

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

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Para 4.7 Decision(DRAFT)

MEETING NUMBER : 39/82-ALC4/2007 MEETING DATE : 29.01.2008

The Meeting No.39/08 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 31.01.2008 under the Chairmanship of Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No.1/08 dated 09.05.2007, 2/08 dated 16.05.2007, 3/08 dated 23.05.2007, 4/08 dated 30.05.2007, 5/08 dated 06.06.2007 and 38/08 dated 23.01.2008 were ratified by the Committee.

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| Case No.B-515                                                                                                                                                                                                                                                                                                                                                                            | M/S Om Shree Pharmachem Pvt. Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                         | F.No.01/83/50/1378/AM07           |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                 | RLA F.No.03/95/40/1605/AM07       |
| Adv.Lic.No.0310424623 dated 27.03.2007                                                                                                                                                                                                                                                                                                                                                   |                                   |
| <p>Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.</p> <p>Committee observed that firm has sought deferment of personal hearing for two weeks. Accordingly, Committee decided to call representative of firm for personal hearing on 12.02.2008. Accordingly, case was deferred for two weeks.</p> |                                   |

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| Case No.B-516                                                                                                                                                                                                                                                                                                                                                                            | M/S Om Shree Pharmachem Pvt. Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                         | F.No.01/83/50/725/AM08            |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                 | RLA F.No.03/95/40/230/AM08        |
| Adv.Lic.No.0310432141 dated 08.06.2007                                                                                                                                                                                                                                                                                                                                                   |                                   |
| <p>Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.</p> <p>Committee observed that firm has sought deferment of personal hearing for two weeks. Accordingly, Committee decided to call representative of firm for personal hearing on 12.02.2008. Accordingly, case was deferred for two weeks.</p> |                                   |

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| Case No.B-517                                                                                                                                                                                                                                                                                                                                                                            | M/S Om Shree Pharmachem Pvt. Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                         | F.No.01/83/50/1267/AM07           |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                 | RLA F.No.03/95/40/1424/AM07       |
| Adv.Lic.No.0310420407 dated 21.02.2007                                                                                                                                                                                                                                                                                                                                                   |                                   |
| <p>Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.</p> <p>Committee observed that firm has sought deferment of personal hearing for two weeks. Accordingly, Committee decided to call representative of firm for personal hearing on 12.02.2008. Accordingly, case was deferred for two weeks.</p> |                                   |

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| Case No.B-518                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | M/S Lupin Ltd.          |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | F.No.01/82/162/285/AM06 |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |
| <p>Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 3C7ACCA (SION A-2119).</p> <p>The representative of Department of Revenue present in the meeting handed over a copy of DO letter No.605/46/2007-DBK dated 15.01.2008 from Revenue Secretary to Secretary, MOC wherein it has been stated that there is no need to add any additional item or change value cap at this stage when DEPB scheme is on its last legs.</p> <p>In view of above, Committee did not fix the value addition in this case and decided to refer the matter to DEPB Committee for their comments as to whether the value addition is to be fixed where data for fixation of DEPB rate or fix value addition norms has been received.</p> |                         |

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| Case No.B-519                                                                                                                                                   | M/S Penam Laboratories Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                | F.No.01/82/162/450/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                        |                             |
| <p>Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product 6-Amino Penicillanic Acid (SION A-33).</p> |                             |

The representative of Department of Revenue present in the meeting handed over a copy of DO letter No.605/46/2007-DBK dated 15.01.2008 from Revenue Secretary to Secretary, MOC wherein it has been stated that there is no need to add any additional item or change value cap at this stage when DEPB scheme is on its last legs.

In view of above, Committee did not fix the value addition in this case and decided to refer the matter to DEPB Committee for their comments as to whether the value addition is to be fixed where data for fixation of DEPB rate or fix value addition norms has been received.

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| Case No.B-520                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | M/S Wockhardt Ltd.      |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | F.No.01/82/162/215/AM08 |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                         |
| <p>Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product Dextropropoxyphene Sapsylate USP (SION A-175).</p> <p>The representative of Department of Revenue present in the meeting handed over a copy of DO letter No.605/46/2007-DBK dated 15.01.2008 from Revenue Secretary to Secretary, MOC wherein it has been stated that there is no need to add any additional item or change value cap at this stage when DEPB scheme is on its last legs.</p> <p>In view of above, Committee did not fix the value addition in this case and decided to refer the matter to DEPB Committee for their comments as to whether the value addition is to be fixed where data for fixation of DEPB rate or fix value addition norms has been received.</p> |                         |

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| Case No.B-521                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | M/S Wockhardt Ltd.      |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | F.No.01/82/162/548/AM07 |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                         |
| <p>Committee considered case as per agenda for fixation of value addition for DEPB rate in respect of export product D-Oxyphene Base (Powder) (SION A-166).</p> <p>The representative of Department of Revenue present in the meeting handed over a copy of DO letter No.605/46/2007-DBK dated 15.01.2008 from Revenue Secretary to Secretary, MOC wherein it has been stated that there is no need to add any additional item or change value cap at this stage when DEPB scheme is on its last legs.</p> |                         |

In view of above, Committee did not fix the value addition in this case and decided to refer the matter to DEPB Committee for their comments as to whether the value addition is to be fixed where data for fixation of DEPB rate or fix value addition norms has been received.

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| Case No.B-522                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | M/S Wockhardt Ltd.      |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | F.No.01/83/162/428/AM07 |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |
| <p>Committee considered case as per agenda for fixation of value addition for revision of DEPB rate in respect of export product Dextromethorphan hydrobromide (SION A-173).</p> <p>The representative of Department of Revenue present in the meeting handed over a copy of DO letter No.605/46/2007-DBK dated 15.01.2008 from Revenue Secretary to Secretary, MOC wherein it has been stated that there is no need to add any additional item or change value cap at this stage when DEPB scheme is on its last legs.</p> <p>In view of above, Committee did not fix the value addition in this case and decided to refer the matter to DEPB Committee for their comments as to whether the value addition is to be fixed where data for fixation of DEPB rate or fix value addition norms has been received.</p> |                         |

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| Case No.B-523                                                                                                                                                                                                                                          | M/S Shreya Life Science Pvt. Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                       |                                   |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                               | RLA F.No.03/95/40/1605/AM07       |
| Adv.Lic.No.0310300924 dated 05.11.2004                                                                                                                                                                                                                 |                                   |
| <p>Committee considered case as per agenda for regularization of additional marginal waste quantity of 3.124kgs.</p> <p>Committee decided to advise firm to get the matter regularized as per provisions of Foreign Trade Policy &amp; Procedures.</p> |                                   |

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| Case No.B-524                    | M/S Dalas Biotech Ltd.      |
| Norms Committee Meeting No.39/08 | F.No.01/82/50/223/AM08      |
| Meeting Date: 29.01.2008         | RLA F.No.05/24/40/1078/AM07 |
| Adv.Lic.No.0510203062 dated      |                             |

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| 27.04.2007                                                                                                                                                                                                                                                           |  |
| <p>Committee considered case as per agenda for revision of norms for export product 7 AVCA under para 4.7 of HBP.</p> <p>Committee observed that there is no basis for enhancement of quantity of inputs. Accordingly, Committee decided to maintain status quo.</p> |  |

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| Case No.B-525                                                                                                                                                                                                                                                                                                                                                                       | M/S Cipla Ltd.             |              |                                                    |                                             |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                    | F.No.01/82/50/927/AM06     |              |                                                    |                                             |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                            | RLA F.No.03/94/40/904/AM06 |              |                                                    |                                             |
| Adv.Lic.No.0310355734 dated 17.11.2005                                                                                                                                                                                                                                                                                                                                              |                            |              |                                                    |                                             |
| <p>Committee considered case as per agenda for ratification of norms for export product Doxazosin Mesylate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 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                                                                                                                                                                                                                                                                                                                                                                      | Export Quantity            | Import items |                                                    | Quantity allowed per unit of export product |
|                                                                                                                                                                                                                                                                                                                                                                                     |                            | Sl.No.       | Product                                            |                                             |
| Doxazoxin Mesylate                                                                                                                                                                                                                                                                                                                                                                  | 1kg.                       | 1.           | 6,7-Dimethoxy-2-(1-piperaziny) 4-amino quinazoline | 1.05kg/kg                                   |
| <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p>                                                                                                                                                                                                                                                                                     |                            |              |                                                    |                                             |

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| Case No.B-526                          | M/S Advy Chemicals         |  |  |  |
| Norms Committee Meeting No.39/08       | F.No.01/87/50/313/AM07     |  |  |  |
| Meeting Date: 29.01.2008               | RLA F.No.03/94/40/310/AM07 |  |  |  |
| Adv.Lic.No.0310387468 dated 29.06.2006 |                            |  |  |  |

Committee considered case as per agenda for ratification of norms for export product HBsAG Subtypes ad Reagent 4000mgs) (Hepatitis B Surface Antigen-Subtypes ad) under para 4.7 of HBP.

Committee decided to defer case for four weeks for comments of DBT.

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| Case No.B-527                          | M/S Alkem Laboratories Ltd. |
| Norms Committee Meeting No.39/08       | F.No.01/87/50/967/AM07      |
| Meeting Date: 29.01.2008               | RLA F.No.03/94/40/1200/AM07 |
| Adv.Lic.No.0310418737 dated 07.02.2007 |                             |

Committee considered case as per agenda for revision of norms for export product Amoxicillin and Clavulanate Potassium Tablet 375mg under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/71/2006-PI-III dated 31.01.2008 decided to revise norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

| Export product                                                             | Export Quantity | Import items |                                         | Total Quantity allowed |
|----------------------------------------------------------------------------|-----------------|--------------|-----------------------------------------|------------------------|
|                                                                            |                 | Sl.No.       | Product                                 |                        |
| Amoxycillin and Clavulanate Potassium Tablets 375mg. (ITC(HS)No.30041000)  | 13,00,000Nos    | 1)           | Amoxicillin Trihydrate                  | 377.91kg               |
|                                                                            |                 | 2)           | Clavulanate Potassium with Avicel (1:1) | 394.485kgs.            |
| Amoxycillin and Clavulanate Potassium Tablets 625mg. (ITC(HS)No.30041000)  | 20,00,000Nos    | 1)           | Amoxicillin Trihydrate                  | 1162.80kgs.            |
|                                                                            |                 | 2)           | Clavulanate Potassium with Avicel (1:1) | 606.90kgs.             |
| Amoxycillin and Clavulanate Potassium Tablets 1000mg. (ITC(HS)No.30041000) | 66,00,000Nos    | 1)           | Amoxicillin Trihydrate                  | 671.52kgs.             |
|                                                                            |                 | 2)           | Clavulanate Potassium with Avicel (1:1) | 200.277kgs.            |

RA concerned may check the quantity of imported input as per record before allowing revised norms and take further necessary action as per above decision of Norms Committee.

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| Case No.B-528                                                                                                                                                                                                                                                                                                                                                                            | M/S Alliance Laboratories Ltd.                           |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                         | F.No.01/82/50/424/AM08<br>F.No.01/83/50/1037/AM08        |
| Meeting Date:29.01.2008                                                                                                                                                                                                                                                                                                                                                                  | RLA F.No.03/94/40/160/AM08<br>RLA F.No.03/94/40/556/AM08 |
| Adv.Lic.No.0310430399 dated<br>23.05.2007<br>Adv. Lic.No.0310441279 dated<br>30.08.2007                                                                                                                                                                                                                                                                                                  |                                                          |
| <p>Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.</p> <p>Committee observed that firm has sought deferment of personal hearing for two weeks. Accordingly, Committee decided to call representative of firm for personal hearing on 12.02.2008. Accordingly, case was deferred for two weeks.</p> |                                                          |

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| Case No.A-989                                                                                                                                                                                                                                     | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                  | F.No.01/82/50/226/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                          | RLA F.No.09/24/40/192/AM08 |
| Adv.Lic.No.0910031252 dated<br>27.08.2007                                                                                                                                                                                                         |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate 300mg tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-990                                                                                                                                                                                                                | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                             | F.No.01/82/50/234/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                     | RLA F.No.09/24/40/188/AM08 |
| Adv.Lic.No.0910031126 dated<br>13.08.2007                                                                                                                                                                                    |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Valsartan Tablets 40mg under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-991 | M/S Matrix Lab. Ltd. |
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| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                       | F.No.01/82/50/227/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                               | RLA F.No.09/24/40/204/AM08 |
| Adv.Lic.No.0910031354 dated 31.08.2007                                                                                                                                                                                                                                 |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate 300mg and Lamidudine 300mg tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-992                                                                                                                                                                                                                                                             | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                          | F.No.01/82/50/233/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                  | RLA F.No.09/24/40/196/AM08 |
| Adv.Lic.No.0910031321 dated 30.08.2007                                                                                                                                                                                                                                    |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Emtricitabine 200mg and Tenofovir Disoproxil Fumarate 300mg Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-993                                                                                                                                                                                                                          | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                       | F.No.01/82/50/231/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                               | RLA F.No.09/24/40/191/AM08 |
| Adv.Lic.No.0910031127 dated 13.08.2007                                                                                                                                                                                                 |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Quetiapine Fumarate Tablet 25 mg under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-994                                                                                                                                                                                                                                                                    | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                 | F.No.01/82/50/229/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                         | RLA F.No.09/24/40/202/AM08 |
| Adv.Lic.No.0910031202 dated 24.08.2007                                                                                                                                                                                                                                           |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Didanosine Delayed Release Capsules-125mg, 200mg, 250mg and 400mg Capsules under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |



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| Case No.A-995                                                                                                                                                                                                                                            | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                         | F.No.01/82/50/232/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                 | RLA F.No.09/24/40/216/AM08 |
| Adv.Lic.No.0910031186 dated<br>21.08.2007                                                                                                                                                                                                                |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Citalopram Tablets-10mg, 20mg, 30mg, 40mg and 60mg under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-996                                                                                                                                                                                                                        | M/S Matrix Lab. Ltd.       |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                     | F.No.01/82/50/230/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                             | RLA F.No.09/24/40/187/AM08 |
| Adv.Lic.No.0910031251 dated<br>27.08.2007                                                                                                                                                                                            |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Abacavir Sulfate-300mg tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-997                                                                                                                                                                                                       | M/S Intervet India Pvt. Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                                                                    | F.No.01/82/162/392/AM08      |
| Meeting Date: 29.01.2008                                                                                                                                                                                            | RLA F.No.09/24/40/329/AM03   |
| Adv.Lic.No.0910013828 dated<br>03.04.2003                                                                                                                                                                           |                              |
| <p>Committee considered case as per agenda for ratification of norms for export product ND Clon 30 Vaccine 2ml under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of DBT.</p> |                              |

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| Case No.A-998                             | M/S Medreich Ltd.          |
| Norms Committee Meeting No.39/08          | F.No.01/82/50/1790/AM07    |
| Meeting Date:29.01.2008                   | RLA F.No.07/24/40/718/AM07 |
| Adv.Lic.No.0710049763 dated<br>24.01.2007 |                            |

Committee considered case as per agenda for ratification of norms for export product Paracetamol 450mg + Caffiene Anhydrous 45mg or 50mg or 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 31.01.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

| Export product                                                                                                                                | Export Quantity | Import items |                                          | Quantity allowed per unit of export product                                             |
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|                                                                                                                                               |                 | Sl.No        | Product                                  |                                                                                         |
| Paracetamol 450mg + Caffiene Anhydrous 45mg or 50mg or 30mg + Doxylamine Succinate 5mg + Codeine Phosphate 10mg Tablets (ITC(HS)No.300490 39) | 1 Tablet        | 1.           | Paracetamol                              | 459mg/tablet                                                                            |
|                                                                                                                                               |                 | 2.           | Doxylamine Succinate                     | 5.1mg/tablet                                                                            |
|                                                                                                                                               |                 | 3.           | Spectracolquinoline yellow 800744 B20    | Neither description nor CI No. matches with description given in MBF. Hence not allowed |
|                                                                                                                                               |                 | 4.           | Spectracolquinoline yellow LK 80500 2B10 | -d0-                                                                                    |

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

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| Case No.A-999                          | M/S Lyka BDR Intl. Ltd.     |
| Norms Committee Meeting No.39/08       | F.No.01/82/50/89/AM08       |
| Meeting Date: 29.01.2008               | RLA F.No.03/95/40/1309/AM07 |
| Adv.Lic.No.0310419266 dated 12.02.2007 |                             |

Committee considered case as per agenda for ratification of norms for export product (1) Clobetasole Propionate Cream 10gm (Dermotyl Cream 10gm), (2) Clobetasole Propionate Cream 15gm (Dermotyl Cream 15gm), (3) Clobetasole Propionate Cream 30gm (Dermotyl Cream 30gm), (4) Clobetasol Propionate Topical Solution 0.05% W/V and (5) Clobetasol Propionate Topical Sodution 0.05% W/V under para 4.7 of HBP.

Committee decided to call from the firm calculation sheet showing the wastage. Accordingly case was deferred for six weeks.

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| Case No.A-1000                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | M/S Cipla Ltd.             |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | F.No.01/82/50/255/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | RLA F.No.03/94/40/798/AM08 |
| Adv.Lic.No.0310448930 dated 02.11.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablet/Lamivudine Tablet 150mg, Lamivir S-30 Tablets/Lamivudine and Stavudine tablets, Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, Lamivir S Junior Tablets/Lamivudine and Stavudine Tablets, Lamivir S Baby Tablets/Lamivudine and Stavudine Tablets, Lamivir HBV Tablets 100mg/Lamivudine 100mg Tablets, Lamivudine and Zidovudine Tablets/Duovir/Bivir, Lamivudine, Zidovudine and nevirapine Tablets/Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-1001                                                                                                                                                                                                                                                                                               | M/S Cipla Ltd.             |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                             | F.No.01/82/50/256/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                     | RLA F.No.03/94/40/797/AM08 |
| Adv.Lic.No.0310448512 dated 31.10.2007                                                                                                                                                                                                                                                                       |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Efavir Capsule 200mg/Efavirenz 200mg Capsules and Efavir 600mg Tablets/Efavirenz 600mg Tablets tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-1002                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | M/S Cipla Ltd.             |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | F.No.01/82/50/215/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | RLA F.No.03/94/40/621/AM08 |
| Adv.Lic.No.0310443538 dated 18.09.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product (1) Lamivir 150 mg Tablets/Lamivudine Tablet 150mg, (2) Lamivir S-30 Tablets/Lamivudine and Stavudine Tablets, (3) Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, (4) Lamivir S Junior Tablets Lamivudine and Stavudine Tablets and (5) Lamivir S Baby Tablets lamivudine and Stavudine Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-1003                                                                                                                                                                                                                                                                                         | M/S Cipla Ltd.             |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                       | F.No.01/82/50/216/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                                               | RLA F.No.03/94/40/688/AM08 |
| Adv.Lic.No.0310445044 dated 03.10.2007                                                                                                                                                                                                                                                                 |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimune under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

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| Case No.A-1004                                                                                                                                                                                                                                                                                                        | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                                                                            | F.No.01/82/50/194/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                                               | RLA F. No. 03/94/40/582/AM08 |
| Adv. Lic. No.0310441827 dt.05.09.2007                                                                                                                                                                                                                                                                                 |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Nevimune 200 MG Tablets/Nevirapine 200MG Tablets (2) Nevirapine Oral Suspension 50 MG/5 ML/Nevimune under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1005                                                                                                                                                                                                                                                         | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                             | F.No.01/82/50/210/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                | RLA F. No. 03/94/40/578/AM08 |
| Adv. Lic. No.0310441906 dt.21.08.2007                                                                                                                                                                                                                                  |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lamivir 150MG Tablets/Lamivudine Tablets 150 MG under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1006                                 | M/S Cipla Ltd.                 |
| Norms Committee Meeting No.39/08               | F.No.01/82/50/212/AM08/DES-III |
| Meeting Date:29.01.2008                        | RLA F.No.03/94/40/590/AM08     |
| Advance licence No.0310442077 dated 06.09.2007 |                                |

Committee considered case as per agenda for ratification of norms for export product Terbinafine Hcl under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

| Export product                             | Export Quantity | Import items |                                       | Quantity allowed per unit of export product |
|--------------------------------------------|-----------------|--------------|---------------------------------------|---------------------------------------------|
|                                            |                 | Sl.No.       | Product                               |                                             |
| Terbinafine Hcl<br>ITC(HS)No.294200<br>90) | 1kg.            | 1            | 1-chloro-6,6-dimethyl-2-heptene-4-yne | 0.87kg/kg                                   |
|                                            |                 | 2            | N-methyl-1-naphthyl methylamine Hcl   | 1.14kg/kg                                   |

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

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| Case No.A-1007                                                                                                                  | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                      | F.No.01/82/50/264/AM 08      |
| Meeting Date 29.01.2008                                                                                                         | RLA F. No. 03/94/40/865/AM08 |
| Adv. Lic. No.0310450789<br>dt.20.11.2007                                                                                        |                              |
| The Committee considered the case as per agenda for ratification of norms for the export product Lamivir under para 4.7 of HBP. |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                     |                              |

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| Case No.A-1008                                                                                                                                                                                                                                   | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                       | F.No.01/82/50/265/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                          | RLA F. No. 03/94/40/857/AM08 |
| Adv. Lic. No.0310450548<br>dt.16.11.2007                                                                                                                                                                                                         |                              |
| The Committee considered the case as per agenda for ratification of norms for the export product 1. Irinotecan Hydrochloride Injection 40mg/2ml (each Vial 2ml) 2. Irinotecan Hydrochloride Injection 100mg/5ml (each Vial 5ml) para 4.7 of HBP. |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                                                                                                                                      |                              |

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| Case No.A-1009                                                                                                                                                                                                            | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                | F.No.01/82/50/250/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                   | RLA F. No. 03/94/40/749/AM08 |
| Adv. Lic. No.0310447493<br>dt.23.10.2007                                                                                                                                                                                  |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Lamivir under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1010                                                                                                                                                                                                                                                                                         | M/S Cipla Ltd.                 |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                       | F.No.01/82/50/224/AM08/DES-III |
| Meeting Date:29.01.2008                                                                                                                                                                                                                                                                                | RLA F.No.03/94/40/708/AM08     |
| Advance licence No.0310445737 dated<br>09.10.2007                                                                                                                                                                                                                                                      |                                |
| <p>Committee considered case as per agenda for ratification of norms for export product Nevimune 200mg Tablets/Nevirapine 200mg Tablets and Nevirapine Oral Suspension 50mg/5ml Nevimyne under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                |

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| Case No.A-1011                                                                                                                                                                                                                                                                                                            | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                                                                                | F.No.01/82/50/251/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                                                   | RLA F. No. 03/94/40/747/AM08 |
| Adv. Lic. No.0310447486<br>dt.23.10.2007                                                                                                                                                                                                                                                                                  |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product (1) Nevimune 200 MG Tablets/Nevirapine 200MG Tablets (2) Nevirapine Oral Suspension 50 MG/5 ML/Nevimune under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1012          | M/s Cipla Ltd.               |
| M.No.39/08              | F.No.01/82/50/214/AM 08      |
| Meeting Date 29.01.2008 | RLA F. No. 03/94/40/674/AM08 |

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| Adv. Lic. No.0310445040<br>dt.03.10.2007                                                                                                                                                                                                                 |  |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Telmisartan and Amlodipin Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |  |

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| Case No.A-1013                                                                                                                                                                                                                                                     | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                         | F.No.01/82/50/155/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                            | RLA F. No. 03/94/40/473/AM08 |
| Adv. Lic. No.0310438672<br>dt.07.08.2007                                                                                                                                                                                                                           |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Nevimune 200 MG Tablets/Nevirapine 200MG Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1014                                                                                                                                                                                                                                                                                                              | M/S Cipla Ltd.                 |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                            | F.No.01/82/50/168/AM08/DES-III |
| Meeting Date:29.01.2008                                                                                                                                                                                                                                                                                                     | RLA F.No.03/94/40/17/AM08      |
| Advance licence No.0310426065 dated<br>10.04.2007                                                                                                                                                                                                                                                                           |                                |
| <p>Committee considered case as per agenda for ratification of norms for export product Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets and Triomune 40/Lamivudine, Stavudine and nevirapine Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                |

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| Case No.A-1015                           | M/s Cipla Ltd.               |
| M.No.39/08                               | F.No.01/82/50/211/AM 08      |
| Meeting Date 29.01.2008                  | RLA F. No. 03/94/40/553/AM08 |
| Adv. Lic. No.0310440694<br>dt.27.08.2007 |                              |

The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lamivir 150MG Tablets/Lamivudine Tablets 150 MG under para 4.7 of HBP.

Committee decided to defer case for four weeks for comments of PI Division.

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| Case No.A-1016                                                                                                                                                                                                                                                                                                        | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                                                                            | F.No.01/82/50/213/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                                               | RLA F. No. 03/94/40/534/AM08 |
| Adv. Lic. No.0310440647<br>dt.23.08.2007                                                                                                                                                                                                                                                                              |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Efavir Capsules 200MG/Efavirenz 200 Capsules (2) Efavir 600 MG Tablets/Efavirenz 600MG Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1017                                                                                                                                                                                                                                                                                                                                   | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                                                                                                       | F.No.01/82/50/270/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                                                                          | RLA F. No. 03/94/40/860/AM08 |
| Adv. Lic. No.0310450692<br>dt.19.11.2007                                                                                                                                                                                                                                                                                                         |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product 1. Irinotecan Hydrochloride Injection 40mg/2ml (each Vial 2ml) 2. Irinotecan Hydrochloride Injection 100mg/5ml (each Vial 5ml) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1018                                                                                                                                                                                                                                                            | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                                | F.No.01/82/50/152/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                   | RLA F. No. 03/94/40/437/AM08 |
| Adv. Lic. No.0310437618<br>dt.27.07.2007                                                                                                                                                                                                                                  |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Triomune 30/Lamivudine Stavudine and Nevirapine Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |



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| Case No.A-1019                                                                                                                                                                                                                                                                                                                           | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                                                                                                               | F.No.01/82/50/160/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                                                                  | RLA F. No. 03/94/40/524/AM08 |
| Adv. Lic. No.0310440273<br>dt.21.08.2007                                                                                                                                                                                                                                                                                                 |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Irinotecan Hydrochloride Injection 40MG/2ML(each Vial 2ML)/Irinotecan Hydrochloride Injection 100MG/5ML(each Vial 5ML) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1020                                                                                                                                                                                                                                         | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                             | F.No.01/82/50/188/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                | RLA F. No. 03/94/40/554/AM08 |
| Adv. Lic. No.0310441419<br>dt.30.08.2007                                                                                                                                                                                                               |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Lopinavir and Ritonavir Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | M/S Cipla Ltd.                 |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | F.No.01/82/50/223/AM08/DES-III |
| Meeting Date:29.01.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | RLA F.No.03/94/40/706/AM08     |
| Advance licence No.0310445735 dated<br>09.10.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                |
| <p>Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablets/Lamivudine Tablet 150mg, Lamivir S-30 Tablets/Lamivudine and Stavudine Tablets, Lamivir S-40 Tablets/Lamivudine and Stavudine Tablets, Lamivir S Junior Tablets lamivudine and Stavudine Tablets, Lamivir S Baby Tablets Lamivudine and Stavudine Tables, Lamivir HBV Tablets 100mg/Lamivudine 100mg Tablets, Lamivudine and Zidovudine Tablets/Duovir/Bivir, Lamivudine, Zidovudine and nevirapine Tablets Duovir-N and Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP.</p> |                                |

Committee decided to defer case for four weeks for comments of PI Division.

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| Case No.A-1022                                                                                                                                                                        | M/S Cipla Ltd.                 |
| Norms Committee Meeting No.39/08                                                                                                                                                      | F.No.01/82/50/136/AM08/DES-III |
| Meeting Date:29.01.2008                                                                                                                                                               | RLA F.No.03/94/40/383/AM08     |
| Advance licence No.0310436156 dated 13.07.2007                                                                                                                                        |                                |
| Committee considered case as per agenda for ratification of norms for export product Stavir 15mg, 20mg, 30mg, 40 mg Capsules and Lamivir S-30 and S-40 Tablets under para 4.7 of HBP. |                                |
| Committee decided to defer case for four weeks for comments of PI Division.                                                                                                           |                                |

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| Case No.A-1023                                                                                                                                                                                                              | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                  | F.No.01/82/50/158/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                     | RLA F. No. 03/94/40/535/AM08 |
| Adv. Lic. No.0310440429 dt.22.08.2007                                                                                                                                                                                       |                              |
| The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Budccort 200 Inhaler (200 MD) Aerobud Inhaler (200 MD)/Budesonide Generis 200 Inhaler (200 MD) under para 4.7 of HBP. |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                                                                                                                 |                              |

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| Case No.A-1024                                                                                                                                                                                   | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                       | F.No.01/82/50/193/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                          | RLA F. No. 03/94/40/540/AM08 |
| Adv. Lic. No.0310440643 dt.23.08.2007                                                                                                                                                            |                              |
| The Committee considered the case as per agenda for ratification of norms for the export product 62/0 Cyproterone Acetate Tablets 100MG/Cyproterone Acetate Tablets 50 MG under para 4.7 of HBP. |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                                                                                      |                              |

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| Case No.A-1025          | M/s Cipla Ltd.               |
| M.No.39/08              | F.No.01/82/50/169/AM 08      |
| Meeting Date 29.01.2008 | RLA F. No. 03/94/40/250/AM08 |

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| Adv. Lic. No.0310432136<br>dt.08.06.2007                                                                                                                                                                                                |  |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Stavir 15 MG Capsules under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |  |

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| Case No.A-1026                                                                                                                                                                                                                             | M/s Cipla Ltd.               |
| M.No.39/08                                                                                                                                                                                                                                 | F.No.01/82/50/153/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                    | RLA F. No. 03/94/40/485/AM08 |
| Adv. Lic. No.0310439033<br>dt.09.08.2007                                                                                                                                                                                                   |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Gemcitabine Okasa Pharma under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1027                                                                                                                                                                                                               | M/s Glenmark Pharmaceuticals Ltd. |
| M.No.39/08                                                                                                                                                                                                                   | F.No.01/82/50/267/AM 08           |
| Meeting Date 29.01.2008                                                                                                                                                                                                      | RLA F. No. 03/94/40/805/AM08      |
| Adv. Lic. No.0310450439<br>dt.16.11.2007                                                                                                                                                                                     |                                   |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Cilazapril under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                   |

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| Case No.A-1028                                                                                                                                                                                                                                                                                        | M/s Arch Pharma Labs Ltd.    |
| M.No.39/08                                                                                                                                                                                                                                                                                            | F.No.01/82/50/268/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                               | RLA F. No. 03/94/40/715/AM08 |
| Adv. Lic. No.0310451131<br>dt.22.11.2007                                                                                                                                                                                                                                                              |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product (1 R2,S,5 R)-Methyl-5S-(Cytosine-I-YL) 1-3-Oxathiolane -2R-Carboxylate/CME Compound under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

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| Case No.A-1029                                                                                                                                                                                                                                                                                        | M/s Arch Pharma Labs Ltd.    |
| M.No.39/08                                                                                                                                                                                                                                                                                            | F.No.01/82/50/269/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                                                                                               | RLA F. No. 03/94/40/713/AM08 |
| Adv. Lic. No.0310451128<br>dt.22.11.2007                                                                                                                                                                                                                                                              |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product (1 R2,S,5 R)-Methyl-5S-(Cytosine-I-YL) 1-3-Oxathiolane -2R-Carboxylate/CME Compound under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

|                                                                                                                                                                                                                              |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| Case No.A-1030                                                                                                                                                                                                               | M/s Aurobindo Pharma Ltd.    |
| M.No.39/08                                                                                                                                                                                                                   | F.No.01/82/50/266/AM 08      |
| Meeting Date 29.01.2008                                                                                                                                                                                                      | RLA F. No. 09/24/40/380/AM08 |
| Adv. Lic. No.0910032134<br>dt.22.11.2007                                                                                                                                                                                     |                              |
| <p>The Committee considered the case as per agenda for ratification of norms for the export product Didanosine under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                              |

|                                                                                                                                                                                                                                                                            |                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Case No.A-1031                                                                                                                                                                                                                                                             | M/S Cadila Healthcare Ltd. |
| Norms Committee Meeting No.39/08                                                                                                                                                                                                                                           | F.No.01/82/50/278/AM08     |
| Meeting Date: 29.01.2008                                                                                                                                                                                                                                                   | RLA F.No.08/24/40/203/AM08 |
| Adv.Lic.No.0810068702 dated<br>28.11.2007                                                                                                                                                                                                                                  |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Warfarin 1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 6mg, 7.5mg and 10mg tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                            |

|                                                                                                                                                                          |                                 |
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| Case No.C-30                                                                                                                                                             | M/S DCM Shriram Industries Ltd. |
| Norms Committee Meeting No.35/08                                                                                                                                         | F.No.01/83/162/286/AM08         |
| Meeting Date: 01.01.2008                                                                                                                                                 |                                 |
| <p>Committee considered case as per agenda for modification of SION A-3011 in respect of export product D(-) Para Hydroxy Phenyl Glycine Methyl Potassium Dane Salt.</p> |                                 |

Committee decided to defer case for four weeks for comments of PI Division.

|   |                                                                                                                                                                                                                           |                                     |                                            |                           |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 1 | Case No.:61/24/87-ALC1/2007                                                                                                                                                                                               | Party Name:ALEMBIC LIMITED          | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|   | HQ File :<br>01/87/050/00084/AM06/                                                                                                                                                                                        | RLA File :<br>34/24/040/00007/AM06/ | Lic.No/Date:3410013261<br>27.04.2005       | Defer Date:<br>26.02.2008 |
|   | <p>Decision :Committee considered case as per agenda for ratification of norms for export product Modafinil under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                     |                                            |                           |

| 2                                                        | Case No.:303/24/87-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Party Name:ASENCE INC               | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved                    |                |             |              |  |                                         |        |         |                                                          |      |    |                                      |
|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------------------|----------------|-------------|--------------|--|-----------------------------------------|--------|---------|----------------------------------------------------------|------|----|--------------------------------------|
|                                                          | HQ File :<br>01/87/050/00401/AM06/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | RLA File :<br>34/24/040/00032/AM06/ | Lic.No/Date:3410013808<br>11.07.2005       |                                         |                |             |              |  |                                         |        |         |                                                          |      |    |                                      |
|                                                          | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Vitamin C BP/USP (Ascorbic Acid BP) under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 36/87 meeting held on 19.01.2005 vide Case No.2/36/87 and in consultation with representative of PI Division 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> <table border="1"> <thead> <tr> <th rowspan="2">Export product</th><th rowspan="2">Export Qty.</th><th colspan="2">Import items</th><th rowspan="2">Qty. allowed per unit of export product</th></tr> <tr> <th>Sl.No.</th><th>Product</th></tr> </thead> <tbody> <tr> <td>Vitamin C BP/USP (Ascorbic Acid BP) (ITC(HS)No.30041000)</td><td>1kg.</td><td>1.</td><td>2 KGA (2 Keto L-Gulonic Acid) BP/USP</td><td>1.476kg/kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                            |                                         | Export product | Export Qty. | Import items |  | Qty. allowed per unit of export product | Sl.No. | Product | Vitamin C BP/USP (Ascorbic Acid BP) (ITC(HS)No.30041000) | 1kg. | 1. | 2 KGA (2 Keto L-Gulonic Acid) BP/USP |
| Export product                                           | Export Qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Import items                        |                                            | Qty. allowed per unit of export product |                |             |              |  |                                         |        |         |                                                          |      |    |                                      |
|                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Sl.No.                              | Product                                    |                                         |                |             |              |  |                                         |        |         |                                                          |      |    |                                      |
| Vitamin C BP/USP (Ascorbic Acid BP) (ITC(HS)No.30041000) | 1kg.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 1.                                  | 2 KGA (2 Keto L-Gulonic Acid) BP/USP       | 1.476kg/kg                              |                |             |              |  |                                         |        |         |                                                          |      |    |                                      |

| 3                                                     | Case No.:10/20/87-ALC1/2005                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Party Name:ALKALOIDS CORP           | Meet No/Date:39/82-ALC4/2007<br>29.01.2008          | Status:Case Approved                    |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-----------------------------------------------------|-----------------------------------------|----------------|-------------|--------------|--|-----------------------------------------|---------|---------|-------------------------------------------------------|------|----|-----------------------------------------------------|
|                                                       | HQ File :<br>01/87/050/00429/AM06/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>02/24/040/00081/AM06/ | Lic.No/Date:0210080076<br>15.07.2005                |                                         |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
|                                                       | <p>Decision : 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>Committee in light of report forwarded by Department of MSME vide their U.O. No.23(17)/2005-Chem dated 22.01.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.</p> <table border="1"> <thead> <tr> <th rowspan="2">Export product</th><th rowspan="2">Export Qty.</th><th colspan="2">Import items</th><th rowspan="2">Qty. allowed per unit of export product</th></tr> <tr> <th>Sl.N o.</th><th>Product</th></tr> </thead> <tbody> <tr> <td>Aescin (Horse Chestnut Extract)<br/>ITC(HS)No.32019090</td><td>1kg.</td><td>1.</td><td>Horse Chestnut (Aesculus hippocastanum) dried seeds</td><td>66.2kgs/kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                                     |                                         | Export product | Export Qty. | Import items |  | Qty. allowed per unit of export product | Sl.N o. | Product | Aescin (Horse Chestnut Extract)<br>ITC(HS)No.32019090 | 1kg. | 1. | Horse Chestnut (Aesculus hippocastanum) dried seeds |
| Export product                                        | Export Qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Import items                        |                                                     | Qty. allowed per unit of export product |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
|                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Sl.N o.                             | Product                                             |                                         |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
| Aescin (Horse Chestnut Extract)<br>ITC(HS)No.32019090 | 1kg.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 1.                                  | Horse Chestnut (Aesculus hippocastanum) dried seeds | 66.2kgs/kg                              |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
| 4                                                     | Case No.:31/30/87-ALC1/2005                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Party Name:ALKALOIDS CORP           | Meet No/Date:39/82-ALC4/2007<br>29.01.2008          | Status:Case Withdrawn                   |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
|                                                       | HQ File :<br>01/87/050/00870/AM06/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>02/24/040/00154/AM06/ | Lic.No/Date:0210082777<br>17.10.2005                |                                         |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
|                                                       | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cascara Dry Extract under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as the case has already been approved ny NC in its 38/08 meeting held on 23.01.2008.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                     |                                                     |                                         |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |
| 5                                                     | Case No.:250/24/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Party Name:PHAKT OVERSEAS           | Meet No/Date:39/82-ALC4/2007<br>29.01.2008          | Status:Case Approved                    |                |             |              |  |                                         |         |         |                                                       |      |    |                                                     |

|                                    |                                     |                                          |  |
|------------------------------------|-------------------------------------|------------------------------------------|--|
| HQ File :<br>01/83/050/00558/AM06/ | RLA File :<br>03/95/040/01006/AM06/ | Lic.No/Date:03103604<br>60<br>21.12.2005 |  |
|------------------------------------|-------------------------------------|------------------------------------------|--|

Decision : Committee considered case as per agenda for ratification of norms for export product Gentamicin Eye/Ear Drops 5ml under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/185/2005-PI-III dated 31.01.2008 and 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.

| Export product                                 | Export Qty. | Import items |                                    | Qty. allowed per unit of export product |
|------------------------------------------------|-------------|--------------|------------------------------------|-----------------------------------------|
|                                                |             | Sl.N o.      | Product                            |                                         |
| Gentamycin eye/ear drops, 0.3%W/V in 5ml Vials | 1 Vial      | 1.           | Gentamycin Sulphate                | 16.88mg/Vial                            |
|                                                |             | 2.           | Relevant glass vials               | Net to Net                              |
|                                                |             | 3.           | Relevant Grey butyl rubber stopper | Net to Net                              |
|                                                |             | 4.           | Aluminium Seal                     | Net to Net                              |

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

|                                                                                                                                                                                                                                                                                                                                                                                                     |                                    |                                     |                                            |                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|--------------------------------------------|----------------------|
| 6                                                                                                                                                                                                                                                                                                                                                                                                   | Case No.:8/10/87-ALC1/2006         | Party Name:ALKALOIDS CORP           | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
|                                                                                                                                                                                                                                                                                                                                                                                                     | HQ File :<br>01/87/050/00096/AM07/ | RLA File :<br>02/24/040/00020/AM07/ | Lic.No/Date:02100887<br>34<br>28.04.2006   |                      |
| <p>Decision : 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>Committee in light of report forwarded by Department of MSME vide their U.O. No.23(17)/2005-Chem dated 22.01.2008 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                     | Export                              | Import items                               | Qty. allowed per     |

|                                                                                          | Qty. | Sl.No. | Product                                             | unit of export product |
|------------------------------------------------------------------------------------------|------|--------|-----------------------------------------------------|------------------------|
| Aescin (Horse Chestnut Extract)<br>ITC(HS)No.32019090                                    | 1kg. | 1.     | Horse Chestnut (Aesculus hippocastanum) dried seeds | 66.2kgs/kg             |
| RA concerned may take further necessary action as per above decision of Norms Committee. |      |        |                                                     |                        |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                      |                                            |                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|----------------------|
| Case No.:1/23/87-ALC1/2006                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Party Name:ALCHEM INTERNATIONAL LTD. | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Rejected |
| HQ File :<br>01/87/050/00336/AM07/                                                                                                                                                                                                                                                                                                                                                                                                                                         | RLA File :<br>05/24/040/00255/AM07/  | Lic.No/Date:0510185276<br>21.06.2006       |                      |
| <p>7 Decision : Committee considered case as per agenda for ratification of norms for export product Silymarin Extract under para 4.7 of HBP.</p> <p>Committee in consultation with technical authorities present in meeting observed that item of import and export are same and therefore, 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> |                                      |                                            |                      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                        |                                            |                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------------|----------------------|
| 8 Case No.:12/20/82-ALC1/2006                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Party Name:JUPITER BIOSCIENCE LIMITED, | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
| HQ File :<br>01/82/050/00502/AM07/                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>09/24/040/00121/AM07/    | Lic.No/Date:0910026738<br>05.07.2006       |                      |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product N-T-Boc-L-Phenylalanine 99% purity under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2006-PI-III dated 21.01.2008 and 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> |                                        |                                            |                      |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Export                                 | Import items                               | Qty. allowed         |



|                                                 | Qty. | Sl.No. | Product                                 | per unit of export product |
|-------------------------------------------------|------|--------|-----------------------------------------|----------------------------|
| N-T-BOC-L-Phenyl Alanine<br>ITC(HS)No.29374 000 | 1kg. | 1.     | L-Phenyl Alanine                        | 0.622kg/kg                 |
|                                                 |      | 2.     | Di-Tertiary-Butyl Dicarbonate Anhydride | 0.821kg/kg                 |
|                                                 |      | 3.     | Isopropyl Alcohol                       | 0.394kg/kg                 |
|                                                 |      | 4.     | N-Hexane                                | 0.986kg/kg                 |
|                                                 |      | 5.     | Ethyl Acetate                           | 1.134kg/kg                 |
|                                                 |      | 6.     | Sodium Hydroxide                        | 0.150kg/kg                 |

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

|                                    |                                     |                                            |                      |
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| Case No.:16/27/87-ALC1/2006        | Party Name:ALKALOIDS CORP           | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
| HQ File :<br>01/87/050/00419/AM07/ | RLA File :<br>02/24/040/00123/AM07/ | Lic.No/Date:02100921<br>25<br>02.08.2006   |                      |

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

Committee in light of report forwarded by Department of MSME vide their U.O. No.23(17)/2005-Chem dated 22.01.2008 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower.

| Export product | Export Qty. | Import items |                       | Qty. allowed per unit of export product |
|----------------|-------------|--------------|-----------------------|-----------------------------------------|
|                |             | Sl.No.       | Product               |                                         |
| Kola Extract   | 1kg.        | 1.           | Kola Nuts (Cola Nuts) | 7.9kgs/kg                               |

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

|    |                            |                                    |                                            |                      |
|----|----------------------------|------------------------------------|--------------------------------------------|----------------------|
| 10 | Case No.:2/46/82-ALC1/2006 | Party Name:MATRIX LABORATORIES LTD | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred |
|    | HQ File :                  | RLA File :                         | Lic.No/Date:09100286                       | Defer                |

|                                                                                                                                                                                      |                       |                  |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------|---------------------|
| 01/82/050/01441/AM07/                                                                                                                                                                | 09/24/040/00390/AM07/ | 34<br>13.12.2006 | Date:<br>26.02.2008 |
| Decision : Committee considered case as per agenda for ratification of norms for export product N-Trifluoro Acetylcysteine-Lysine-Praline (Lyspro) (Isolated) under para 4.7 of HBP. |                       |                  |                     |
| Committee decided to defer case for four weeks for comments of PI Division.                                                                                                          |                       |                  |                     |

|                                    |                                                                                                                                                                    |                                            |                              |
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| Case No.:16/49/82-ALC1/2006        | Party Name:LUPIN LIMITED                                                                                                                                           | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
| HQ File :<br>01/82/050/01721/AM07/ | RLA File :<br>03/95/040/01297/AM07/                                                                                                                                | Lic.No/Date:03104167<br>16<br>22.01.2007   | Defer<br>Date:<br>26.02.2008 |
| 11                                 | Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium – Non Infringing under para 4.7 of HBP. |                                            |                              |
|                                    | Committee decided to examine case on file as the application for firm is based on non-fringing process.                                                            |                                            |                              |

|    |                                                                                                                                       |                                                              |                                         |                       |
|----|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-----------------------------------------|-----------------------|
| 12 | Case No.:3/19/82-ALC4/2007                                                                                                            | Party Name:JUBILANT ORGANOSYS LTD (FORMERLY VAM ORGANIC CHEM | Meet No/Date:39/82-ALC4/2007 29.01.2008 | Status:Case Withdrawn |
|    | HQ File : 01/82/050/01663/AM07/                                                                                                       | RLA File : 05/24/040/00951/AM07/                             | Lic.No/Date:05101998 28 21.02.2007      |                       |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Nalidixic Acid under para 4.7 of HBP. |                                                              |                                         |                       |
|    | Committee decided to withdraw case as same has already been approved in its 38/08 meeting held on 22.01.2008.                         |                                                              |                                         |                       |

|                                    |                                                                                                                                                   |                                            |                              |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------------------------|
| Case No.:852/21/82-ALC4/2007       | Party Name:METROCHEM API PVT. LTD.                                                                                                                | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
| HQ File :<br>01/82/050/01678/AM07/ | RLA File :<br>09/24/040/00436/AM07/                                                                                                               | Lic.No/Date:09100294<br>25<br>22.02.2007   | Defer<br>Date:<br>11.03.2008 |
| 13                                 | Decision : Committee considered case as per agenda for ratification of norms for export product Lansoprazole Pellets 11.2% under para 4.7 of HBP. |                                            |                              |

Committee decided to call for a copy of DML from firm. Accordingly, case was deferred for six weeks.

|    |                                                                                                                                                                                                                                  |                                           |                                            |                           |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------|---------------------------|
| 14 | Case No.:879/21/82-ALC4/2007                                                                                                                                                                                                     | Party Name:LAKE CHEMICALS PRIVATE LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/01714/AM07/                                                                                                                                                                                               | RLA File :<br>07/24/040/00780/AM07/       | Lic.No/Date:0710050314<br>27.02.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Dorzolamide HCL under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                           |                                            |                           |

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                     |                                            |                           |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 15 | Case No.:7/2/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/01804/AM07/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>03/94/040/01443/AM07/ | Lic.No/Date:0310422972<br>13.03.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product (1) Triomune 30/ Lamivudine, Stavudine and Nevirapine Tablets. Each uncoated tablet contains: Stavudine 30mg, Lamivudine 150mg, Nevirapine 200mg. and (2) Triomune 40/ Lamivudine, Stavudine and Nevirapine Tablets. Each uncoated tablet contains: Stavudine 40mg, Lamivudine 150mg, Nevirapine 200mg. under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                     |                                            |                           |

|    |                                                                                                                                                                                                                                                                                                                                              |                                     |                                            |                           |
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| 16 | Case No.:17/9/82-ALC4/2007                                                                                                                                                                                                                                                                                                                   | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/01837/AM07/                                                                                                                                                                                                                                                                                                           | RLA File :<br>03/94/040/01468/AM07/ | Lic.No/Date:0310423777<br>21.03.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : 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 technical information has been called for from firm which has not been received. It was, therefore, decided to await reply of firm and to defer case for four weeks.</p> |                                     |                                            |                           |

|    |                             |                                             |                              |                      |
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| 17 | Case No.:25/14/83-ALC1/2007 | Party Name:ALCHYMARS ICM SM PRIVATE LIMITED | Meet No/Date:39/82-ALC4/2007 | Status:Case Deferred |
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|                                                                                                                                      |                                     |                                          |                              |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|------------------------------|
|                                                                                                                                      |                                     | 29.01.2008                               |                              |
| HQ File :<br>01/83/050/00016/AM08/                                                                                                   | RLA File :<br>04/24/040/00501/AM07/ | Lic.No/Date:04100887<br>27<br>02.04.2007 | Defer<br>Date:<br>26.02.2008 |
| Decision : Committee considered case as per agenda for ratification of norms for export product Allylestrenol under para 4.7 of HBP. |                                     |                                          |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                          |                                     |                                          |                              |

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| 18 | Case No.:19/19/83-<br>ALC1/2007                                                                                                                                          | Party Name:GRANULES<br>INDIA LIMITED | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Cas<br>e Deferred     |
|    | HQ File :<br>01/83/050/00029/AM08/                                                                                                                                       | RLA File :<br>09/24/040/00534/AM07/  | Lic.No/Date:09100298<br>86<br>04.04.2007       | Defer<br>Date:<br>26.02.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Naproxen Granules DC Grade 80% (Compresso NAP 80) under para 4.7 of HBP. |                                      |                                                |                              |
|    | Committee decided to defer case for four weeks for comments of PI Division.                                                                                              |                                      |                                                |                              |

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| 19 | Case No.:566/24/83-<br>ALC1/2007                                                                                                                        | Party Name:MOREPEN<br>LABORATORIES LTD., | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Cas<br>e<br>Withdrawn |
|    | HQ File :<br>01/83/050/00239/AM08/                                                                                                                      | RLA File :<br>05/24/040/00080/AM08/      | Lic.No/Date:05102032<br>07<br>03.05.2007       |                              |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Montelukast Sodium Min Assay 97% under para 4.7 of HBP. |                                          |                                                |                              |
|    | Committee decided to withdraw case as case has been approved by NC in its 38/08 meeting held on 23.01.2008.                                             |                                          |                                                |                              |

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| 20 | Case No.:27/19/83-<br>ALC1/2007                                                                                                                     | Party Name:GRANULES<br>INDIA LIMITED | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Cas<br>e Deferred     |
|    | HQ File :<br>01/83/050/00232/AM08/                                                                                                                  | RLA File :<br>09/24/040/00024/AM08/  | Lic.No/Date:09100301<br>58<br>03.05.2007       | Defer<br>Date:<br>11.03.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product PhenazopyridineHydrochloride under para 4.7 of HBP. |                                      |                                                |                              |
|    | Committee decided to defer case for six weeks for comments of PI Division.                                                                          |                                      |                                                |                              |

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| 21                                                                                                                                                                                                                                                                                                                                                                                                        | Case No.:20/21/82-ALC4/2007        | Party Name:RANBAXY LABORATORIES LTD | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                                                                                                                                                                           | HQ File :<br>01/82/050/00028/AM08/ | RLA File :<br>05/24/040/00097/AM08/ | Lic.No/Date:05102033<br>44<br>07.05.2007   | Defer Date:<br>26.02.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin Carbomer Granules 44% (Bulk Drug/ Pharmacopeal Grade) under para 4.7 of HBP.</p> <p>Committee observed that RA concerned was requested to furnish a copy of application, but same has not been received. Accordingly, it was decided to remind RA and to defer case for four weeks.</p> |                                    |                                     |                                            |                           |

| 22                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Case No.:29/9/82-ALC4/2007         | Party Name:S.M. HERBALS PVT.LTD.    | Meet No/Date:39/82-ALC4/2007<br>29.01.2008                     | Status:Case Approved                    |                |             |              |  |                                         |         |         |                                                                 |      |    |                                                                |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|----------------------------------------------------------------|-----------------------------------------|----------------|-------------|--------------|--|-----------------------------------------|---------|---------|-----------------------------------------------------------------|------|----|----------------------------------------------------------------|----------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | HQ File :<br>01/82/050/00039/AM08/ | RLA File :<br>05/24/040/01075/AM07/ | Lic.No/Date:0510203<br>751<br>16.05.2007                       |                                         |                |             |              |  |                                         |         |         |                                                                 |      |    |                                                                |          |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Camptothecin under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by Deptt. Of MSME vide their U.O. No.5(9)/2005-Chem dated 21.01.2008 and in consultation with representative of D/O MSME 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> <table border="1"> <thead> <tr> <th rowspan="2">Export product</th><th rowspan="2">Export Qty.</th><th colspan="2">Import items</th><th rowspan="2">Qty. allowed per unit of export product</th></tr> <tr> <th>Sl.N o.</th><th>Product</th></tr> </thead> <tbody> <tr> <td>Camptothecin<br/>purity<br/>Minimum 99%<br/>ITC(HS)No.1302<br/>1919</td><td>1kg.</td><td>1.</td><td>Mappia foetida<br/>(containing<br/>Camptothecin 0.14%<br/>± 0.02%</td><td>952kg/kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                    |                                     |                                                                |                                         | Export product | Export Qty. | Import items |  | Qty. allowed per unit of export product | Sl.N o. | Product | Camptothecin<br>purity<br>Minimum 99%<br>ITC(HS)No.1302<br>1919 | 1kg. | 1. | Mappia foetida<br>(containing<br>Camptothecin 0.14%<br>± 0.02% | 952kg/kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Export Qty.                        | Import items                        |                                                                | Qty. allowed per unit of export product |                |             |              |  |                                         |         |         |                                                                 |      |    |                                                                |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                    | Sl.N o.                             | Product                                                        |                                         |                |             |              |  |                                         |         |         |                                                                 |      |    |                                                                |          |
| Camptothecin<br>purity<br>Minimum 99%<br>ITC(HS)No.1302<br>1919                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1kg.                               | 1.                                  | Mappia foetida<br>(containing<br>Camptothecin 0.14%<br>± 0.02% | 952kg/kg                                |                |             |              |  |                                         |         |         |                                                                 |      |    |                                                                |          |

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| 23 | Case No.:614/24/83- | Party Name:NICHOLAS | Meet No/Date:39/82- | Status:Cas |
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| ALC1/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | PIRAMAL INDIA LTD.                  | ALC4/2007<br>29.01.2008                  | e Deferred                   |
| HQ File :<br>01/83/050/00369/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>03/95/040/01471/AM07/ | Lic.No/Date:03104300<br>58<br>21.05.2007 | Defer<br>Date:<br>26.02.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Ultrazyme Tablets (7458X)[Contact lens cleaning tablets] under para 4.7 of HBP.</p> <p>Committee observed that Department of Bio-technology have given NOC for export of Ultrazyme tablets 7458X. As regards technical comments for ratification of norms under para 4.7 of HBP, Department of Bio-technology vide their letter No.BT/IL/05/228/2006-PID dated 26.07.2007 has indicated that the item sought to be exported/imported duty free are chemical products and no biotech product component is involved.</p> <p>Committee, therefore, decided to write to Department of Bio-technology as to how the item of import and export are chemical product when they have issued NOC for import/export of Bio-technology items. Accordingly, case was deferred for four weeks.</p> |                                     |                                          |                              |

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|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------------|
| Case No.:622/24/83-<br>ALC1/2007   | Party Name:SHODHANA<br>LABORATORIES LTD.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Case<br>Deferred      |
| HQ File :<br>01/83/050/00388/AM08/ | RLA File :<br>09/24/040/00048/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Lic.No/Date:09100303<br>34<br>24.05.2007       | Defer<br>Date:<br>11.03.2008 |
| 24                                 | <p>Decision : 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>Committee observed that RA has furnished copy of Advance Authorisation for export product 2-(2-Methoxy Phenoxy) Ethylamine while the application has been forwarded for export product 4-(2,3-Epoxy Propoxy) Carbazole. Committee decided to call for a copy of relevant application form concerned RA. Accordingly, case was deferred for six weeks.</p> |                                                |                              |

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| 25 | Case No.:712/24/83-<br>ALC1/2007   | Party Name:IPCA<br>LABORATORIES LIMITED | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status: Case<br>Approved |
|    | HQ File :<br>01/83/050/00584/AM08/ | RLA File :<br>03/94/040/00192/AM08/     | Lic.No/Date:0310432<br>914<br>18.06.2007       |                          |

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/88/2007-PI-III dated 28.01.2008 and 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.

| Export product                   | Export Qty. | Import items |                          | Qty. allowed per unit of export product |
|----------------------------------|-------------|--------------|--------------------------|-----------------------------------------|
|                                  |             | Sl.N o.      | Product                  |                                         |
| Testosterone ITC(HS)No.29379 000 | 1kg.        | 1.           | Androst-4-ene-3,17 dione | 1.33kg/kg                               |
|                                  |             | 2.           | Triethyl Ortho Formate   | 0.36kg/kg                               |

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

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| Case No.:715/24/83-ALC1/2007       | Party Name:IPCA LABORATORIES LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
| HQ File :<br>01/83/050/00590/AM08/ | RLA File :<br>03/94/040/00243/AM08/  | Lic.No/Date:0310432<br>929<br>18.06.2007   |                      |

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/88/2007-PI-III dated 28.01.2008 and 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.

| Export product                     | Export Qty. | Import items |                                | Qty. allowed per unit of export product |
|------------------------------------|-------------|--------------|--------------------------------|-----------------------------------------|
|                                    |             | Sl.N o.      | Product                        |                                         |
| Norethisterone ITC(HS)No.2937 9000 | 1kg.        | 1            | 19 Nor-4-Androstene-3,17 dione | 1.066kg/kg                              |

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

|    |                                                                                                                                                                                                                                      |                                     |                                            |                           |
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| 27 | Case No.:731/24/83-ALC1/2007                                                                                                                                                                                                         | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/83/050/00624/AM08/                                                                                                                                                                                                   | RLA File :<br>09/24/040/00425/AM07/ | Lic.No/Date:0910030691<br>29.06.2007       | Defer Date:<br>12.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Sertraline Mandelate under para 4.7 of HBP.</p> <p>Committee decided to defer case for two weeks for comments of PI Division.</p> |                                     |                                            |                           |

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| 28 | Case No.:730/24/83-ALC1/2007                                                                                                                                                                                                                                 | Party Name:SUVEN LIFE SCIENCES LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/83/050/00623/AM08/                                                                                                                                                                                                                           | RLA File :<br>09/24/040/00120/AM08/    | Lic.No/Date:0910030686<br>29.06.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product (S) - 3 - Hydroxy - N - Bensyle Pyrrolidine under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                        |                                            |                           |

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| 29 | Case No.:95/21/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Party Name:NICHOLAS PIRAMAL INDIA LTD. | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00144/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>03/95/040/00389/AM08/    | Lic.No/Date:0310437508<br>26.07.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Hydrocare Tablets (Contact Lens Cleaning Tablets) under para 4.7 of HBP.</p> <p>Committee observed that Department of Bio-technology have given NOC for export of Hydrocare Tablets (Contact Lens Cleaning Tablet). As regards technical comments for ratification of norms under para 4.7 of HBP, Department of Bio-technology vide their letter No.BT/IL/05/228/2006-PID dated 26.07.2007 has indicated that the item sought to be exported/imported duty free are chemical products and no biotech product component is involved.</p> |                                        |                                            |                           |



Committee, therefore, decided to write to Department of Bio-technology as to how the item of import and export are chemical product when they have issued NOC for import/export of Bio-technology items. Accordingly, case was deferred for four weeks.

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| Case No.:875/24/83-ALC1/2007                                                                                                                                                                                                                                                                                    | Party Name:GRANULES INDIA LIMITED                                                        | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |                    |                                         |
| HQ File :<br>01/83/050/00879/AM08/                                                                                                                                                                                                                                                                              | RLA File :<br>09/24/040/00177/AM08/                                                      | Lic.No/Date:0910031050<br>06.08.2007       |                      |                    |                                         |
| Decision : Committee considered case as per agenda for ratification of norms for export product Iso Metheptene Mucate under para 4.7 of HBP.                                                                                                                                                                    |                                                                                          |                                            |                      |                    |                                         |
| Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/63/2007-PI-III dated 28.01.2008 and 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. |                                                                                          |                                            |                      |                    |                                         |
| 30                                                                                                                                                                                                                                                                                                              | Export product                                                                           | Export Qty.                                | Import items         |                    | Qty. allowed per unit of export product |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | Sl.No                | Product            |                                         |
|                                                                                                                                                                                                                                                                                                                 | Iso Metheptene Mucate<br>ITC(HS)No.29094200                                              | 1kg.                                       | 1.                   | Lactose            | 1.29kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | 2.                   | Citral             | 1.34kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | 3.                   | Formic Acid        | 1.77kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | 4.                   | Benzene            | 1.46kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | 5.                   | Iso Propyl Alcohol | 1.17kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | 6.                   | Ethyl Acetate      | 2.75kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |                                                                                          |                                            | 7.                   | Methanol           | 0.82kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 | RA concerned may take further necessary action as per above decision of Norms Committee. |                                            |                      |                    |                                         |

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| 31 | Case No.:3/18/82-ALC4/2007         | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
|    | HQ File :<br>01/82/050/00142/AM08/ | RLA File :<br>03/94/040/00455/AM08/ | Lic.No/Date:0310438406<br>06.08.2007       |                      |

Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/ Duovit/ Bivit/ Arved Tablets (Each film coated Tablets contains Lamivudine 150mg and Zidovudine USP 300mg) under para 4.7 of HBP.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 and 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.

| Export product                                                   | Export Qty.  | Import items |                                  | Qty. allowed per unit of export product |
|------------------------------------------------------------------|--------------|--------------|----------------------------------|-----------------------------------------|
|                                                                  |              | Sl.N o.      | Product                          |                                         |
| Lamivudine 150mg and Stavudine 300mg Tablets ITC(HS)No.300490 99 | 1000 Tablets | 1.           | 3'-Azido-3'-5-o-trityl thimidine | 0.728kg/1000 Tablets                    |

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

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|------------------------------------|-----------------------------------------|--------------------------------------------|---------------------------|
| Case No.:113/21/82-ALC4/2007       | Party Name:NECTAR LIFESCIENCES LIMITED, | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00157/AM08/ | RLA File :<br>22/24/040/00030/AM08/     | Lic.No/Date:2210006984<br>20.08.2007       | Defer Date:<br>26.02.2008 |

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Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil (off white to pale yellow powder) under para 4.7 of HBP.

Committee observed that firm was requested to furnish technical details as per Appendix 33 vide letter dated 21.01.2008, but information has not been received. Committee, therefore, decided to await reply of firm. Accordingly, case was deferred for four weeks.

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| Case No.:7/25/83-ALC1/2007         | Party Name:ASTRIX LABORATORIES LTD., | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred |
| HQ File :<br>01/83/050/01032/AM08/ | RLA File :<br>09/24/040/00231/AM08/  | Lic.No/Date:0910031314                     | Defer Date:          |

|                                                                                                                                   |  |            |            |
|-----------------------------------------------------------------------------------------------------------------------------------|--|------------|------------|
|                                                                                                                                   |  | 29.08.2007 | 26.02.2008 |
| Decision : Committee considered case as per agenda for ratification of norms for export product Didanosine under para 4.7 of HBP. |  |            |            |
| Committee decided to defer case for four weeks for comments of PI Division.                                                       |  |            |            |

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| 34 | Case No.:42/25/83-ALC1/2007                                                                                                         | Party Name:AARTI DRUGS LIMITED      | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/83/050/01067/AM08/                                                                                                  | RLA File :<br>03/94/040/00299/AM08/ | Lic.No/Date:03104414<br>32<br>30.08.2007   | Defer<br>Date:<br>12.02.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Nitazoxanide under para 4.7 of HBP. |                                     |                                            |                              |
|    | Committee decided to defer case for two weeks for comments of PI Division.                                                          |                                     |                                            |                              |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|----------------------------------|-----------------------------------------|
| Case No.:5/22/82-ALC4/2007                                                                                                                                                                                                                                                                                      | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved             |                                         |
| HQ File :<br>01/82/050/00175/AM08/                                                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/00571/AM08/ | Lic.No/Date:0310441<br>556<br>31.08.2007   |                                  |                                         |
| Decision : Committee considered case as per agenda for ratification of norms for export product Lamivudine and Zidovudine Tablets/ Duovit/Bivit/ Arved Tablets (Each Film coated Tablets contains Lamivudine 150mg and Zidovudine USP 300mg) under para 4.7 of HBP.                                             |                                     |                                            |                                  |                                         |
| Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 and 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. |                                     |                                            |                                  |                                         |
| Export product                                                                                                                                                                                                                                                                                                  | Export Qty.                         | Import items                               |                                  | Qty. allowed per unit of export product |
|                                                                                                                                                                                                                                                                                                                 |                                     | Sl.N o.                                    | Product                          |                                         |
| Lamivudine 150mg and Stavudine 300mg Tablets                                                                                                                                                                                                                                                                    | 1000 Tablets                        | 1.                                         | 3'-Azido-3'-5-o-trityl thimidine | 0.728kg/1000 Tablets                    |

|                                                                                          |  |  |  |  |
|------------------------------------------------------------------------------------------|--|--|--|--|
| ITC(HS)No.                                                                               |  |  |  |  |
| RA concerned may take further necessary action as per above decision of Norms Committee. |  |  |  |  |

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|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 36 | Case No.:12/27/83-ALC1/2007                                                                                                                                                                                                                                       | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/83/050/01086/AM08/                                                                                                                                                                                                                                | RLA File :<br>03/94/040/00555/AM08/ | Lic.No/Date:03104415<br>61<br>31.08.2007   | Defer<br>Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Saquinavit 200mg Capsules/ Saqvir 200mg Capsules under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                     |                                            |                              |

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| 37 | Case No.:5/27/83-ALC1/2007                                                                                                                                                                                                   | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/83/050/01079/AM08/                                                                                                                                                                                           | RLA File :<br>09/24/040/00234/AM08/ | Lic.No/Date:09100313<br>29<br>31.08.2007   | Defer<br>Date:<br>12.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Florefenicol under para 4.7 of HBP.</p> <p>Committee decided to defer case for two weeks for comments of PI Division.</p> |                                     |                                            |                              |

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|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|------------------------------|
| 38 | Case No.:9/27/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                                      | Party Name:OM SHREE PHARMACHEM PVT.LTD. | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/83/050/01083/AM08/                                                                                                                                                                                                                                                                                                                                                                              | RLA File :<br>03/95/040/00534/AM08/     | Lic.No/Date:03104415<br>37<br>31.08.2007   | Defer<br>Date:<br>12.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Iso Sorbide - 5 - Mononitrate under para 4.7 of HBP.</p> <p>Committee observed that the firm was called for personal hearing, but they have sought deferment for two weeks. Committee, therefore, decided to call firm for personal hearing on 12.02.2008. Accordingly, case was deferred for two weeks.</p> |                                         |                                            |                              |

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|----|-----------------------------|-------------------------------------|------------------------------|----------------------|
| 39 | Case No.:33/27/83-ALC1/2007 | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:39/82-ALC4/2007 | Status:Case Deferred |
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|  |                                                                                                                                         |                                     | 29.01.2008                               |                              |
|  | HQ File :<br>01/83/050/01107/AM08/                                                                                                      | RLA File :<br>09/24/040/00192/AM07/ | Lic.No/Date:09100314<br>03<br>05.09.2007 | Defer<br>Date:<br>12.02.2008 |
|  | Decision : Committee considered case as per agenda for ratification of norms for export product GCLE – Stage – 1 under para 4.7 of HBP. |                                     |                                          |                              |
|  | Committee decided to defer case for two weeks for comments of PI Division.                                                              |                                     |                                          |                              |

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| 40 | Case No.:54/27/83-<br>ALC1/2007                                                                                                   | Party Name:GLENMARK<br>PHARMACEUTICALS LTD., | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Cas<br>e Deferred     |
|    | HQ File :<br>01/83/050/01128/AM08/                                                                                                | RLA File :<br>03/94/040/00525/AM08/          | Lic.No/Date:03104419<br>78<br>06.09.2007       | Defer<br>Date:<br>26.02.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP. |                                              |                                                |                              |
|    | Committee decided to defer case for four weeks for comments of PI Division.                                                       |                                              |                                                |                              |

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|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|------------------------------------------------|------------------------------|
| 41 | Case No.:69/27/83-<br>ALC1/2007                                                                                                                                                                                       | Party Name:CODEXIS<br>LABORATORIES INDIA<br>PVT.LTD, | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Cas<br>e Deferred     |
|    | HQ File :<br>01/83/050/01143/AM08/                                                                                                                                                                                    | RLA File :<br>05/24/040/00396/AM08/                  | Lic.No/Date:05102087<br>76<br>10.09.2007       | Defer<br>Date:<br>26.02.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product (4R-CIS)-1, 1-Dimethylethyl-6-Cyanomethyl-2, 2-Dimethyl-1-3-Dioxane-4- Acetate (ATS-8) NLT 99% under para 4.7 of HBP. |                                                      |                                                |                              |
|    | Committee decided to defer case for four weeks for comments of PI Division.                                                                                                                                           |                                                      |                                                |                              |

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| 42 | Case No.:72/27/83-<br>ALC1/2007                                                                                                                                  | Party Name:LUPIN LIMITED            | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Cas<br>e Deferred |
|    | HQ File :<br>01/83/050/01146/AM08/                                                                                                                               | RLA File :<br>03/95/040/00570/AM08/ | Lic.No/Date:03104424<br>36<br>11.09.2007       | DeferDate:<br>26.02.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium-Non Infringing under para 4.7 of HBP. |                                     |                                                |                          |
|    | Committee decided to examine the case on file as the application is based on non-infringing process.                                                             |                                     |                                                |                          |

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|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 43 | Case No.:10/22/82-ALC4/2007                                                                                                                                                                                                                      | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/82/050/00180/AM08/                                                                                                                                                                                                               | RLA File :<br>03/94/040/00615/AM08/ | Lic.No/Date:03104428<br>78<br>12.09.2007   | Defer<br>Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                     |                                            |                              |

| 44                                     | Case No.:111/27/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008                                                                 | Status:Case Approved                    |                |             |              |  |                                         |         |         |                                        |     |    |                                                                                                            |           |    |                 |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------|-------------|--------------|--|-----------------------------------------|---------|---------|----------------------------------------|-----|----|------------------------------------------------------------------------------------------------------------|-----------|----|-----------------|
|                                        | HQ File :<br>01/83/050/01185/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | RLA File :<br>03/94/040/00622/AM08/ | Lic.No/Date:0310443<br>342<br>17.09.2007                                                                   |                                         |                |             |              |  |                                         |         |         |                                        |     |    |                                                                                                            |           |    |                 |
|                                        | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Losartan Potassium under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 and 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> <table border="1"> <thead> <tr> <th rowspan="2">Export product</th><th rowspan="2">Export Qty.</th><th colspan="2">Import items</th><th rowspan="2">Qty. allowed per unit of export product</th></tr> <tr> <th>Sl.N o.</th><th>Product</th></tr> </thead> <tbody> <tr> <td rowspan="2">Losartan Potassium ITC(HS)No.29012 990</td><td rowspan="2">1kg</td><td>1.</td><td>2-Butyl-4-chloro-1-[(2'-(3-triphenyl methyl-1H-tetrazole-2yl)(1,1'-biphenyl)-4yl)-1H-imidazole-5-methanol]</td><td>2.00kg/kg</td></tr> <tr> <td>2.</td><td>Tetrahydrofuran</td><td>1.80kg/kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision</p> |                                     |                                                                                                            |                                         | Export product | Export Qty. | Import items |  | Qty. allowed per unit of export product | Sl.N o. | Product | Losartan Potassium ITC(HS)No.29012 990 | 1kg | 1. | 2-Butyl-4-chloro-1-[(2'-(3-triphenyl methyl-1H-tetrazole-2yl)(1,1'-biphenyl)-4yl)-1H-imidazole-5-methanol] | 2.00kg/kg | 2. | Tetrahydrofuran |
| Export product                         | Export Qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Import items                        |                                                                                                            | Qty. allowed per unit of export product |                |             |              |  |                                         |         |         |                                        |     |    |                                                                                                            |           |    |                 |
|                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Sl.N o.                             | Product                                                                                                    |                                         |                |             |              |  |                                         |         |         |                                        |     |    |                                                                                                            |           |    |                 |
| Losartan Potassium ITC(HS)No.29012 990 | 1kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1.                                  | 2-Butyl-4-chloro-1-[(2'-(3-triphenyl methyl-1H-tetrazole-2yl)(1,1'-biphenyl)-4yl)-1H-imidazole-5-methanol] | 2.00kg/kg                               |                |             |              |  |                                         |         |         |                                        |     |    |                                                                                                            |           |    |                 |
|                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 2.                                  | Tetrahydrofuran                                                                                            | 1.80kg/kg                               |                |             |              |  |                                         |         |         |                                        |     |    |                                                                                                            |           |    |                 |

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|  | of Norms Committee. |
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| 45 | Case No.:154/27/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Party Name:ALEMBIC LIMITED          | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Rejected |
|    | HQ File :<br>01/83/050/01228/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>34/24/040/00140/AM08/ | Lic.No/Date:3410019698<br>25.09.2007       |                      |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Venlafaxine Hydrochloride Extended Release Pellets Stage1 under para 4.7 of HBP.</p> <p>Committee observed that firm was requested to furnish a copy of DML vide letter dated 12.12.2007, but same has not been received. Committee, therefore, decided to close the case as no norms can be fixed in absence of DML.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                            |                      |

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| 46 | Case No.:1/25/82-ALC4/2007                                                                                                                                                                                                                     | Party Name:AMOL PHARMACEUTICALS PVT. LTD. | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00195/AM08/                                                                                                                                                                                                             | RLA File :<br>13/24/040/00019/AM08/       | Lic.No/Date:1310025071<br>01.10.2007       | Defer Date:<br>12.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Alpha Lipoic Acid Granules 95% under para 4.7 of HBP.</p> <p>Committee decided to defer case for two weeks for comments of PI Division.</p> |                                           |                                            |                           |

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| 47 | Case No.:2/25/82-ALC4/2007                                                                                                                                                                                                                       | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00196/AM08/                                                                                                                                                                                                               | RLA File :<br>03/94/040/00664/AM08/ | Lic.No/Date:0310445042<br>03.10.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Abacavir Sulphate Tablets 300mg under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                     |                                            |                           |

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| 48 | Case No.:7/29/83- | Party Name:CODEXIS | Meet No/Date:39/82- | Status:Cas |
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| ALC1/2007                                                                                                                                                                                                                                                                                                      | LABORATORIES INDIA<br>PVT.LTD,      | ALC4/2007<br>29.01.2008                  | e Deferred                   |
| HQ File :<br>01/83/050/01272/AM08/                                                                                                                                                                                                                                                                             | RLA File :<br>05/24/040/00518/AM08/ | Lic.No/Date:05102098<br>61<br>03.10.2007 | Defer<br>Date:<br>26.02.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product (4R-CIS)-1, 1-Dimethylethyl-6-Cyanomethyl-2, 2-Dimethyl-1-3-Dioxane-4-Acetate (ATS-8) NLT 99% under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                     |                                          |                              |

49

| Case No.:95/29/83-ALC1/2007                                                                                                                                                                                                                                                                                     | Party Name:IPCA<br>LABORATORIES LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008                                                         | Status:Case Approved |  |         |         |                                         |
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| HQ File :<br>01/83/050/01360/AM08/                                                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/00673/AM08/     | Lic.No/Date:03104465<br>03<br>16.10.2007                                                           |                      |  |         |         |                                         |
| Decision : Committee considered case as per agenda for ratification of norms for export product Hydrochlorothiazide under para 4.7 of HBP.                                                                                                                                                                      |                                         |                                                                                                    |                      |  |         |         |                                         |
| Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/88/2007-PI-III dated 28.01.2008 and 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. |                                         |                                                                                                    |                      |  |         |         |                                         |
| Export product                                                                                                                                                                                                                                                                                                  | Export Qty.                             | <table><tr><th colspan="2">Import items</th></tr><tr><th>Sl.N o.</th><th>Product</th></tr></table> | Import items         |  | Sl.N o. | Product | Qty. allowed per unit of export product |
| Import items                                                                                                                                                                                                                                                                                                    |                                         |                                                                                                    |                      |  |         |         |                                         |
| Sl.N o.                                                                                                                                                                                                                                                                                                         | Product                                 |                                                                                                    |                      |  |         |         |                                         |
| Hydrochlorothiazide<br>ITC(HS)No.29350090                                                                                                                                                                                                                                                                       | 1kg.                                    | 1. 2,4-Disulfonamide-5-chloroaniline<br>(Chloraminophenamide)                                      | 1.194kg/kg           |  |         |         |                                         |
|                                                                                                                                                                                                                                                                                                                 |                                         | 2. Methanol                                                                                        | 3.79kg/kg            |  |         |         |                                         |

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

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| 50 | Case No.:2/26/82-<br>ALC4/2007 | Party Name:CIRON DRUGS<br>& PHARMACEUTICALS P.<br>LTD., | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Case<br>Approved |
|    | HQ File :                      | RLA File :                                              | Lic.No/Date:03104473                           |                         |



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| 01/82/050/00220/AM08/                                                                                                                                                                                                          | 03/94/040/00755/AM08/ | 19<br>22.10.2007 |                        |                       |
| Decision : Committee considered case as per agenda for ratification of norms for export product Drugs Formulations Drops Namely Fecistil Drops Containing Dimetindene Maleate BP 1 mg/ml (10 ml Bottle) under para 4.7 of HBP. |                       |                  |                        |                       |
| 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:-                                  |                       |                  |                        |                       |
| Export product                                                                                                                                                                                                                 | Export Qty.           | Import items     |                        | Total Qty.<br>allowed |
|                                                                                                                                                                                                                                |                       | Sl.No.           | Product                |                       |
| Drug Formulations Drops namely Fecistil Drops containing Dimetindene Maleate BP 1mg/ml (10ml Bottle)<br>ITC(HS)No.300490<br>11                                                                                                 | 95200N os.            | 1.               | Dimetindene Maleate BP | 0.971kg.              |
| RA concerned may take further necessary action as per above decision of Norms Committee.                                                                                                                                       |                       |                  |                        |                       |

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| Case No.:3/30/85-ALC3/2007         | Party Name:PREGNA INTERNATIONAL LTD.                                                                                                                                                                                                                                                            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Transferred |
| HQ File :<br>01/85/050/00107/AM08/ | RLA File :<br>31/24/040/00238/AM08/                                                                                                                                                                                                                                                             | Lic.No/Date:3110031257<br>23.10.2007       |                         |
| 51                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Intrauterine Contraceptive Device Copper 380A with Silver Core under para 4.7 of HBP.</p> <p>Committee decided to transfer case to DES-VII as export product pertains to Plastic Sector.</p> |                                            |                         |

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| 52 | Case No.:24/30/83-ALC1/2007 | Party Name:AUCTUS PHARMA PRIVATE LIMITED | Meet No/Date:39/82-ALC4/2007 | Status:Case Deferred |
|----|-----------------------------|------------------------------------------|------------------------------|----------------------|

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|                                                                                                                                  |                                     | 29.01.2008                               |                              |
| HQ File :<br>01/83/050/01393/AM08/                                                                                               | RLA File :<br>09/24/040/00319/AM08/ | Lic.No/Date:09100318<br>43<br>23.10.2007 | Defer<br>Date:<br>26.02.2008 |
| Decision : Committee considered case as per agenda for ratification of norms for export product Rifaximin under para 4.7 of HBP. |                                     |                                          |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                      |                                     |                                          |                              |

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|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|------------------------------|
| 53                                                                          | Case No.:53/30/83-ALC1/2007                                                                                                                            | Party Name:MANTENA LABORATORIES LIMITED | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|                                                                             | HQ File :<br>01/83/050/01422/AM08/                                                                                                                     | RLA File :<br>09/24/040/00560/AM07/     | Lic.No/Date:09100318<br>81<br>24.10.2007   | Defer<br>Date:<br>26.02.2008 |
|                                                                             | Decision : Committee considered case as per agenda for ratification of norms for export product Cyclopropyl Diol Cyclic Sulfite under para 4.7 of HBP. |                                         |                                            |                              |
| Committee decided to defer case for four weeks for comments of PI Division. |                                                                                                                                                        |                                         |                                            |                              |

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|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 54                                                                          | Case No.:51/30/83-ALC1/2007                                                                                                               | Party Name:HETERO DRUGS LIMITED,    | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|                                                                             | HQ File :<br>01/83/050/01420/AM08/                                                                                                        | RLA File :<br>09/24/040/00276/AM08/ | Lic.No/Date:0910031879<br>24.10.2007       | Defer<br>Date:<br>26.02.2008 |
|                                                                             | Decision : Committee considered case as per agenda for ratification of norms for export product Indinavir Sulphate under para 4.7 of HBP. |                                     |                                            |                              |
| Committee decided to defer case for four weeks for comments of PI Division. |                                                                                                                                           |                                     |                                            |                              |

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|    | Case No.:24/32/83-ALC1/2007                                                                                                                                                                                                                                                                       | Party Name:ANUH PHARMA LTD.         | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
|    | HQ File :<br>01/83/050/01446/AM08/                                                                                                                                                                                                                                                                | RLA File :<br>03/94/040/00456/AM08/ | Lic.No/Date:03104481<br>95<br>29.10.2007   |                      |
| 55 | Decision : Committee considered case as per agenda for ratification of norms for export product Aceclofenac under para 4.7 of HBP.                                                                                                                                                                |                                     |                                            |                      |
|    | Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/264/2006-PI-III dated 31.01.2008 in the case of M/S IPCA Laboratories Ltd and 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.

| Export product                           | Export Qty. | Import items |                   | Qty. allowed per unit of export product |
|------------------------------------------|-------------|--------------|-------------------|-----------------------------------------|
|                                          |             | Sl.N o.      | Product           |                                         |
| Aceclofenac BP<br>ITC(HS)No.294200<br>90 | 1kg.        | 1.           | Diclofenec Sodium | 1.11kg/kg                               |

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

|                                    |                                     |                                                |                      |
|------------------------------------|-------------------------------------|------------------------------------------------|----------------------|
| Case No.:69/32/83-<br>ALC1/2007    | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Case Approved |
| HQ File :<br>01/83/050/01491/AM08/ | RLA File :<br>03/94/040/00803/AM08/ | Lic.No/Date:03104489<br>36<br>02.11.2007       |                      |

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 and 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.

| Export product                        | Export Qty. | Import items |                           | Qty. allowed per unit of export product |
|---------------------------------------|-------------|--------------|---------------------------|-----------------------------------------|
|                                       |             | Sl.N o.      | Product                   |                                         |
| Simvastatin<br>ITC(HS)No.290129<br>90 | 1kg.        | 1.           | Simvastatin Ammonium Salt | 1.20kg/kg                               |
|                                       |             | 2.           | Acetonitrile              | 4.05kg/kg                               |
|                                       |             | 3.           | N-Heptane                 | 1.33kg/kg                               |

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

|    |                                 |                                        |                                  |                      |
|----|---------------------------------|----------------------------------------|----------------------------------|----------------------|
| 57 | Case No.:82/32/83-<br>ALC1/2007 | Party Name:AUROBINDO<br>PHARMA LIMITED | Meet No/Date:39/82-<br>ALC4/2007 | Status:Case Deferred |
|----|---------------------------------|----------------------------------------|----------------------------------|----------------------|

|                                                                                                                                                                                                           |                                     |                                          |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|------------------------------|
|                                                                                                                                                                                                           |                                     | 29.01.2008                               |                              |
| HQ File :<br>01/83/050/01504/AM08/                                                                                                                                                                        | RLA File :<br>09/24/040/00051/AM08/ | Lic.No/Date:09100319<br>91<br>05.11.2007 | Defer<br>Date:<br>12.02.2008 |
| Decision : Committee considered case as per agenda for ratification of norms for export product Cefepime HCL for injection (Cefepime HCL Sterile Buffered with L-Arginine Sterile) under para 4.7 of HBP. |                                     |                                          |                              |
| Committee decided to defer case for two weeks for comments of PI Division.                                                                                                                                |                                     |                                          |                              |

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| Case No.:106/32/83-ALC1/2007                                                                                                                                                                                                                                                                                    | Party Name:CIPLA LIMITED                                                                     | Meet No/Date:39/82-ALC4/2007<br>29.01.2008                                                                                               | Status:Case Approved |                                                                                              |           |         |                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------------------------------------------------------------------------------|-----------|---------|-----------------------------------------|
| HQ File :<br>01/83/050/01528/AM08/                                                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/00804/AM08/                                                          | Lic.No/Date:0310449<br>208<br>05.11.2007                                                                                                 |                      |                                                                                              |           |         |                                         |
| 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.35011/83/2007-PI-III dated 28.01.2008 and 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. |                                                                                              |                                                                                                                                          |                      |                                                                                              |           |         |                                         |
| Export product                                                                                                                                                                                                                                                                                                  | Export Qty.                                                                                  | <table><tr><th colspan="2">Import items</th></tr><tr><th>Sl.N o.</th><th>Product</th></tr></table>                                       | Import items         |                                                                                              | Sl.N o.   | Product | Qty. allowed per unit of export product |
| Import items                                                                                                                                                                                                                                                                                                    |                                                                                              |                                                                                                                                          |                      |                                                                                              |           |         |                                         |
| Sl.N o.                                                                                                                                                                                                                                                                                                         | Product                                                                                      |                                                                                                                                          |                      |                                                                                              |           |         |                                         |
| Lamivudine<br>ITC(HS)No.29349<br>000                                                                                                                                                                                                                                                                            | 1kg.                                                                                         | <table><tr><td>1.</td><td>(2R.5S)-5-[4-Aceta,odp-2-Pxp-1(2H)-Pyrimidinyl]-1,3-Oxathiolan-2-YL, Methyl Methyl Carbonate</td></tr></table> | 1.                   | (2R.5S)-5-[4-Aceta,odp-2-Pxp-1(2H)-Pyrimidinyl]-1,3-Oxathiolan-2-YL, Methyl Methyl Carbonate | 2.63kg/kg |         |                                         |
| 1.                                                                                                                                                                                                                                                                                                              | (2R.5S)-5-[4-Aceta,odp-2-Pxp-1(2H)-Pyrimidinyl]-1,3-Oxathiolan-2-YL, Methyl Methyl Carbonate |                                                                                                                                          |                      |                                                                                              |           |         |                                         |

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

|    |                                    |                                                                       |                                                |                            |
|----|------------------------------------|-----------------------------------------------------------------------|------------------------------------------------|----------------------------|
| 59 | Case No.:101/32/83-<br>ALC1/2007   | Party Name:JUBILANT<br>ORGANOSYS LTD<br>(FORMERLY VAM ORGANIC<br>CHEM | Meet No/Date:39/82-<br>ALC4/2007<br>29.01.2008 | Status:Case<br>Transferred |
|    | HQ File :<br>01/83/050/01523/AM08/ | RLA File :<br>05/24/040/00477/AM08/                                   | Lic.No/Date:05102117<br>02                     |                            |

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|                                                                                                                                                                                                                                                                                                                                        | 06.11.2007 |  |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product 5-Methylnicotinic Acid HCL under para 4.7 of HBP.</p> <p>Committee observed that firm has indicated end use of export product for manufacture of Fine Chemicals. Accordingly, Committee decided to transfer the case to DES-IV.</p> |            |  |

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| Case No.:93/32/83-ALC1/2007                                                                                                                                                                                                                                                                                     | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved                                                                                  |                                         |
| HQ File :<br>01/83/050/01515/AM08/                                                                                                                                                                                                                                                                              | RLA File :<br>03/94/040/00815/AM08/ | Lic.No/Date:0310449<br>498<br>06.11.2007   |                                                                                                       |                                         |
| Decision : Committee considered case as per agenda for ratification of norms for export product Efavirenz under para 4.7 of HBP.                                                                                                                                                                                |                                     |                                            |                                                                                                       |                                         |
| Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 and 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. |                                     |                                            |                                                                                                       |                                         |
| Export product                                                                                                                                                                                                                                                                                                  | Export Qty.                         | Import items                               |                                                                                                       | Qty. allowed per unit of export product |
|                                                                                                                                                                                                                                                                                                                 |                                     | Sl.No.                                     | Product                                                                                               |                                         |
| Efavirenz<br>ITC(HS)No.29419090                                                                                                                                                                                                                                                                                 | 1kg.                                | 1.                                         | (S)-5-chloro-alpha-(Cyclopropylethyl)-2-Amino-alpha-(Trifluoromethyl) Benzenemethanol (EV-1 compound) | 1.092kg/kg                              |
| RA concerned may take further necessary action as per above decision of Norms Committee.                                                                                                                                                                                                                        |                                     |                                            |                                                                                                       |                                         |

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|----|------------------------------------|-------------------------------------|--------------------------------------------|----------------------|
| 61 | Case No.:7/33/83-ALC1/2007         | Party Name:CIPLA LIMITED            | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
|    | HQ File :<br>01/83/050/01536/AM08/ | RLA File :<br>03/94/040/00822/AM08/ | Lic.No/Date:03104496<br>80                 |                      |

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|                                                                                                                                                                                                                                                                                                                 | 07.11.2007  |              |                                                                                                                            |                                         |
| Decision : Committee considered case as per agenda for ratification of norms for export product Fluticasone Propionate under para 4.7 of HBP.                                                                                                                                                                   |             |              |                                                                                                                            |                                         |
| Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/83/2007-PI-III dated 28.01.2008 and 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. |             |              |                                                                                                                            |                                         |
| Export product                                                                                                                                                                                                                                                                                                  | Export Qty. | Import items |                                                                                                                            | Qty. allowed per unit of export product |
|                                                                                                                                                                                                                                                                                                                 |             | Sl.No.       | Product                                                                                                                    |                                         |
| Fluticasone Propionate<br>ITC(HS)No.2901 2990                                                                                                                                                                                                                                                                   | 1kg.        | 1.           | Androsta-1,4-Diene-3-OXO-17 $\beta$ -Caroxylicacid-16a-Methyl 11 $\beta$ ,17a-Dihydroxy-6,9-Difluoro (Fluticasone Stage 1) | 2.415kg/kg                              |
|                                                                                                                                                                                                                                                                                                                 |             | 2.           | Chloride                                                                                                                   | 1.45kg/kg                               |
|                                                                                                                                                                                                                                                                                                                 |             | 3.           | Tetrahydrofuran                                                                                                            | 2.25kg/kg                               |
| RA concerned may take further necessary action as per above decision of Norms Committee.                                                                                                                                                                                                                        |             |              |                                                                                                                            |                                         |

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|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|---------------------------|
| 62 | Case No.:32/33/83-ALC1/2007                                                                                                                                                                                                       | Party Name:ASTRIX LABORATORIES LTD., | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/83/050/01561/AM08/                                                                                                                                                                                                | RLA File :<br>09/24/040/00256/AM08/  | Lic.No/Date:0910032090<br>14.11.2007       | Defer Date:<br>26.02.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cyclohexyl Ester under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                      |                                            |                           |

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|----|-----------------------------|-------------------------------------|--------------------------------------------|-------------------------|
| 63 | Case No.:60/39/83-ALC1/2007 | Party Name:SANJAY SALES CORPORATION | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Transferred |
|    | HQ File :                   | RLA File :                          | Lic.No/Date:03104516                       | :                       |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------|--|
| 01/83/050/01639/AM08/                                                                                                                                                                                                                              | 03/95/040/00792/AM08/ | 62<br>27.11.2007 |  |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Sodium Salicylate under para 4.7 of HBP.</p> <p>Committee decided to transfer case to DES-IV as export product pertains to Chemical Sector.</p> |                       |                  |  |

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| Case No.:34/39/83-ALC1/2007                                                                                                                                                                                                                                             | Party Name:SRINI PHARMACEUTICALS LTD., | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred      |
| HQ File :<br>01/83/050/01613/AM08/                                                                                                                                                                                                                                      | RLA File :<br>09/24/040/00385/AM08/    | Lic.No/Date:0910032245<br>28.11.2007       | Defer Date:<br>26.02.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product (s)Alpha-Ethyl-2-Oxo-1-Pyrrolidineacetic Acid (LVA-40) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                        |                                            |                           |

| 65                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Case No.:123/39/83-ALC1/2007       | Party Name:G AMPHRAY LABORATORIES,  | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved                    |                |             |              |  |                                         |        |         |                                               |      |   |                            |            |    |             |            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------------------|----------------|-------------|--------------|--|-----------------------------------------|--------|---------|-----------------------------------------------|------|---|----------------------------|------------|----|-------------|------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HQ File :<br>01/83/050/01702/AM08/ | RLA File :<br>03/94/040/00817/AM08/ | Lic.No/Date:0310452997<br>07.12.2007       |                                         |                |             |              |  |                                         |        |         |                                               |      |   |                            |            |    |             |            |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Piperazine Adipate BP/USP under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 10/08 meeting held on 10.07.2007 vide case No.A-264 and 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> <table border="1"> <thead> <tr> <th rowspan="2">Export product</th><th rowspan="2">Export Qty.</th><th colspan="2">Import items</th><th rowspan="2">Qty. allowed per unit of export product</th></tr> <tr> <th>Sl.No.</th><th>Product</th></tr> </thead> <tbody> <tr> <td rowspan="2">Piperazine Adipate BP/USP ITC(HS)No.29333 200</td><td rowspan="2">1kg.</td><td>1</td><td>Diethyl Diamine Piperazine</td><td>0.380kg/kg</td></tr> <tr> <td>2.</td><td>Adipic Acid</td><td>0.675kg/kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision</p> |                                    |                                     |                                            |                                         | Export product | Export Qty. | Import items |  | Qty. allowed per unit of export product | Sl.No. | Product | Piperazine Adipate BP/USP ITC(HS)No.29333 200 | 1kg. | 1 | Diethyl Diamine Piperazine | 0.380kg/kg | 2. | Adipic Acid | 0.675kg/kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Export Qty.                        | Import items                        |                                            | Qty. allowed per unit of export product |                |             |              |  |                                         |        |         |                                               |      |   |                            |            |    |             |            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                    | Sl.No.                              | Product                                    |                                         |                |             |              |  |                                         |        |         |                                               |      |   |                            |            |    |             |            |
| Piperazine Adipate BP/USP ITC(HS)No.29333 200                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 1kg.                               | 1                                   | Diethyl Diamine Piperazine                 | 0.380kg/kg                              |                |             |              |  |                                         |        |         |                                               |      |   |                            |            |    |             |            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                    | 2.                                  | Adipic Acid                                | 0.675kg/kg                              |                |             |              |  |                                         |        |         |                                               |      |   |                            |            |    |             |            |

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| of Norms Committee. |
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| 66 | Case No.:169/39/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                      | Party Name:THEMIS MEDICARE LIMITED  | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
|    | HQ File :<br>01/83/050/01748/AM08/                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>03/95/040/01108/AM07/ | Lic.No/Date:03104537<br>20<br>12.12.2007   |                      |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Lovastatin 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 applied by firm.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                                     |                                            |                      |

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|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|----------------------|
| 67 | Case No.:167/39/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                      | Party Name:THEMIS MEDICARE LIMITED  | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
|    | HQ File :<br>01/83/050/01746/AM08/                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>03/95/040/01109/AM07/ | Lic.No/Date:03104537<br>02<br>12.12.2007   |                      |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Lovastatin 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 applied by firm.</p> <p>RA concerned may take further necessary action as per above decision of Norms committee.</p> |                                     |                                            |                      |

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|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 68 | Case No.:1/40/83-ALC1/2007                                                                                                                                                                                                                                                                                                                                                                           | Party Name:PARABOLIC DRUGS LTD.,    | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/83/050/01766/AM08/                                                                                                                                                                                                                                                                                                                                                                   | RLA File :<br>22/24/040/00050/AM08/ | Lic.No/Date:22100073<br>08<br>19.12.2007   | Defer<br>Date:<br>11.03.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Ampicillin Sodium + Cloxacillin Sodium Sterile Crystalline (1:1 Blend) (A white or almost white crystalline powder) under para 4.7 of HBP.</p> <p>Committee observed that firm has been permitted to export 1500kgs. of export product under DML, while they have sought export of 10,000kgs.</p> |                                     |                                            |                              |



of export product. Committee, therefore, decided to advise firm to get the DML amended from DCGI. Accordingly Committee decided to close the case.

|                                    |                                         |                                            |                      |
|------------------------------------|-----------------------------------------|--------------------------------------------|----------------------|
| Case No.:10/40/83-ALC1/2007        | Party Name:IND-SWIFT LABORATORIES LTD., | Meet No/Date:39/82-ALC4/2007<br>29.01.2008 | Status:Case Approved |
| HQ File :<br>01/83/050/01775/AM08/ | RLA File :<br>22/24/040/00058/AM08/     | Lic.No/Date:22100073<br>30<br>27.12.2007   |                      |

Decision : Committee considered case as per agenda for ratification of norms for export product Clopidogrel Hydrogen Sulphate under para 4.7 of HBP.

Committee in light of its earlier decision taken in its 26/82 meeting held on 30.10.2007 vide Case No.8/12/83 and 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.

| Export product                                       | Export Qty. | Import items |                                           | Qty. allowed per unit of export product |
|------------------------------------------------------|-------------|--------------|-------------------------------------------|-----------------------------------------|
|                                                      |             | Sl.No.       | Product                                   |                                         |
| Clopidogrel Hydrogen Sulphate<br>ITC(HS)No.29415 000 | 1kg.        | 1.           | Alpha Bromo (2-chloro Phenyl) Acetic Acid | 1.18kg/kg                               |
|                                                      |             | 2.           | Methylene chloride                        | 2.41kg/kg                               |
|                                                      |             | 3.           | Dimethyl formamide                        | 3.39kg/kg                               |
|                                                      |             | 4.           | Acetone                                   | 3.91kg/kg                               |
|                                                      |             | 5.           | Thiophene-2-Ethanol                       | 1.00kg/kg                               |
|                                                      |             | 6.           | L(-)Camphor Sulphonic Acid                | 0.70kg/kg                               |

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

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|----|----------------------------|--------------------------------|------------------------------|----------------------|
| 70 | Case No.:9/40/83-ALC1/2007 | Party Name:KUDOES CHEMIE LTD., | Meet No/Date:39/82-ALC4/2007 | Status:Case Deferred |
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|                                                                                                                                 |                                     | 29.01.2008                               |                              |
| HQ File :<br>01/83/050/01774/AM08/                                                                                              | RLA File :<br>22/24/040/00059/AM08/ | Lic.No/Date:22100073<br>29<br>27.12.2007 | Defer<br>Date:<br>26.02.2008 |
| Decision : Committee considered case as per agenda for ratification of norms for export product Caffeine under para 4.7 of HBP. |                                     |                                          |                              |
| Committee decided to defer case for four weeks for comments of PI Division.                                                     |                                     |                                          |                              |