 of HBP.

Committee observed that firm has been requested to furnish technical details as per Appendix 33 vide letter dated 12.11.2007, but same has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.

|    |                                                                                                                                                                                                                                                                                                                                                                                  |                                         |                                            |                              |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|------------------------------|
| 16 | <b>Case No.:500/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                              | Party Name:IND-SWIFT LABORATORIES LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00062/AM08/                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>22/24/040/00297/AM07/     | Lic.No/Date:221000<br>6482<br>13.02.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ezitimibe under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                         |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                |                                         |                                            |                              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|------------------------------|
| 17 | <b>Case No.:4/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                              | Party Name:NECTAR LIFESCIENCES LIMITED, | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/82/050/00006/AM08/                                                                                                                                                                                                                                                                                             | RLA File :<br>22/24/040/00295/AM07/     | Lic.No/Date:221000<br>6538<br>27.02.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cephalothin for Injection under para 4.7 of HBP.</p> <p>Committee decided to remind RA to furnish a copy of application alongwith a copy of Advance Authorisation. Accordingly, case was deferred for six weeks.</p> |                                         |                                            |                              |

|    |                                                                                                                                               |                                                  |                                            |                              |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------|------------------------------|
| 18 | <b>Case No.:6/9/82-ALC4/2007</b>                                                                                                              | Party Name:COVALENT LABORATORIES PRIVATE LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/82/050/01728/AM07/                                                                                                            | RLA File :<br>09/24/040/00488/AM07/              | Lic.No/Date:091002<br>9504<br>01.03.2007   | Defer<br>Date:<br>18.12.2007 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP.</p> |                                                  |                                            |                              |

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for two weeks. Committee, accordingly, decided to defer case for two weeks.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                            |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:3/1/87-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Party Name:AVON ORGANICS LTD.,      | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
| HQ File :<br>01/87/050/01107/AM07/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>09/24/040/00487/AM07/ | Lic.No/Date:0910029668<br>14.03.2007       |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 5-Aceto Acetyl Amino Benzimidazolone (AABZ) (OR) 5-Aceto Acetyl Amino Benzimidazolone-2 (AABI) under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/100/2005-PI-III dated 30.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>5-Aceto Acetyl Amino Benzimidazolone or<br/>5-Aceto Acetyl Amino Benzimidaxolone-2(AAB)-----1kg.</p> <p>19 Import items:</p> <ol style="list-style-type: none"> <li>1. Acetic Acid-----1.43kg/kg</li> <li>2. Triethyl phosphate (TEP)-----0.0050kg/kg</li> <li>3. DABCO Crystalline (1,4 diazobicyclo (2,2,2)-Octane---0.0013kg/kg</li> <li>4. Methanol-----0.70kg/kg</li> <li>5. 5-amino Benzimidazolone -----0.89kg/kg</li> </ol> <p style="text-align: center;"><b>OR</b></p> <ol style="list-style-type: none"> <li>5a Ortho Phenylene Diamine-----0.95kg/kg</li> <li>5b Urea-----0.57kg/kg</li> <li>5c Chlorobenzene-----0.57kg/kg</li> <li>5d Sodium hydroxide flakes/Caustic Soda flakes-----0.061kg/kg</li> <li>5e Raney Nickel-----0.100kg/kg</li> <li>5f Activated Carbon-----0.050kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.</p> |                                     |                                            |                             |

|                                        |                                   |                              |                    |
|----------------------------------------|-----------------------------------|------------------------------|--------------------|
| 20 <b>Case No.:950/21/82-ALC4/2007</b> | Party Name:LAKE CHEMICALS PRIVATE | Meet No/Date:31/82-ALC4/2007 | <b>Status:Case</b> |
|----------------------------------------|-----------------------------------|------------------------------|--------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                     |                                          |                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|-----------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | LIMITED                             | 04.12.2007                               | <b>Approved</b> |
| HQ File :<br>01/82/050/01812/AM07/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>07/24/040/00829/AM07/ | Lic.No/Date:071005<br>0672<br>15.03.2007 |                 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Midazolam Maleate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O.35011/70/2005-PI-III dated 04.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Midazolam Maleate-----1kg.</p> <p>Import item:</p> <ol style="list-style-type: none"> <li>1. 2-Aminomethyl-7-chloro-2,3-dihydro-5-(2-fluorophenyl)1H-1,4-benzodiazepine dimaleate-----2.52kg/kg</li> <li>2. Triethyl ortho acetate-----1.18kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.</p> |                                     |                                          |                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                     |                                     |                                            |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 21                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Case No.:954/21/82-ALC4/2007</b> | Party Name:MERCK LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case approved</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | HQ File :<br>01/82/050/01815/AM07/  | RLA File :<br>03/95/040/01559/AM07/ | Lic.No/Date:031042<br>3260<br>15.03.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product DL-Alpha Tocopheryl Acetate USP under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 30/82 meeting held on 08.11.2006 vide Case No.954/21/82 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>DL-Alpha Tocopherol Acetate USP (Vitamin E Acetate USP)-----1kg.</p> <p>Import item:</p> |                                     |                                     |                                            |                             |

1. Isophytol-----0.738kg/kg
2. 2,3,5-Trimethyl Hydroquinone-----0.385kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|    |                                                                                                                                                                                                                                                                                                      |                                     |                                            |                              |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 22 | <b>Case No.:17/9/82-ALC4/2007</b>                                                                                                                                                                                                                                                                    | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/82/050/01837/AM07/                                                                                                                                                                                                                                                                   | RLA File :<br>03/94/040/01468/AM07/ | Lic.No/Date:031042<br>3777<br>21.03.2007   | Defer<br>Date:<br>18.12.2007 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Exemestane under para 4.7 of HBP.</p> <p>Committee observed that firm has been called for personal hearing on 18.12.2007. It was therefore decided to re-list this case on 18.12.2007.</p> |                                     |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                  |                                     |                                            |                              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 23 | <b>Case No.:3/22/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                | Party Name:RA CHEM PHARMA LIMITED.  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/01367/AM07/                                                                                                                                                                                                                                                                                                               | RLA File :<br>09/24/040/00505/AM07/ | Lic.No/Date:091002<br>9769<br>26.03.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 1-Acetylamino-5-Nitro-2-Propoxy Benzene under para 4.7 of HBP.</p> <p>Committee observed that this case has been transferred from DES-IV on 23.11.2007. Committee decided to defer case for six weeks for comments of PI Division.</p> |                                     |                                            |                              |

|    |                                    |                                     |                                            |                              |
|----|------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 24 | <b>Case No.:23/9/82-ALC4/2007</b>  | Party Name:LUPIN LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/82/050/01901/AM07/ | RLA File :<br>03/95/040/01622/AM07/ | Lic.No/Date:031042<br>4915<br>29.03.2007   | Defer<br>Date:<br>01.01.2008 |

**Decision :** Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

|                                                                                                                                                                                                                                                                                                                                                                                     |                                    |                                        |                                            |                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------------------------|--------------------------------------------|--------------------------------|
| 25                                                                                                                                                                                                                                                                                                                                                                                  | <b>Case No.:2/4/85-ALC3/2007</b>   | Party Name:HEINZ INDIA PRIVATE LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Transferred</b> |
|                                                                                                                                                                                                                                                                                                                                                                                     | HQ File :<br>01/85/050/00259/AM07/ | RLA File :<br>03/94/040/01338/AM07/    | Lic.No/Date:031042<br>4928<br>29.03.2007   |                                |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Vitamin-Mineral Food Supplement Sprinkle under para 4.7 of HBP.</p> <p>Committee observed that firm has not submitted copy of DML alongwith their application and company states that item is a food item. It was, therefore, decided to transfer the case to DES-VI.</p> |                                    |                                        |                                            |                                |

26

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                                            |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:2/3/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Party Name:ALEMBIC LIMITED          | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
| HQ File :<br>01/82/050/00005/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>34/24/040/00301/AM07/ | Lic.No/Date:341001<br>8454<br>30.03.2007   |                             |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Azithromycin Crude under para 4.7 of HBP.<br><br>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/227/2006-PI-III dated 12.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.<br><br>Export product:<br>Azithromycin Crude Purity NLT 94.5%-----1Kg.<br><br>Import items: |                                     |                                            |                             |
| Sl.No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Description of import items         | Quantity allowed                           |                             |
| 1.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Erythromycin base                   | 1.75kg/kg                                  |                             |
| 2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Acetone                             | 6.45kg/kg                                  |                             |
| 3.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Ethyl Alcohol                       | 2.81kg/kg                                  |                             |
| 4.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Hydroxylamine Hcl                   | 0.91kg/kg                                  |                             |
| 5.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Methane Sulfonyl chloride           | 0.72kg/kg                                  |                             |
| 6.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Methanol                            | 2.72kg/kg                                  |                             |



|                                                                                                                                                                                                                                                                                                    |                                                                         |                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-------------------------------------------|
| 7.                                                                                                                                                                                                                                                                                                 | Platinum Catalyst with base of activated Carbon (5% Platinum on Carbon) | 1.00gm/kg                                 |
| 8.                                                                                                                                                                                                                                                                                                 | Hyflo                                                                   | Not a raw material.<br>Hence not allowed. |
| <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA Concerned may take further necessary action as per above decision of Norms Committee.</p> |                                                                         |                                           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                    |                                     |                                            |                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 27                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Case No.:9/21/82-ALC4/2007</b>  | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | HQ File :<br>01/82/050/00009/AM08/ | RLA File :<br>09/24/040/00543/AM07/ | Lic.No/Date:0910029931<br>10.04.2007       | Defer Date:<br>01.01.2008   |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 7-Amino-3[(Z/E)-1-Propen-1-YL]-3-Cephem-4-Carboxylic Acid (APRA) under para 4.7 of HBP.</p> <p>Committee observed that a copy of application along a copy of Advance Authorisation was called for form concerned RA vide letter dated 22.11.2007, but same has not been received. Committee, therefore, decided to remind RA and defer case for four weeks.</p> |                                    |                                     |                                            |                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                                     |                                            |                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 28                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Case No.:519/24/83-ALC1/2007</b> | Party Name:RANBAXY LABORATORIES LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | HQ File :<br>01/83/050/00107/AM08/  | RLA File :<br>05/24/040/00017/AM08/ | Lic.No/Date:0510202504<br>13.04.2007       |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Isotretinoin under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Isotretinoin-----1kg.</p> <p>Import items:</p> |                                     |                                     |                                            |                             |

1. Acetone-----0.48kg/kg
2. Activated Carbon-----0.100kg/kg
3. Beta Ionone-----3.20kg/kg
4. Dimethy Acrylic Acid-----2.37kg/kg
5. Hexane-----9.69kg/kg
6. Lithium Aluminium Hydride-----0.40kg/kg
7. Methanol-----8.56kg/kg
8. Methylene chloride-----9.36kg/kg
9. N-Butyl Lithium 30%-----0.89kg/kg
10. Tetrahydrofuran-----6.59kg/kg
11. Toluene-----7.53kg/kg
12. Triethylphosphone Acetate-----4.10kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                           |                                            |                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:18/7/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Party Name:RESONANCE LABORATORIES PVT LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Rejected</b> |
| HQ File :<br>01/83/050/00171/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>07/24/040/00048/AM08/       | Lic.No/Date:0710051363<br>23.04.2007       |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 1-[2,6 Dichloro-4(Trifluoromethyl)Phenyl]-5-[Pyridine-2-YL Methylene) Amino] 1H-Pyrazole-3-Carbonitrile (C-6900) under para 4.7 of HBP.</p> <p>Committee observed that firm has not submitted technical details as per Appendix 33 alongwith their application and in absence of technical details, norms can not be fixed. Accordingly, Committee decided to close the case.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                           |                                            |                             |

|                                                                                                                                                            |                                     |                                            |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 30 <b>Case No.:20/17/83-ALC1/2007</b>                                                                                                                      | Party Name:DALAS BIOTECH LTD.       | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
| HQ File :<br>01/83/050/00222/AM08/                                                                                                                         | RLA File :<br>05/24/040/01077/AM07/ | Lic.No/Date:0510203060<br>27.04.2007       |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefixime Methyl Ester under para 4.7 of HBP.</p> |                                     |                                            |                             |

Committee in light of its earlier decision taken in its 11/82 meeting held on 17.07.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Methyl Ester of Cefixime-----1kg.

Import items:

1. GCLE-----1.57kg/kg
2. Mica Acid-----0.77kg/kg
3. Tri Phenyl Phosphine-----1.30kg/kg
4. Methylene chloride-----4.32kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                    |                                                          |                                            |                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------------------------------------------|--------------------------------------------|-----------------------------|
| 31                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Case No.:18/21/82-ALC4/2007</b> | Party Name:KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | HQ File :<br>01/82/050/00025/AM08/ | RLA File :<br>07/24/040/00064/AM08/                      | Lic.No/Date:071005<br>1499<br>03.05.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ceftriaxone for Inj 500mg BP under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 41/82 meeting held on 24.01.2007 vide Case No.23/41/82 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Cefriaxone USP 500mg Injection-----1 Vial</p> <p>Import item:<br/>Cefriaxone Sodium-----624.70mg/Vial</p> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> |                                    |                                                          |                                            |                             |

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                      |                                                          |                                            |                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:19/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                   | Party Name:KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
| HQ File :<br>01/82/050/00026/AM08/                                                                                                                                                                                                                                                                                   | RLA File :<br>07/24/040/00063/AM08/                      | Lic.No/Date:0710051501<br>03.05.2007       |                             |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ceftriazone for Inj. USP 1gm Vial under para 4.7 of HBP.                                                                                                                                                      |                                                          |                                            |                             |
| <p>Committee in light of its earlier decision taken in its 41/82 meeting held on 24.01.2007 vide Case No.22/41/82 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> |                                                          |                                            |                             |
| <p>Export product:<br/>Cefriaxone USP 1000mg Injection-----1 Vial</p>                                                                                                                                                                                                                                                |                                                          |                                            |                             |
| <p>Import items:<br/>Cefriazone Sodium-----1249.50mg/Vial</p>                                                                                                                                                                                                                                                        |                                                          |                                            |                             |
| <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p>                                                                                                                   |                                                          |                                            |                             |
| <p>RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.</p>                                                                                                                                                                                                |                                                          |                                            |                             |

|                                                                                                                                                                                                                                                        |                                     |                                            |                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:15/18/83-ALC1/2007</b>                                                                                                                                                                                                                     | Party Name:GRANULES INDIA LIMITED   | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
| HQ File :<br>01/83/050/00252/AM08/                                                                                                                                                                                                                     | RLA File :<br>09/24/040/00023/AM08/ | Lic.No/Date:0910030174<br>04.05.2007       | Defer Date:<br>01.01.2008   |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Iso Metheptene Mucate under para 4.7 of HBP.                                                                                                    |                                     |                                            |                             |
| <p>Committee observed that firm was requested to furnish technical details as per Appendix 33 vide letter dated 29.10.2007, but same has not been received. Committee, therefore, decided to remind the firm and to defer the case for four weeks.</p> |                                     |                                            |                             |

|    |                                                                                                                                                                                                                                                                                                                                                                                                             |                                        |                                            |                             |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------------|-----------------------------|
| 34 | <b>Case No.:20/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                          | Party Name:RANBAXY LABORATORIES LTD    | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|    | HQ File :<br>01/82/050/00028/AM08/                                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>05/24/040/00097/AM08/    | Lic.No/Date:0510203344<br>07.05.2007       | DeferDate :<br>01.01.2008   |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Clarithromycin Carbomer Granules 44% under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                        |                                            |                             |
| 35 | <b>Case No.:575/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                         | Party Name:MATRIX LABORATORIES LTD     | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|    | HQ File :<br>01/83/050/00265/AM08/                                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>09/24/040/00445/AM07/    | Lic.No/Date:0910030195<br>07.05.2007       | DeferDate:<br>01.01.2008    |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Nelfinavir Mesylate under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p>                  |                                        |                                            |                             |
| 36 | <b>Case No.:589/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                         | Party Name:SUVEN LIFE SCIENCES LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|    | HQ File :<br>01/83/050/00308/AM08/                                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>09/24/040/00013/AM08/    | Lic.No/Date:0910030250<br>14.05.2007       | DeferDate:<br>01.01.2008    |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Benzhydryl Thioacetamide under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p>             |                                        |                                            |                             |
| 37 | <b>Case No.:29/9/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                           | Party Name:S.M. HERBALS PVT.LTD.       | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                     |                                          |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|------------------------------|
| HQ File :<br>01/82/050/00039/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>05/24/040/01075/AM07/ | Lic.No/Date:051020<br>3751<br>16.05.2007 | Defer<br>Date:<br>01.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Camptothecin under para 4.7 of HBP.</p> <p>Committee observed that firm has been requested to furnish following information vide Department of MSME vide their letter No.5(9)/2005-Chem. Dated 26.11.2007.</p> <p>I) Purity of the export product.<br/> II) Technical Literature of Mappia Foetida.<br/> III) Percentage of Comptothecin in Mappia Foetida.<br/> IV) Details of the extraction process along with the percentage yield as each step of the extraction.</p> <p>Committee, therefore, decided to remind the firm to furnish the above information. Accordingly, case was deferred for four weeks.</p> |                                     |                                          |                              |

|                                                                                                                                                                                                                                                                                                |                                                  |                                                |                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------------------------------|----------------------------------|
| <b>Case No.:37/16/83-ALC1/2007</b>                                                                                                                                                                                                                                                             | Party Name:ELPPE<br>CHEMICALS PRIVATE<br>LIMITED | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Withdrawn</b> |
| HQ File :<br>01/83/050/00385/AM08/                                                                                                                                                                                                                                                             | RLA File :<br>03/94/040/00170/AM08/              | Lic.No/Date:031043<br>0424<br>23.05.2007       |                                  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Niclosamide Piperazine Salt under para 4.7 of HBP.</p> <p>Committee decided to withdraw this case as the same has already been approved in its 27/82 meeting held on 06.11.2007.</p> |                                                  |                                                |                                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                      |                                          |                                                |                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|------------------------------------------------|---------------------------------|
| <b>Case No.:624/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                  | Party Name:SHODHANA<br>LABORATORIES LTD. | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Deferred</b> |
| HQ File :<br>01/83/050/00390/AM08/                                                                                                                                                                                                                                                                                                                                                                                   | RLA File :<br>09/24/040/00040/AM08/      | Lic.No/Date:091003<br>0336<br>24.05.2007       | Defer<br>Date:<br>01.01.2008    |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 3-Oxo-4-Aza-5a-Androstane-17b-Carboxylic Acid under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                          |                                                |                                 |

|    |                                                                                                                                                                                                                                                                                                                                                                                                         |                                       |                                            |                              |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------------|------------------------------|
| 40 | <b>Case No.:622/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                     | Party Name:SHODHANA LABORATORIES LTD. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00388/AM08/                                                                                                                                                                                                                                                                                                                                                                      | RLA File :<br>09/24/040/00048/AM08/   | Lic.No/Date:091003<br>0334<br>24.05.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 2-(2-Methoxy Phenoxy) Ethylamine under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                       |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                                       |                                       |                                            |                              |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------------|------------------------------|
| 41 | <b>Case No.:623/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                   | Party Name:SHODHANA LABORATORIES LTD. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00389/AM08/                                                                                                                                                                                                                                                                                                                                                                    | RLA File :<br>09/24/040/00049/AM08/   | Lic.No/Date:091003<br>0335<br>24.05.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 4-(2,3-Epoxy Propoxy)Carbazole under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                       |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                                            |                             |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 42 | <b>Case No.:24/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Party Name:CE-CHEM PHARMACEUTICALS, | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :<br>01/82/050/00046/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>07/24/040/00136/AM08/ | Lic.No/Date:071005<br>1761<br>25.05.2007   |                             |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Pencillin V Pottasium 250mg Tablets under para 4.7 of HBP.</p> <p>Committee in consultation with representative of PI Division present in meeting decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Pencillin V Pottsasium Tablet 250mg<br/>Each tablet containing Pencillin V Potassium</p> |                                     |                                            |                             |

|                                                                                                                                                                                             |  |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| Equivalent to 250mg Pencillin V                                                                                                                                                             |  |  |  |
| Import item:<br>Pencillin V Pottasium BP-----282.36mg/tablet                                                                                                                                |  |  |  |
| Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms. |  |  |  |
| RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.                                                                              |  |  |  |

|    |                                                                                                                                                                                                                                                                                 |                                                          |                                                |                                  |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|------------------------------------------------|----------------------------------|
| 43 | <b>Case No.:628/24/83-ALC1/2007</b>                                                                                                                                                                                                                                             | Party Name:INVENTIS<br>DRUG DELIVERY<br>SYSTEMS PVT LTD. | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>withdrawn</b> |
|    | HQ File :<br>01/83/050/00397/AM08/                                                                                                                                                                                                                                              | RLA File :<br>09/24/040/00047/AM08/                      | Lic.No/Date:091003<br>0344<br>25.05.2007       |                                  |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Fenofibrate Pellets under para 4.7 of HBP.<br><br>Committee decided to withdraw this case as same has been decided to be closed in its 27/82 meeting held on 06.11.2007. |                                                          |                                                |                                  |

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                                |                                 |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------------|---------------------------------|
| 44 | <b>Case No.:35/9/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Party Name:ALEMBIC<br>LIMITED       | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Approved</b> |
|    | HQ File :<br>01/82/050/00051/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>34/24/040/00035/AM08/ | Lic.No/Date:341001<br>8854<br>28.05.2007       |                                 |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Azithromycin Step 3 under para 4.7 of HBP.<br><br>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/227/2006-PI-III dated 12.11.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.<br><br>Export product:<br>Azithromycin Step 3 (Aza Azithromycin)-----1kg.<br><br>Import item:<br>1. Erythromycin base-----1.86kg/kg<br>2. Acetone-----1.27kg/kg |                                     |                                                |                                 |



3. Ethyl Alcohol-----3.00ltr/kg
4. Hydroxylamine Hcl-----0.97kg/kg
5. Methane sulfonyl chloride-----0.69kg/kg
6. Methanol-----1.09kg/kg
7. Platinum Catalyst with base of activated Carbon (5% Platinum Carbon)-----1.00gm/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|    |                                                                                                                                                                                                                                                                                                                                                                                             |                                     |                                            |                              |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 45 | <b>Case No.:653/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                         | Party Name:LUPIN LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00456/AM08/                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>03/95/040/00187/AM08/ | Lic.No/Date:031043<br>1079<br>30.05.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                        |                                            |                             |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------------|-----------------------------|
| 46 | <b>Case No.:648/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Party Name:SUVEN LIFE SCIENCES LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :<br>01/83/050/00442/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | RLA File :<br>09/24/040/00017/AM08/    | Lic.No/Date:091003<br>0402<br>31.05.2007   |                             |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Doxofylline under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 vide Case No.455/24/83 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Doxofylline-----1kg.</p> <p>Import items:</p> |                                        |                                            |                             |

1. Theophylline-----1.17kg/kg
2. Chloro acetaldehyde dimethyl acetal---0.81kg/kg
3. Potassium carbonate-----0.89kg/kg
4. Methanol-----0.63kg/kg
5. Dimethyl formamide-----0.56kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                    |                                     |                                            |                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 47                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Case No.:32/21/82-ALC4/2007</b> | Party Name:NEULAND LABORATORIES LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | HQ File :<br>01/82/050/00060/AM08/ | RLA File :<br>09/24/040/00052/AM08/ | Lic.No/Date:091003<br>0410<br>01.06.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ramipril under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 22/82 meeting held on 04.10.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Ramipril-----1kg.</p> <p>Import items;</p> <ol style="list-style-type: none"> <li>1. Racemic-2-azabicyclo(3,3,0) Octane-3-carboxylic acid benzylester Hcl// or (S,S)-2-azabicyclo(3.3.0) octane-3-carbocylic acid benzylester hydrochloride-----2.70kg/kg</li> <li>2. S(+)-Mandelic acid-----0.81kg/kg</li> <li>3. Methylene chloride-----2.50kg/kg</li> <li>4. Cyclohexane-----2.50kg/kg</li> <li>5. Isopropyl Alcohol-----2.50kg/kg</li> <li>6. ECPP Alanine-----1.23kg/kg</li> <li>7. 1-Hydroxy Benzotriazole-----0.72kg/kg</li> <li>8. Dicyclohexyl Carbodimide-----1.00kg/kg</li> <li>9. Di-isopropyl ether-----2.50kg/kg</li> <li>10.5% Palladium on carbon-----0.20kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on</p> |                                    |                                     |                                            |                             |

file within the validity period of such adhoc norms.

RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms Committee.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                           |                                            |                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:27/22/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Party Name:METROPOLITAN OVERSEAS LIMITED, | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Rejected</b> |
| HQ File :<br>01/83/050/00596/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | RLA File :<br>03/95/040/00198/AM08/       | Lic.No/Date:031043<br>1481<br>04.06.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product N-[1-(S)-Ethoxy Carbonyl-3-Phenyl Propyl]-L-Alanine under para 4.7 of HBP.</p> <p>Committee noted that against earlier Advance Authorisation for same export and import products, firm was requested to furnish technical justification alongwith calculations for working out the quantitative requirement as applied by them, but same was not received. Committee observed that in this case also, they have not furnished same. It was, therefore, decided to close the case.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                           |                                            |                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                     |                                            |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 49 <b>Case No.:657/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Party Name:LEPRO HERBALS PVT. LTD.  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
| HQ File :<br>01/83/050/00469/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>05/24/040/00155/AM08/ | Lic.No/Date:051020<br>4504<br>05.06.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Griffonia Dry Extract under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 30/82 meeting held on 27.11.2007 vide Case No.627/24/83 in the case of M/S Siris Impex and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Griffonia Simplicifolia Extract-----1kg.</p> <p>Import item:<br/>Griffonia Simplicifolia Dried seeds<br/>Containing 10% 5HTP by HPLC-----2.40kg/kg</p> |                                     |                                            |                             |

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action as per above decision of Norms Committee.

|    |                                                                                                                                                                                                                                                                                                                                                                                                    |                                     |                                            |                              |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 50 | <b>Case No.:661/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00490/AM08/                                                                                                                                                                                                                                                                                                                                                                 | RLA File :<br>09/24/040/00094/AM08/ | Lic.No/Date:091003<br>0486<br>08.06.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                       |                                      |                                            |                              |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|------------------------------|
| 51 | <b>Case No.:715/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                   | Party Name:IPCA LABORATORIES LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00590/AM08/                                                                                                                                                                                                                                                                                                                                                    | RLA File :<br>03/94/040/00243/AM08/  | Lic.No/Date:031043<br>2929<br>18.06.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Norethisterone under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                      |                                            |                              |

|    |                                                                                                                                                |                                     |                                            |                              |
|----|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 52 | <b>Case No.:706/24/83-ALC1/2007</b>                                                                                                            | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00563/AM08/                                                                                                             | RLA File :<br>09/24/040/00080/AM08/ | Lic.No/Date:091003<br>0641<br>22.06.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Efavirenz under para 4.7 of HBP.</p> |                                     |                                            |                              |

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

|    |                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                                            |                              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 53 | <b>Case No.:789/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                  | Party Name:LUPIN LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00742/AM08/                                                                                                                                                                                                                                                                                                                                                   | RLA File :<br>03/95/040/00276/AM08/ | Lic.No/Date:031043<br>3502<br>22.06.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Levetiracetam under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                     |                                            |                             |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 54 | <b>Case No.:37/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Party Name:SARACA LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Rejected</b> |
|    | HQ File :<br>01/82/050/00075/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | RLA File :<br>09/24/040/00029/AM08/ | Lic.No/Date:091003<br>0654<br>25.06.2007   |                             |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Gabapentin Hcl (Technical) Powder under para 4.7 of HBP.</p> <p>Committee observed that firm has not submitted technical details as per Appendix 33 alongwith their application and without technical details, norms can not be fixed. Committee, therefore, decided to close the case.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                            |                             |

|    |                                                                                                                                                                                                                                                      |                                     |                                            |                                |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|--------------------------------|
| 55 | <b>Case No.:10/23/83-ALC1/2007</b>                                                                                                                                                                                                                   | Party Name:KAIVAL CHEMICALS P LTD   | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Transferred</b> |
|    | HQ File :<br>01/83/050/00575/AM08/                                                                                                                                                                                                                   | RLA File :<br>34/24/040/00063/AM08/ | Lic.No/Date:341001<br>9062<br>25.06.2007   |                                |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Dibenzoyl-D-(+)tartaric acid under para 4.7 of HBP.</p> <p>Committee decided to transfer the case to DES-IV as export product pertains</p> |                                     |                                            |                                |

to Chemical Sector.

|    |                                                                                                                                                                                                                                                                                                                                                                                                           |                                                    |                                            |                              |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------|------------------------------|
| 56 | <b>Case No.:726/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                       | Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00613/AM08/                                                                                                                                                                                                                                                                                                                                                                        | RLA File :<br>04/24/040/00113/AM08/                | Lic.No/Date:041009<br>0130<br>28.06.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 2-Fluoro Adenosin Triacetate (2-FAT) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                                    |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                             |                                                    |                                            |                              |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------|------------------------------|
| 57 | <b>Case No.:728/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                         | Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00615/AM08/                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>04/24/040/00111/AM08/                | Lic.No/Date:041009<br>0132<br>28.06.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Clopidogrel Bisulphate under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                                    |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                    |                                                    |                                            |                              |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------|------------------------------|
| 58 | <b>Case No.:727/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                | Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00614/AM08/                                                                                                                                                                                                                                                                                                                                                 | RLA File :<br>04/24/040/00112/AM08/                | Lic.No/Date:041009<br>0131<br>28.06.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Levetiracetam under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                                    |                                            |                              |

|                                                                                                                                                                                                                                                                                                                                                                                             |                                     |                                     |                                            |                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 59                                                                                                                                                                                                                                                                                                                                                                                          | <b>Case No.:731/24/83-ALC1/2007</b> | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                                                                                                                                                                                                                                                             | HQ File :<br>01/83/050/00624/AM08/  | RLA File :<br>09/24/040/00425/AM07/ | Lic.No/Date:091003<br>0691<br>29.06.2007   | Defer<br>Date:<br>01.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Sertraline Mandelate under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                     |                                            |                              |

|                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                        |                                            |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------------------------|--------------------------------------------|------------------------------|
| 60                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Case No.:730/24/83-ALC1/2007</b> | Party Name:SUVEN LIFE SCIENCES LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                                                                                                                                                                                                                                                                           | HQ File :<br>01/83/050/00623/AM08/  | RLA File :<br>09/24/040/00120/AM08/    | Lic.No/Date:091003<br>0686<br>29.06.2007   | Defer<br>Date:<br>01.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product (S)-3-Hydroxy-N-Benzyl Pyrrolidine under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                        |                                            |                              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                    |                                        |                                            |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------------------------|--------------------------------------------|-----------------------------|
| 61                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Case No.:54/21/82-ALC4/2007</b> | Party Name:SRINI PHARMACEUTICALS LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | HQ File :<br>01/82/050/00104/AM08/ | RLA File :<br>09/24/040/00116/AM08/    | Lic.No/Date:091003<br>0710<br>02.07.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Levofloxacin Hemihydrate Solid under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/147/2006-PI-III dated 04.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Levofloxacin Hemihydrate-----1kg.</p> |                                    |                                        |                                            |                             |

Import item:  
 (-)-9,10-difluoro-2,3-dihydro-3-methyl-7-oxo-7H  
 pyrido(1,2,3-de)-1,4-benzoxazine-6-carboxylic  
 acid (Levofloxacin Q-acid)-----1.01kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action as per above decision of Norms Committee.

|    |                                                                                                                                                                                                                                                                                                                 |                                     |                                            |                              |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 62 | <b>Case No.:739/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                             | Party Name:PONALAB                  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00640/AM08/                                                                                                                                                                                                                                                                              | RLA File :<br>07/24/040/00223/AM08/ | Lic.No/Date:071005<br>2285<br>03.07.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 8-Hydroxyquinoline under para 4.7 of HBP.<br><br>Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for six weeks. |                                     |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                                            |                              |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 63 | <b>Case No.:743/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                            | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00665/AM08/                                                                                                                                                                                                                                                                                                                                                                             | RLA File :<br>09/24/040/00511/AM07/ | Lic.No/Date:091003<br>0757<br>04.07.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 5,11-Dihydro(1)-Benzoxepino(3,1-b)-Pyridin-5-One under para 4.7 of HBP.<br><br>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |                                     |                                            |                              |

|    |                                     |                                    |                                            |                             |
|----|-------------------------------------|------------------------------------|--------------------------------------------|-----------------------------|
| 64 | <b>Case No.:757/24/83-ALC1/2007</b> | Party Name:MATRIX LABORATORIES LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|----|-------------------------------------|------------------------------------|--------------------------------------------|-----------------------------|



|                                                                                                                                                                                                                                                                                                                                                                                                          |                                     |                                          |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|--|
| HQ File :<br>01/83/050/00687/AM08/                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>09/24/040/00112/AM08/ | Lic.No/Date:091003<br>0802<br>06.07.2007 |  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product L-Menthyl Glyoxylate Hydroate (MGH) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                          |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                     |                                            |                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------------------|
| <b>Case No.:81/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Party Name:KOPRAN LIMITED           | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Deffered and Re-indexed</b> |
| HQ File :<br>01/82/050/00131/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>03/94/040/00173/AM08/ | Lic.No/Date:031043<br>5412<br>09.07.2007   | Defer Date:04.12.2007                 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Azithromycin Dihydrate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/28/2007-PI-III dated 04.12.2007 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Azithromycin-----1kg.</p> <p>Import items:<br/>1. Azithromycin amine-----1.04kg/kg<br/>2. Acetone-----0.90kg/kg<br/>3. Formic Acid-----0.210kg/kg</p> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                            |                                       |

|    |                                     |                                                  |                                            |                             |
|----|-------------------------------------|--------------------------------------------------|--------------------------------------------|-----------------------------|
| 66 | <b>Case No.:761/24/83-ALC1/2007</b> | Party Name:COVALENT LABORATORIES PRIVATE LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :<br>01/83/050/00694/AM08/  | RLA File :<br>09/24/040/00100/AM08/              | Lic.No/Date:091003<br>0845                 |                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |            |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|------------|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | 11.07.2007 |  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefposoxime Proxetil under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/103/2006-PI-III dated 04.12.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Cefpodoxime Proxetil-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. 7 Amino Cephalosporanic Acid (7-ACA)-----1.25kg/kg</li> <li>2. Mercaptobenzothiozol-2-Aminothiozol-4YL-Methoxoyimino Acetate-----1.25kg/kg</li> <li>3. Alpha-chloro Ethyl Isoporopyl Carbonate (CEIPC)-----0.558kg/kg</li> <li>4. 1,8-Duatabuctui (5.4.0)-7-Undecene (DBU)—0.364kg/kg</li> <li>5. Methanol-----1.08kg/kg</li> <li>6. Methylene Chloride-----1.66kg/kg</li> <li>7. Acetone-----1.79kg/kg</li> <li>8. Tetrahydrofuran-----3.36kg/kg</li> <li>9. Cyclohexane-----2.50kg/kg</li> <li>10. Sodium Iodide-----0.39kg/kg</li> <li>11. Activated Carbon-----0.100kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |  |            |  |

|                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                       |                                                                                        |                                                                                                 |                                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------|
| 67                                                                                                                                                                                                                                                                                                                                                                                                  | <p><b>Case No.:764/24/83-ALC1/2007</b></p> <p>HQ File :<br/>01/83/050/00698/AM08/</p> | <p>Party Name:RANBAXY LABORATORIES LTD</p> <p>RLA File :<br/>05/24/040/00274/AM08/</p> | <p>Meet No/Date:31/82-ALC4/2007<br/>04.12.2007</p> <p>Lic.No/Date:0510206046<br/>11.07.2007</p> | <p><b>Status:Case Approved</b></p> |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Fosinopril Sodium under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> |                                                                                       |                                                                                        |                                                                                                 |                                    |

Export product:  
Fosiniopril Sodium-----1kg.

Import items:

1. Acetone-----3.63kg/kg
2. Activated Carbon-----0.100kg/kg
3. Cyclohexane-----0.60kg/kg
4. Diisopropyl ether-----4.58kg/kg
5. Isobutyral dehyde-----0.43kg/kg
6. Methyl Iso Butyl Ketone-----0.30kg/kg
7. Toluene-----4.95kg/kg.
8. Trans-4-Hydroxy-L-proline-----1.592kg/kg
9. Triethylamine-----5.869kg/kg
10. 4-Phenyl-1 Butene-----3.06kg/kg
11. 5% Rhodium-----1.286gm/kg
12. Cinchonidine-----0.2379kgs.
13. Diisopropyl Azodicarboxylate-----2.535kg/kg
14. Hexamethyl Disilazane-----4.922kg/kg
15. Methanol-----2.97kg/kg
16. Methylene chloride-----12.40kg/kg
17. Palladium on carbon 10%-----0.039kg/kg
18. Pivaloyl chloride-----0.417kg/kg
19. Propionyl chloride-----1.77kg/kg
20. Pyridine-----0.139kg/kg
21. Tetrahydrofuran-----3.24kg/kg
22. Trimethyl Chlorosilane-----3.301kg/kg
23. Triphenyl Phosphine-----3.293kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action as per above decision of Norms Committee.

|                                                                                                                                                             |                                     |                                           |                                            |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------------|--------------------------------------------|------------------------------|
| 68                                                                                                                                                          | <b>Case No.:771/24/83-ALC1/2007</b> | Party Name:PRACHI PHARMACEUTICALS PVT LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                             | HQ File :<br>01/83/050/00709/AM08/  | RLA File :<br>03/95/040/00308/AM08/       | Lic.No/Date:031043<br>5714<br>11.07.2007   | Defer<br>Date:<br>15.01.2008 |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Thiamine Hydrochloride BP/USP under para 4.7 of HBP. |                                     |                                           |                                            |                              |
| Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six        |                                     |                                           |                                            |                              |

weeks. Committee, accordingly, decided to defer case for six weeks.

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                      |                                            |                             |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|-----------------------------|
|    | <b>Case No.:773/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Party Name:ASTRIX LABORATORIES LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :<br>01/83/050/00717/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>09/24/040/00119/AM08/  | Lic.No/Date:091003<br>0868<br>12.07.2007   |                             |
| 69 | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ritonavir under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No. 35011/58/2007-PI-III dated 04.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Ritonavir-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. L-Phenyl Alanine-----1.23kg/kg</li> <li>2. L-Valine-----0.510kg/kg</li> <li>3. 1,2 Dimethoxy Ethane-----15.453kg/kg</li> <li>4. 5-Hydroxy Methyl Thiazole-----0.440kg/kg</li> <li>5. Isobutramide-----0.660kg/kg</li> <li>6. Sodium Borohydride-----0.790kg/kg</li> <li>7. Diteritary Butyl Dicarbonate-----0.773kg/kg</li> <li>8. Acetonitrile-----0.530kg/kg</li> <li>9. Methanol-----4.98kg/kg</li> <li>10. Tetrahydrofuran-----4.81kg/kg</li> <li>11. N-Heptane-----1.39kg/kg</li> <li>12. Iso Propyl Alcohol-----4.95kg/kg</li> <li>13. Methyl Tertiary Butyl Ether-----3.70kg/kg</li> <li>14. Methylene chloride-----2.44kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                      |                                            |                             |

|    |                                     |                                      |                                            |                             |
|----|-------------------------------------|--------------------------------------|--------------------------------------------|-----------------------------|
| 70 | <b>Case No.:774/24/83-ALC1/2007</b> | Party Name:ASTRIX LABORATORIES LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :                           | RLA File :                           | Lic.No/Date:091003                         |                             |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                       |                    |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--|
| 01/83/050/00718/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 09/24/040/00118/AM08/ | 0869<br>12.07.2007 |  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Lopinavir under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/58/2007-PI-III dated 04.12.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Lopinavir-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. L-Phenyl Alanine-----1.36kg/kg</li> <li>2. L-Valine-----1.58kg/kg</li> <li>3. Triphosgene-----0.715kg/kg</li> <li>4. 2,6 Dimethy Phenol-----0.73kg/kg</li> <li>5. (L)-Pyroglutamic acid-----0.57kg/kg</li> <li>6. Sodium Borohydride-----0.89kg/kg</li> <li>7. Phenyl chloro formate-----2.21kg/kg</li> <li>8. 1,2 Dimethyl Ethane-----29.38kg/kg</li> <li>9. Methanol-----10.59kg/kg</li> <li>10. Tetrahydrofuran-----12.20kg/kg</li> <li>11. N-Heptane-----2.91kg/kg</li> <li>12. Iso Propyl Alcohol-----2.43kg/kg</li> <li>13. Methyl Tertiary Butyl Ether-----14.92kg/kg</li> <li>14. Methylene chloride-----7.75kg/kg</li> <li>15. Acetomitrile-----0.58kg/kg</li> <li>16. Dimethyl formamide-----1.82kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                       |                    |  |

|                                                                                                                                                 |                                     |                                     |                                            |                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 71                                                                                                                                              | <b>Case No.:768/24/83-ALC1/2007</b> | Party Name:LIQUORS INDIA LTD,       | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                 | HQ File :<br>01/83/050/00702/AM08/  | RLA File :<br>09/24/040/00142/AM08/ | Lic.No/Date:091003<br>0864<br>12.07.2007   | Defer<br>Date:<br>15.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Lovastatin under para 4.7 of HBP.</p> |                                     |                                     |                                            |                              |

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                     |                                            |                              |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 72 | <b>Case No.:801/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00760/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                 | RLA File :<br>09/24/040/00115/AM08/ | Lic.No/Date:091003<br>0917<br>18.07.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product (S)-5-Chloro-a-(Cyclopropylethynyl)-2-[(4-Methoxy phenyl) methyl) amino]-a-(Trifluoromethyl) Benzene Methanol under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                            |                                        |                                            |                              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------------|------------------------------|
| 73 | <b>Case No.:28/23/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                         | Party Name:KESHAHA ORGANICS PVT. LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00775/AM08/                                                                                                                                                                                                                                                                                                                                                         | RLA File :<br>03/94/040/01507/AM07/    | Lic.No/Date:031043<br>6591<br>18.07.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Chlorpheniramine Base under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                        |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                    |                                                         |                                            |                              |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------|------------------------------|
| 74 | <b>Case No.:905/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                | Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD) | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00915/AM08/                                                                                                                                                                                                                                                                                                                                                 | RLA File :<br>03/95/040/01473/AM07/                     | Lic.No/Date:031043<br>6839<br>19.07.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Carvedilol BP under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                                         |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                                  |                                                         |                                            |                              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------|------------------------------|
| 75 | <b>Case No.:906/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                              | Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD) | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00916/AM08/                                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>03/95/040/01472/AM07/                     | Lic.No/Date:031043<br>6843<br>19.07.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Setralone (Tetralone) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p>       |                                                         |                                            |                              |
| 76 | <b>Case No.:909/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                              | Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD) | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00920/AM08/                                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>03/95/040/01516/AM07/                     | Lic.No/Date:031043<br>6993<br>20.07.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ibuprofen DC Granules 65% under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                                         |                                            |                              |
| 77 | <b>Case No.:908/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                              | Party Name:WANBURY LIMITED(FORMERLY PEARL ORGANICS LTD) | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/00919/AM08/                                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>03/95/040/01517/AM07/                     | Lic.No/Date:031043<br>6987<br>20.07.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ibuprofen DC Granules 90% under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                                         |                                            |                              |
| 78 | <b>Case No.:82/21/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                               | Party Name:RANBAXY LABORATORIES LTD                     | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approve</b>   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                                          |          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|----------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                     |                                          | <b>d</b> |
| HQ File :<br>01/82/050/00132/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>05/24/040/00311/AM08/ | Lic.No/Date:051020<br>6654<br>24.07.2007 |          |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Simvastatin under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/85/2007-PI-III dated 20.11.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Simvastatin-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. Lovastatin-----1.648kg/kg</li> <li>2. Acetone-----1.042kg/kg</li> <li>3. Activated carbon-----0.035kg/lg</li> <li>4. Cyclohexane-----1.33kg/kg</li> <li>5. Cyclopropylamine-----1.23kg/kg</li> <li>6. Methanol-----19.82kg/kg</li> <li>7. N. Butyl Lithium-----2.382kg/kg</li> <li>8. Pyrrolidine-----1.53kg/kg</li> <li>9. Tetrahydrofuran-----6.58kg/kg</li> <li>10. Caustic flakes-----1.484kg/kg</li> <li>11. Iodine-----0.5917kg/kg</li> <li>12. Ethyl acetate-----4.49kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                          |          |

|                                                                                                                                                                                                                                                                                                            |                                     |                                        |                                            |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------------------------|--------------------------------------------|------------------------------|
| 79                                                                                                                                                                                                                                                                                                         | <b>Case No.:840/24/83-ALC1/2007</b> | Party Name:SMILAX LABORATORIES LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|                                                                                                                                                                                                                                                                                                            | HQ File :<br>01/83/050/00837/AM08/  | RLA File :<br>09/24/040/00155/AM08/    | Lic.No/Date:091003<br>0999<br>25.07.2007   | Defer<br>Date:<br>15.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product {3-5[Bromo-1-(fluorophenyl)(1,3-dihydro isobenzofuranyl)]-propyl]dimehylamine oxalate under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that</p> |                                     |                                        |                                            |                              |



case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     |                                            |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:845/24/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
| HQ File :<br>01/83/050/00842/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | RLA File :<br>09/24/040/00423/AM07/ | Lic.No/Date:091003<br>1011<br>27.07.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Nevirapine Hemihydrate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/81/2007-PI-III dated 19.09.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Nevirapine-----1kg.</p> <p>80 Import items:</p> <ol style="list-style-type: none"> <li>1. 2-chloro Nicotinic Acid-----1.13kg/kg</li> <li>2. Cyclo Propylamine-----1.20kg/kg</li> <li>3. Malono Nitrile-----1.088kg/kg</li> <li>4. Acetone-----2.31kg/kg</li> <li>5. Pyridine-----0.566kg/kg</li> <li>6. Diglyme-----2.16kg/kg</li> <li>7. Methylene chloride-----1.30kg/kg</li> <li>8. Methanol-----8.43kg/kg</li> <li>9. Activated Carbon-----0.100kg/kg</li> <li>10.Acetic Acid-----1.073kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                            |                             |

|                                        |                                     |                                            |                              |
|----------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 81 <b>Case No.:876/24/83-ALC1/2007</b> | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
| HQ File :<br>01/83/050/00880/AM08/     | RLA File :<br>09/24/040/00161/AM08/ | Lic.No/Date:091003<br>1051<br>06.08.2007   | Defer<br>Date:<br>15.01.2008 |

**Decision :** Committee considered case as per agenda for ratification of norms for export product Cyclohexyl Ester under para 4.7 of HBP.

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

**Case No.:937/24/83-ALC1/2007**

Party Name:HETERO DRUGS LIMITED,

Meet No/Date:31/82-ALC4/2007  
04.12.2007

**Status:Case Approved**

HQ File :  
01/83/050/00951/AM08/

RLA File :  
09/24/040/00180/AM08/

Lic.No/Date:091003  
1081  
10.08.2007

**Decision :** Committee considered case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/87/2007-PI-III dated 03.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

Lamivudine-----1kg.

Import items:

1. Glyoxylic acid 50%-----1.80kg/kg
2. 1,4-dithiane-2,5-dihydroxy-----0.739kg/kg
3. Cytosine-----0.955kg/kg
4. Hexamethyl disilazane-----1.89kg/kg
5. Salicylic acid-----0.79kg/kg
6. Sodium borohydride-----0.48kg/kg
7. Dimethyl formamide-----0.83kg/kg
8. N-Hexane-----3.75kg/kg
9. Methylene dichloride-----5.75kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action as per above decision of Norms Committee.

83 **Case No.:936/24/83-ALC1/2007**

Party Name:HETERO LABS LTD.

Meet No/Date:31/82-ALC4/2007  
04.12.2007

**Status:Case Approved**

HQ File :

RLA File :

Lic.No/Date:091003

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                       |                    |  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------|--|
|  | 01/83/050/00950/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 09/24/040/00181/AM08/ | 1080<br>10.08.2007 |  |
|  | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Nevirapine under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 38/82 meeting held on 03.01.2007 vide case No.62/23/82 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Nevirapine-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. Malononitrile-----1.088kg/kg</li> <li>2. Methylene chloride-----6.71kg/kg</li> <li>3. 2-chloro nicotinic acid-----1.13kg/kg</li> <li>4. Pyridine-----0.566kg/kg</li> <li>5. Methyl Ter. Buyl Eher-----3.01kg/kg</li> <li>6. Cyclopropylamine-----1.20kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                       |                    |  |

|    |                                                                                                                                                                                                                                                         |                                                  |                                                |                                 |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------------------------------|---------------------------------|
|    | <b>Case No.:962/24/83-ALC1/2007</b>                                                                                                                                                                                                                     | Party Name:ELPPE<br>CHEMICALS PRIVATE<br>LIMITED | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Approved</b> |
| 84 | HQ File :<br>01/83/050/00978/AM08/                                                                                                                                                                                                                      | RLA File :<br>03/94/040/00493/AM08/              | Lic.No/Date:031043<br>9377<br>14.08.2007       |                                 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Phenyl Thio Proline under para 4.7 of HBP.</p> <p>Committee decided to defer the case for four weeks for want of comments of PI Division.</p> |                                                  |                                                |                                 |
| 85 | <b>Case No.:45/25/83-ALC1/2007</b>                                                                                                                                                                                                                      | Party Name:VITAL<br>HEALTHCARE PVT.LTD.          | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Approved</b> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                     |                                          |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|--|
| HQ File :<br>01/83/050/01070/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | RLA File :<br>03/95/040/00532/AM08/ | Lic.No/Date:031044<br>1438<br>30.08.2007 |  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Quinine Hydrochloride under para 4.7 of HBP.</p> <p>Committee in light of DGFT Report decided to ratify norms decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <p>Export product:<br/>Quinine Hydrochloride BP/USP/EP-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. Cinchona Bark-----29kg/kg</li> <li>2. Toluene-----34.30kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                          |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |                                            |                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------|-----------------------------|
| <b>Case No.:32/25/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Party Name:METROPOLITAN OVERSEAS LIMITED, | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Rejected</b> |
| HQ File :<br>01/83/050/01057/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>03/95/040/00511/AM08/       | Lic.No/Date:031044<br>1319<br>30.08.2007   |                             |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product N-[1-(S)-Ethoxy Carbonyl-3-phenyl Propyl]-L-Alanine (ECPP-Alanina Ale) under para 4.7 of HBP.</p> <p>Committee noted that against earlier Advance Authorisation, firm was requested to furnish technical justification alongwith calculations for working out the quantative requirement as applied by them, but same was not received. Committee observed that in this case also, they have not furnished same. It was, therefore, decided to close the case.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                           |                                            |                             |

|    |                                    |                          |                                            |                             |
|----|------------------------------------|--------------------------|--------------------------------------------|-----------------------------|
| 87 | <b>Case No.:12/27/83-ALC1/2007</b> | Party Name:CIPLA LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|----|------------------------------------|--------------------------|--------------------------------------------|-----------------------------|

|                                                                                                                                                                                                                                                                |                                     |                                          |                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|----------------------------------|
| HQ File :<br>01/83/050/01086/AM08/                                                                                                                                                                                                                             | RLA File :<br>03/94/040/00555/AM08/ | Lic.No/Date:031044<br>1561<br>31.08.2007 | Defer<br>Date:<br>18.12.200<br>7 |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Saqunavir 200mg Capsules/Saqvir 200mg Capsules under para 4.7 of HBP.<br><br>Committee decided to call for the firm for personal hearing on 18.12.2007. |                                     |                                          |                                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                     |                                                |                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------------|---------------------------------|
| <b>Case No.:26/27/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Party Name:HETERO<br>LABS LTD.      | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Approved</b> |
| HQ File :<br>01/83/050/01100/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | RLA File :<br>09/24/040/00227/AM08/ | Lic.No/Date:091003<br>1385<br>03.09.2007       |                                 |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Irbesartan under para 4.7 of HBP.<br><br>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/87/2007-PI-III dated 03.10.2007 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.<br><br>88 Export product:<br>Irbesartan-----1kg.<br><br>Import items:<br>1. 1-2-Cyanobiophenyl-4-yl)methyl)-2-n-butyl-4-spirocyclopentane-2-imidazoloin-5-one----1.36kg/kg<br>2. Methylene chloride-----6.15kg/kg<br>3. Acetone-----2.83kg/kg<br><br>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.<br><br>RA concerned may take further necessary action as per above decision of Norms Committee. |                                     |                                                |                                 |

|                                       |                                     |                                                |                                 |
|---------------------------------------|-------------------------------------|------------------------------------------------|---------------------------------|
| 89 <b>Case No.:25/27/83-ALC1/2007</b> | Party Name:HETERO<br>DRUGS LIMITED, | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Approved</b> |
| HQ File :                             | RLA File :                          | Lic.No/Date:091003                             |                                 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |                       |                    |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|--------------------|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 01/83/050/01099/AM08/ | 09/24/040/00229/AM08/ | 1384<br>03.09.2007 |  |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Lisinopril under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.</p> <p>Export product:<br/>Lisinopril-----1kg.</p> <p>Import items:</p> <ol style="list-style-type: none"> <li>1. N 2-[(1-S)-Ethoxy Carbonyl-3-Phenyl Propyl]<br/>-N 6-trifluoro acetyl-L-lysine benzyl ester-----2.58kg/kg</li> <li>2. Palladium on carbon 5%-----0.011kg/kg</li> <li>3. L-Proline-----0.927kg/kg</li> <li>4. Methanol-----5.45kg/kg</li> <li>5. Methylene chloride-----10.77kg/kg</li> </ol> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                       |                       |                    |  |

|    |                                                                                                                                                                                                                                                                                                                                                                                |                                     |                                            |                              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 90 | <b>Case No.:22/27/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                             | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/01096/AM08/                                                                                                                                                                                                                                                                                                                                             | RLA File :<br>09/24/040/00166/AM08/ | Lic.No/Date:091003<br>1381<br>03.09.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Efavirenz under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                              |

|    |                                    |                                           |                                            |                             |
|----|------------------------------------|-------------------------------------------|--------------------------------------------|-----------------------------|
| 91 | <b>Case No.:54/27/83-ALC1/2007</b> | Party Name:GLENMARK PHARMACEUTICALS LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|----|------------------------------------|-------------------------------------------|--------------------------------------------|-----------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                          |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|------------------------------|
| HQ File :<br>01/83/050/01128/AM08/                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>03/94/040/00525/AM08/ | Lic.No/Date:031044<br>1978<br>06.09.2007 | Defer<br>Date:<br>01.01.2008 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                          |                              |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                            |                                                |                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------------------------------------------|---------------------------------|
| <b>Case No.:55/27/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Party Name:UNICHEM<br>LABORATORIES LIMITED | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Approved</b> |
| HQ File :<br>01/83/050/01129/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>03/95/040/00559/AM08/        | Lic.No/Date:031044<br>2110<br>07.09.2007       |                                 |
| <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Amlodipine Maleate under para 4.7 of HBP.</p> <p>The Committee in light of its earlier decision taken in its 15/08 meeting held on 14.08.2007 vide Case No.A-466 and in consultation with technical authorities present in meeting decided to ratify the norms on repeat basis under para 4.7 of HBP as per details below or as applied by the firm whichever is lower.</p> <p>Export Product:<br/>Amlodipine Maleate-----1Kg.</p> <p>Import items:<br/>1. Phthaloyl Amlodipine-----1.08kg/kg<br/>2. Methylene chloride-----4.50kg/kg<br/>3. Isopropyl alcohol-----2.40kg/kg</p> <p>Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                            |                                                |                                 |

|    |                                    |                                     |                                                |                                 |
|----|------------------------------------|-------------------------------------|------------------------------------------------|---------------------------------|
| 93 | <b>Case No.:72/27/83-ALC1/2007</b> | Party Name:LUPIN<br>LIMITED         | Meet No/Date:31/82-<br>ALC4/2007<br>04.12.2007 | <b>Status:Case<br/>Deferred</b> |
|    | HQ File :<br>01/83/050/01146/AM08/ | RLA File :<br>03/95/040/00570/AM08/ | Lic.No/Date:031044<br>2436                     | Defer<br>Date:                  |

|                                                                                                                                                                                                                                                          |  |            |            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|------------|------------|
|                                                                                                                                                                                                                                                          |  | 11.09.2007 | 15.01.2008 |
| <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium-Non Infringing under para 4.7 of HBP.<br><br>Committee decided to examine the case on file from the policy view point. |  |            |            |

|    |                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                                            |                                     |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-------------------------------------|
| 94 | <b>Case No.:</b> 111/27/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                             | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:</b> C<br>ase<br>Deferred |
|    | HQ File :<br>01/83/050/01185/AM08/                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>03/94/040/00622/AM08/ | Lic.No/Date:031044<br>3342<br>17.09.2007   | Defer<br>Date:<br>15.01.2008        |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Losartan Potassium under para 4.7 of HBP.<br><br>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |                                     |                                            |                                     |

|    |                                                                                                                                                                                                                                                                                                                                                                                         |                                     |                                            |                                     |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-------------------------------------|
| 95 | <b>Case No.:</b> 129/27/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                    | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:</b> C<br>ase<br>Deferred |
|    | HQ File :<br>01/83/050/01203/AM08/                                                                                                                                                                                                                                                                                                                                                      | RLA File :<br>03/94/040/00632/AM08/ | Lic.No/Date:031044<br>3548<br>18.09.2007   | Defer<br>Date:<br>15.01.2008        |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Sibutramine Hydrochloride under para 4.7 of HBP.<br><br>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |                                     |                                            |                                     |

|    |                                                                                                                                          |                                     |                                            |                                     |
|----|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-------------------------------------|
| 96 | <b>Case No.:</b> 160/27/83-ALC1/2007                                                                                                     | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:</b> C<br>ase<br>Deferred |
|    | HQ File :<br>01/83/050/01234/AM08/                                                                                                       | RLA File :<br>03/94/040/00658/AM08/ | Lic.No/Date:031044<br>4208<br>25.09.2007   | Defer<br>Date:<br>15.01.2008        |
|    | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP. |                                     |                                            |                                     |



Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                    |                                            |                              |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------|------------------------------|
| 97 | <b>Case No.:191/27/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           | Party Name:MALLADI DRUGS & PHARMACEUTICALS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/01265/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>04/24/040/00235/AM08/                | Lic.No/Date:041009<br>1280<br>01.10.2007   | Defer<br>Date:<br>15.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product [Alpha-(Alpha,Beta)]-Beta-Methyl-Alpha-Phenyl-1-Pyrrolidineethanol Base (Pyrrolidiny Nor ephedrine Base) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                                    |                                            |                              |

|    |                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                                            |                              |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 98 | <b>Case No.:6/29/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                | Party Name:RANBAXY LABORATORIES LTD | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|    | HQ File :<br>01/83/050/01271/AM08/                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>05/24/040/00525/AM08/ | Lic.No/Date:051020<br>9857<br>03.10.2007   | Defer<br>Date:<br>01.01.2008 |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefprozil under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                            |                              |

|    |                                                                                                                                                                                                                          |                                                  |                                            |                             |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------|-----------------------------|
| 99 | <b>Case No.:47/29/83-ALC1/2007</b>                                                                                                                                                                                       | Party Name:COVALENT LABORATORIES PRIVATE LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|    | HQ File :<br>01/83/050/01312/AM08/                                                                                                                                                                                       | RLA File :<br>09/24/040/00168/AM08/              | Lic.No/Date:091003<br>1717<br>08.10.2007   |                             |
|    | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 7 AVNA under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 28/82 held on</p> |                                                  |                                            |                             |

13.11.2007 Vide Case No.840/21/82 and in consultation with technical authorities present in meeting decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

Export product:

7-Amino 3-Vinyl Cephalosporanic Acid (7 AVNA)-----1kg.

Import items:

1. 7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid para Methoxy Benzyl Ester (GCLE)-----2.672kg/kg
2. Methylene Chloride-----7.59kg/kg
3. Methanol-----7.78kg/kg

Committee also decided to approve all the pending cases for the above export product with same inputs with the approval of Chairman on file within the validity period of such adhoc norms.

RA concerned may take further necessary action as per above decision of Norms Committee.

|     |                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                            |                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 100 | <b>Case No.:43/29/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01308/AM08/                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>09/24/040/00259/AM08/ | Lic.No/Date:0910031715<br>08.10.2007       | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cytosine Menthyl Ester (CME) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                             |

|     |                                    |                                     |                                            |                             |
|-----|------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 101 | <b>Case No.:67/29/83-ALC1/2007</b> | Party Name:LUPIN LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01332/AM08/ | RLA File :<br>03/95/040/00677/AM08/ | Lic.No/Date:0310445931<br>10.10.2007       | Defer Date:<br>01.01.2008   |

|  |                                                                                                                                                                                                                                                                                                                                                                                             |  |  |  |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
|  | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |  |  |  |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|

|     |                                                                                                                                                                                                                                                                                                                                 |                                             |                                            |                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------------------------------|-----------------------------|
| 102 | <b>Case No.:8/25/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                               | Party Name:SHASUN CHEMICALS & DRUGS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/82/050/00202/AM08/                                                                                                                                                                                                                                                                                              | RLA File :<br>04/24/040/00253/AM08/         | Lic.No/Date:041009<br>1459<br>10.10.2007   | Defer Date:<br>18.12.2007   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets 25mg under para 4.7 of HBP.</p> <p>Committee decided to hand over file to representative of PI Division present in meeting for his comments. Accordingly, case was deferred for two weeks.</p> |                                             |                                            |                             |

|     |                                                                                                                                                                                                                                                                                                                                                                                                    |                                             |                                            |                             |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------------------------------|-----------------------------|
| 103 | <b>Case No.:9/25/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                                                                                  | Party Name:SHASUN CHEMICALS & DRUGS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/82/050/00203/AM08/                                                                                                                                                                                                                                                                                                                                                                 | RLA File :<br>04/24/040/00254/AM08/         | Lic.No/Date:041009<br>1460<br>10.10.2007   | Defer Date:<br>18.12.2007   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets (50mg) under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for two weeks. Committee, accordingly, decided to defer case for two weeks.</p> |                                             |                                            |                             |

|     |                                                                                                                                                                     |                                             |                                            |                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------------------------------|-----------------------------|
| 104 | <b>Case No.:10/25/82-ALC4/2007</b>                                                                                                                                  | Party Name:SHASUN CHEMICALS & DRUGS LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/82/050/00204/AM08/                                                                                                                                  | RLA File :<br>04/24/040/00255/AM08/         | Lic.No/Date:041009<br>1462<br>10.10.2007   | Defer Date:<br>18.12.2007   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets (100mg) under para 4.7 of HBP.</p> |                                             |                                            |                             |

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for two weeks. Committee, accordingly, decided to defer case for two weeks.

|     |                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      |                                            |                             |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|-----------------------------|
| 105 | <b>Case No.:102/29/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                                    | Party Name:ASTRIX LABORATORIES LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01367/AM08/                                                                                                                                                                                                                                                                                                                                                                                                     | RLA File :<br>09/24/040/00271/AM08/  | Lic.No/Date:0910031798<br>16.10.2007       | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 2-Chloro-N-(2-Chloro-4-Methyl-3-Pyridinyl)-3-Pyridine Carboxamide under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                      |                                            |                             |

|     |                                                                                                                                                                                                                                                                                                                                                                                            |                                      |                                            |                             |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|-----------------------------|
| 106 | <b>Case No.:95/29/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                         | Party Name:IPCA LABORATORIES LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01360/AM08/                                                                                                                                                                                                                                                                                                                                                         | RLA File :<br>03/94/040/00673/AM08/  | Lic.No/Date:0310446503<br>16.10.2007       | Defer Date:<br>01.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Hydrochlorothiazide under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                      |                                            |                             |

|     |                                                                                                                                                                         |                                     |                                            |                             |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 107 | <b>Case No.:4/30/83-ALC1/2007</b>                                                                                                                                       | Party Name:RA CHEM PHARMA LIMITED.  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01373/AM08/                                                                                                                                      | RLA File :<br>09/24/040/00304/AM08/ | Lic.No/Date:0910031810<br>17.10.2007       | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 1-Acetylamino-5-Nitro-2-Propoxy Benzene under para 4.7 of</p> |                                     |                                            |                             |

|  |                                                                                                                                                                                                                          |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | HBP.                                                                                                                                                                                                                     |
|  | Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |

|     |                                                                                                                                                                                                                                                                                                                                                                                  |                                     |                                            |                             |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 108 | <b>Case No.:13/30/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                               | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01382/AM08/                                                                                                                                                                                                                                                                                                                                               | RLA File :<br>09/24/040/00330/AM08/ | Lic.No/Date:0910031817<br>19.10.2007       | Defer Date:<br>15.01.2008   |
|     | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Atazanavir Sulfate under para 4.7 of HBP.<br><br>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |                                     |                                            |                             |

|     |                                                                                                                                                                                                                                                                            |                                     |                                            |                             |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 109 | <b>Case No.:23/30/83-ALC1/2007</b>                                                                                                                                                                                                                                         | Party Name:MATRIX LABORATORIES LTD  | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01392/AM08/                                                                                                                                                                                                                                         | RLA File :<br>09/24/040/00299/AM08/ | Lic.No/Date:0910031841<br>22.10.2007       | Defer Date:<br>15.01.2008   |
|     | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Efavirenz-600mg Tablets under para 4.7 of HBP.<br><br>Committee decided to call for a copy of relevant DML from firm. Accordingly, case was deferred for six weeks. |                                     |                                            |                             |

|     |                                                                                                                                                                             |                                       |                                            |                             |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------------|-----------------------------|
| 110 | <b>Case No.:22/30/83-ALC1/2007</b>                                                                                                                                          | Party Name:SHODHANA LABORATORIES LTD. | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01391/AM08/                                                                                                                                          | RLA File :<br>09/24/040/00325/AM08/   | Lic.No/Date:0910031837<br>22.10.2007       | Defer Date:<br>01.01.2008   |
|     | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product 3-Oxo-4-Aza-5a-Androstane-17b-Carboxylic Acid under para 4.7 of HBP. |                                       |                                            |                             |

Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.

|         |                                                                                                                                                                                                                                                                                                                                            |                                          |                                            |                             |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------------------------------------|-----------------------------|
| 11<br>1 | <b>Case No.:1/27/82-ALC4/2007</b>                                                                                                                                                                                                                                                                                                          | Party Name:MISSION PHARMACEUTICALS LTD., | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|         | HQ File :<br>01/82/050/00222/AM08/                                                                                                                                                                                                                                                                                                         | RLA File :<br>03/95/040/00545/AM08/      | Lic.No/Date:031044<br>7430<br>23.10.2007   | Defer Date:<br>15.01.2008   |
|         | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Ciprofloxacin Tabs BP 500mg under para 4.7 of HBP.</p> <p>Committee decided to remind concerned RA to furnish a copy of application alongwith a copy of Advance Authorisation. Accordingly, case was deferred for six weeks.</p> |                                          |                                            |                             |

|         |                                                                                                                                                                                                                                                                                                                                                                               |                                                  |                                            |                             |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------|-----------------------------|
| 11<br>2 | <b>Case No.:52/30/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                            | Party Name:COVALENT LABORATORIES PRIVATE LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|         | HQ File :<br>01/83/050/01421/AM08/                                                                                                                                                                                                                                                                                                                                            | RLA File :<br>09/24/040/00280/AM08/              | Lic.No/Date:091003<br>1880<br>24.10.2007   | Defer Date:<br>18.12.2007   |
|         | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefdinir under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for two weeks. Committee, accordingly, decided to defer case for two weeks.</p> |                                                  |                                            |                             |

|         |                                                                                                                                                         |                                     |                                            |                             |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 11<br>3 | <b>Case No.:51/30/83-ALC1/2007</b>                                                                                                                      | Party Name:HETERO DRUGS LIMITED,    | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|         | HQ File :<br>01/83/050/01420/AM08/                                                                                                                      | RLA File :<br>09/24/040/00276/AM08/ | Lic.No/Date:091003<br>1879<br>24.10.2007   | Defer Date:<br>01.01.2008   |
|         | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Indinavir Sulphate under para 4.7 of HBP.</p> |                                     |                                            |                             |

|  |                                                                                                                                                                                                                            |  |  |  |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
|  | Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks. |  |  |  |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|

|     |                                                                                                                                                                                                                                                                                                                                                                                         |                                     |                                            |                             |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 114 | <b>Case No.:28/32/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                      | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01450/AM08/                                                                                                                                                                                                                                                                                                                                                      | RLA File :<br>03/94/040/00789/AM08/ | Lic.No/Date:031044<br>8309<br>29.10.2007   | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Losartan Potassium under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                             |

|     |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                                            |                             |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 115 | <b>Case No.:60/32/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                                   | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01482/AM08/                                                                                                                                                                                                                                                                                                                                                                                   | RLA File :<br>03/94/040/00799/AM08/ | Lic.No/Date:031044<br>8706<br>01.11.2007   | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Saquinavir 200mg Capsules/Saqvir 200mg Capsules under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                             |

|     |                                                                                                                                                  |                                     |                                            |                             |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 116 | <b>Case No.:69/32/83-ALC1/2007</b>                                                                                                               | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01491/AM08/                                                                                                               | RLA File :<br>03/94/040/00803/AM08/ | Lic.No/Date:031044<br>8936<br>02.11.2007   | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Simvastatin under para 4.7 of HBP.</p> |                                     |                                            |                             |

|  |                                                                                                                                                                                                                          |  |  |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
|  | Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |  |  |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|

|     |                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                            |                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 117 | <b>Case No.:82/32/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                                | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01504/AM08/                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>09/24/040/00051/AM08/ | Lic.No/Date:0910031991<br>05.11.2007       | Defer Date:<br>01.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Cefepime Hcl for Injection under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for four weeks. Committee, accordingly, decided to defer case for four weeks.</p> |                                     |                                            |                             |

|     |                                                                                                                                                                                                                                                                                                                                                                                 |                                     |                                            |                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 118 | <b>Case No.:106/32/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                             | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b> |
|     | HQ File :<br>01/83/050/01528/AM08/                                                                                                                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/00804/AM08/ | Lic.No/Date:0310449208<br>05.11.2007       | Defer Date:<br>15.01.2008   |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Lamivudine under para 4.7 of HBP.</p> <p>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks.</p> |                                     |                                            |                             |

|     |                                                                                                                                                                                                                                                                                                                                 |                                     |                                            |                             |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|
| 119 | <b>Case No.:92/32/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                              | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Approved</b> |
|     | HQ File :<br>01/83/050/01514/AM08/                                                                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/00814/AM08/ | Lic.No/Date:0310449495<br>06.11.2007       |                             |
|     | <p><b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Pantoprazole Sodium Sesquihydrate under para 4.7 of HBP.</p> <p>Committee in consultation with technical authorities present in meeting decided to ratify norms as per SION at SI.No.A-3166 or as applied by firm</p> |                                     |                                            |                             |



whichever is lower.

RA concerned may take further necessary action as per above decision of Norms Committee.

|     |                                                                                                                                                                                                                                                                                                                                                                         |                                     |                                            |                              |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 120 | <b>Case No.:93/32/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                      | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|     | HQ File :<br>01/83/050/01515/AM08/                                                                                                                                                                                                                                                                                                                                      | RLA File :<br>03/94/040/00815/AM08/ | Lic.No/Date:031044<br>9498<br>06.11.2007   | Defer<br>Date:<br>15.01.2008 |
|     | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Efavirenz under para 4.7 of HBP.<br><br>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |                                     |                                            |                              |

|     |                                                                                                                                                                                                                                                                                                                                                                                      |                                     |                                            |                              |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 121 | <b>Case No.:7/33/83-ALC1/2007</b>                                                                                                                                                                                                                                                                                                                                                    | Party Name:CIPLA LIMITED            | Meet No/Date:31/82-ALC4/2007<br>04.12.2007 | <b>Status:Case Deferred</b>  |
|     | HQ File :<br>01/83/050/01536/AM08/                                                                                                                                                                                                                                                                                                                                                   | RLA File :<br>03/94/040/00822/AM08/ | Lic.No/Date:031044<br>9680<br>07.11.2007   | Defer<br>Date:<br>15.01.2008 |
|     | <b>Decision :</b> Committee considered case as per agenda for ratification of norms for export product Fluticasone Propionate under para 4.7 of HBP.<br><br>Representative of PI Division present in meeting informed Committee that case is under examination in his Department and he sought deferment for six weeks. Committee, accordingly, decided to defer case for six weeks. |                                     |                                            |                              |

Date:30.11.2007  
Place:New Delhi

Shyam Lal  
Foreign Trade Development Officer