

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

MEETING NUMBER : 45/82-ALC4/2007 MEETING DATE : 11.03.2008

The Meeting No.44/08 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 11.**03.2008** under the Chairmanship of Export Commissioner, Shri Sanjay Rastogi in his chamber.

At the outset minutes of Norms Committee Meeting No. 27/08 dated 06.11.2007, 43/08 dated 04.03.2008 and 44/08 dated 04.03.2007 were ratified by the Committee.

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| Case No.B-575                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Policy clarification   |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | F.No.01/82/50/369/AM08 |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                        |
| <p>Committee considered case as per agenda and perused the clarification given by Department of Bio-technology vide their D.O. No.BT/0150/2002-PID(Vol.III) dated 05.02.2008 regarding clarification in respect of Biotechnology items where NOC from their Department is required before grant of Advance Authorisation. Department of Biotechnology opined that when the end product and imported items are free from Genetic Modified Organism/Living Modified Organism, despite emanating from LMO/GMO, there is no need of obtaining the NOC from DBT. Further the micro organism, GMOs etc. have already covered under Annexure III of Scheduled 2 of the Exim Policy under SCOMET items where compulsory licence is necessary for export of such product. In order to facilitate the import and export , RAs may issue Advance Authorisations for import/export of bio-technology product on submission of an undertaking to the effect that the particular product under import and end Product is free of LMO/GMO per se, without obtaining NOC from DBT.</p> <p>Committee accepted the above and decided to refer the minutes of NC to Policy Division alongwith comments of DBT for incorporating in Chapter IV of Exim Policy after approval of DGFT.</p> |                        |

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| Case No.B-576                          | M/S Arch Pharma Labs Ltd.  |
| NC Meeting No.45/08                    | F.No.01/82/162/591/AM08    |
| Meeting Date:11.03.2008                | RLA F.No.03/94/40/125/AM07 |
| Adv.Lic.No.0310381222 dated 25.05.2006 |                            |

Committee considered case as per agenda for revision of norms for export product Clopidogrel Bisulphate 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.B-577                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | M/S Alembic Ltd.          |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | F.No.01/82/50/51/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | RLA F.No.34/24/40/35/AM08 |
| Adv.Lic.No.3410018854 dated 28.05.2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                           |
| <p>Committee considered case as per agenda for amendment in the description of export product under para 4.7 of HBP.</p> <p>Committee observed that firm had obtained Advance Authorisation for export of Azithromycin Step-3 (KGA) while in the decision of NC, same was mentioned "Azithromycin Step 3 (Aza Azithromycin)". Committee, therefore, in consultation with representative of PI Division present in meeting decided to allow amendment in the description of export product to read as <b>"Azithromycin Step-3 (KGA)"</b>.</p> <p>RA concerned may take further necessary action as per above decision of Norms Committee.</p> |                           |

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| Case No.B-578                                                                                                                                                                                                                                                                                                                                                                                                                              | M/S Alchem International Ltd.                                                          |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                                                                                                                                        | F.No.01/87/50/393/AM06<br>F.No.01/87/50/1374/AM05<br>F.No.01/87/50/375/AM06            |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                                                                                                    | RLA F.No.05/24/40/201/AM05<br>RLA F.No.05/24/40/542/AM05<br>RLA F.No.05/24/40/242/AM05 |
| Adv.Lic.No.0510161341 dated 04.07.2005<br>Adv.Lic.No.0510148830 dated 17.01.2005<br>Adv.Lic.No.0510160972 dated 29.06.2005                                                                                                                                                                                                                                                                                                                 |                                                                                        |
| <p>Committee considered case as per agenda for revision of norms for export product Hyoscine-n-Bromide under para 4.7 of HBP.</p> <p>Committee observed that advance authorizations were issued in 2005 and also norms were ratified by NC in 2005 while representation of firm for revision of norms has been received on 22.01.2008 i.e. after a gap of more than three years. Committee, therefore, decided to maintain status quo.</p> |                                                                                        |

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| Case No.B-579                                                                                                                                                                                                                                                                                                                                                                                                                                          | M/S Srimi Pharma           |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                                                                                                                                                    | F.No.01/87/50/1456/AM06    |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                                                                                                                | RLA F.No.09/24/40/477/AM06 |
| Adv.Lic.No.0910025616 dated 09.03.2006                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |
| <p>Committee considered case as per agenda for revision of norms for export product (S)-Clopidogrel-(S)-10-Camphor Sulfonate (CPG-35) under para 4.7 of HBP.</p> <p>Committee observed that norms were ratified in its meeting held on 20.09.2006 while representation of firm for revision of norms has been received only on 09.01.2008 i.e. after a gap of more than one and a half year. Committee, therefore, decided to maintain status quo.</p> |                            |

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| Case No.A-1098                                                                                                                                                                                                                        | M/S Intas Pharmaceuticals Ltd. |
| NC Meeting No.45/08                                                                                                                                                                                                                   | F.No.01/82/50/301/AM08         |
| Meeting Date:11.03.2008                                                                                                                                                                                                               | RLA F.No.08/24/40/226/AM08     |
| Adv.Lic.No.0810069241 dated 28.12.2007                                                                                                                                                                                                |                                |
| <p>Committee considered case as per agenda for ratification of norms for export product Doxycycline Hyclate Tablets USP 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-1099                                                                                                                                                                                                                                       | M/S Intervet India Pvt. Ltd. |
| NC Meeting No.45/08                                                                                                                                                                                                                                  | F.No.01/82/162/392/AM08      |
| Meeting Date:11.03.2008                                                                                                                                                                                                                              | RLA F.No.09/24/40/328/AM03   |
| Adv.Lic.No.0910013828 dated 03.04.2003                                                                                                                                                                                                               |                              |
| <p>Committee considered case as per agenda for ratification of norms for export product ND Clone 30-Vaccine 2ml under para 4.7 of HBP.</p> <p>Committee decided to remind DBT for their comments. Accordingly, case was deferred for four weeks.</p> |                              |

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| Case No.A-1100                                                                                                                                                                                                                       | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                                                                                  | F.No.01/82/50/230/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                              | 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 Abacavie 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-1101                                                                                                                                                                                                                                                             | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                                                                                                                        | F.No.01/82/50/233/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                    | RLA F.No.09/24/40/196/AM08 |
| Adv.Lic.No.0910031321 dated<br>30.08.2007                                                                                                                                                                                                                                  |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Emitricitabine 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-1102                                                                                                                                                                                                                                                         | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                                                                                                                    | F.No.01/82/50/227/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                | RLA F.No.09/24/40/204/AM08 |
| Adv.Lic.No.0910031354 dated<br>31.08.2007                                                                                                                                                                                                                              |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate 300mg and Lamivudine 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-1103                            | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                       | F.No.01/82/50/234/AM08     |
| Meeting Date:11.03.2008                   | RLA F.No.09/24/40/188/AM08 |
| Adv.Lic.No.0910031126 dated<br>13.08.2007 |                            |

Committee considered case as per agenda for ratification of norms for export product Valsartan Tablets 40mg, Valsartan Capsules 40mg, Valsartan Tablets 80mg, Valsartan Capsules 80mg, Valsartan Tablets 160mg and Valsartan 160mg 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-1104                                                                                                                                                                                                                                    | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                                                                                               | F.No.01/82/50/226/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                           | RLA F.No.09/24/40/192/AM08 |
| Adv.Lic.No.0910031252 dated 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-1105                                                                                                                                                                                                                                                          | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                                                                                                                     | F.No.01/82/50/229/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                 | 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 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-1106                                                                                                                                                        | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                   | F.No.01/82/50/232/AM08     |
| Meeting Date:11.03.2008                                                                                                                                               | RLA F.No.09/24/40/216/AM08 |
| Adv.Lic.No.0910031186 dated 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> |                            |

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

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| Case No.A-1107                                                                                                                                                                                                                         | M/S Matrix Labs. Ltd.      |
| NC Meeting No.45/08                                                                                                                                                                                                                    | F.No.01/82/50/231/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                | 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 Tablets 25mg 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-1108                                                                                                                                                                                                                                                                                                                                                                                                                             | M/S Nicholas Piramal India Ltd. |        |                                               |                                         |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                                                                                                                                        | F.No.01/82/50/302/AM08          |        |                                               |                                         |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                                                                                                    | RLA F.No.03/24/40/868/AM08      |        |                                               |                                         |
| Adv.Lic.No.0310454138 dated 14.12.2007                                                                                                                                                                                                                                                                                                                                                                                                     |                                 |        |                                               |                                         |
| <p>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 in light of written comments forwarded by Department of Bio-technology vide their O.M. No.BT/IL/05/228/2006-PID dated 20.02.2008 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                 | Sl.No. | Import items                                  | Qty. allowed per unit of export product |
| Ultrazyme tablets (7458X) (Contact lense cleaning tablets)                                                                                                                                                                                                                                                                                                                                                                                 | 1 unit (1000 tablets)           | 1.     | Subtilisin sorbitol                           | 0.01155kg/unit of 1000 tablets          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                 | 2.     | N-Acetyl Cystein                              | 0.03150kg/unit of 1000 tablets          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                 | 3.     | Aluiminium foil plain not exceeding 60 micron | 0.5250kg/unit of 1000 tablets           |

RA concerned may take further necessary action as per above decision

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| of Norms Committee. |
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| Case No.A-1109                                                                                                                                                                                                                                                                                                                                           | M/S Krishna Antioxidants Pvt. Ltd. |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                                                      | F.No.01/83/50/1047/AM08            |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                  | RLA F.No.03/95/40/690/AM08         |
| Adv.Lic.No.0310445406 dated 08.08.                                                                                                                                                                                                                                                                                                                       |                                    |
| <p>Committee considered case as per agenda for ratification of norms for export product 2007Formaldehyde Free Dye Fixing Agent (Aqueous Solution of 2-Hydroxy 3-Dimethyl Amine Chloride Propane Polymer (Active content 55% minimum)under para 4.7 of HBP.</p> <p>Committee decided to defer case for three weeks for comments of Chemical Division.</p> |                                    |

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| Case No.A-1110                                                                                                                                                                                                                                                                                                                    | M/S Morepen Labs. Ltd.     |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                               | F.No.01/83/50/1046/AM08    |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                           | RLA F.No.05/24/40/650/AM08 |
| Adv.Lic.No.0510212495 dated 26.11.2007                                                                                                                                                                                                                                                                                            |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Montelukast Sodium (Intermediate (MT-8) under para 4.7 of HBP.</p> <p>Committee decided to call for details of export product alongwith technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.</p> |                            |

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| Case No.A-1111                                                                                                                                                                                                                                                                                                        | M/S Ranbaxy Labs. Ltd.     |
| NC Meeting No.45/08                                                                                                                                                                                                                                                                                                   | F.No.01/82/50/206/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                               | RLA F.No.05/24/40/401/AM08 |
| Adv.Lic.No.0510207640 dated 17.08.2007                                                                                                                                                                                                                                                                                |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Citalopram Hydrobromide Tablets 10mg under para 4.7 of HBP.</p> <p>Committee observed that the application has been filed based on Non-Infringing process and the firm has been requested to furnish required information</p> |                            |

vide letter dated 13.02.2008, but same 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.A-1112                                                                                                                                                                                                                                                            | M/S Coral Drugs Pvt. Ltd.  |
| NC Meeting No.45/08                                                                                                                                                                                                                                                       | F.No.01/82/50/298/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                   | RLA F.No.05/24/40/699/AM08 |
| Adv.Lic.No.0510213410 dated 12.12.2007                                                                                                                                                                                                                                    |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Finastride under para 4.7 of HBP.</p> <p>Committee decided to call for complete technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.</p> |                            |

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| Case No.A-1113                                                                                                                                                                                                                                                               | M/S Coral Drugs Pvt. Ltd.  |
| NC Meeting No.45/08                                                                                                                                                                                                                                                          | F.No.01/82/50/299/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                                                                                      | RLA F.No.05/24/40/601/AM08 |
| Adv.Lic.No.0510212483 dated 26.11.2007                                                                                                                                                                                                                                       |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Flutamide USP under para 4.7 of HBP.</p> <p>Committee decided to call for complete technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.</p> |                            |

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| Case No.A-1114                                                                                                                                                                                                      | M/S Bal Pharma Ltd.        |
| NC Meeting No.45/08                                                                                                                                                                                                 | F.No.01/82/50/297/AM08     |
| Meeting Date:11.03.2008                                                                                                                                                                                             | RLA F.No.07/24/40/671/AM08 |
| Adv.Lic.No.0710055101 dated 26.12.2007                                                                                                                                                                              |                            |
| <p>Committee considered case as per agenda for ratification of norms for export product Amiloride Hcl 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-1115                                                                                                                                                                                                               | M/S Lupin Ltd.              |
| NC Meeting No.45/08                                                                                                                                                                                                          | F.No.01/82/50/1106/AM05     |
| Meeting Date:11.03.2008                                                                                                                                                                                                      | RLA F.No.03/24/40/1358/AM05 |
| Adv.Lic.No.0310291255 dated<br>14.09.2004                                                                                                                                                                                    |                             |
| <p>Committee considered case as per agenda for ratification of norms for export product L Mandelic Acid under para 4.7 of HBP.</p> <p>Committee decided to defer case for three weeks for comments of Chemical Division.</p> |                             |

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| Case No.A-1116                            | M/S Kopran Ltd.             |
| NC Meeting No.45/08                       | F.No.01/82/50/1346/AM05     |
| Meeting Date:11.03.2008                   | RLA F.No.03/24/40/1738/AM05 |
| Adv.Lic.No.0310299804 dated<br>29.10.2004 |                             |

Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriaxone Sodium under para 4.7 of HBP on the request of RA that no norms has been fixed earlier in this case and no decision of Committee is available with them.

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/65/2007-PI-III dated 11.03.2008 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 | Sl.No. | Import items               | Qty allowed per unit of export product |
|----------------------------|-----------------|--------|----------------------------|----------------------------------------|
| Ceftriaxone Sodium Sterile | 1kg.            | 1.     | Ceftriaxone Sodium Sterile | 1.00kg/kg                              |
|                            |                 | 2.     | Acetone                    | 2.08kg/kg                              |

RA concerned may take further necessary action as per above decision of Norms committee. In case any different decision has been taken contrary to above decision, the onus lies on the RA & firm.

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| Case No.A-1117      | M/S Kopran Ltd.         |
| NC Meeting No.45/08 | F.No.01/82/50/1371/AM07 |

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| Meeting Date:11.03.2008                                                                                                                                                                                                                                                                                                                                                                | RLA F.No.03/94/40/950/AM07 |        |                    |                                        |
| Adv.Lic.No.0310410417 dated 01.12.2006                                                                                                                                                                                                                                                                                                                                                 |                            |        |                    |                                        |
| <p>Committee considered case as per agenda for ratification of norms for export product Azithromycin Dihydrate under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/28/2007-PI-III dated 11.03.2008 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            | Sl.No. | Import items       | Qty allowed per unit of export product |
| Azithromycin Dihydrate                                                                                                                                                                                                                                                                                                                                                                 | 1kg.                       | 1.     | Azithromycin amine | 1.04kg/kg                              |
|                                                                                                                                                                                                                                                                                                                                                                                        |                            | 2.     | Acetone            | 0.90kg/kg                              |
|                                                                                                                                                                                                                                                                                                                                                                                        |                            | 3.     | Formic Acid        | 0.210kg/kg                             |
| <p>RA concerned may take further necessary action as per above decision of Norms committee.</p>                                                                                                                                                                                                                                                                                        |                            |        |                    |                                        |

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| 1 | Case No.:31/21/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                              | Party Name:KUMAR ORGANIC PRODUCTS LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|   | HQ File :<br>01/82/050/00057/AM06/                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>07/24/040/00013/AM06/        | Lic.No/Date:07100374<br>27<br>21.04.2005   | Defer Date:<br>08.04.2008 |
|   | <p>Decision :Committee considered case as per agenda for ratification of norms for export product Minoxidil under para 4.7 of HBP.</p> <p>Committee observed that application was called for from RA vide letter dated 01.03.2008, but same has not been received. Committee, therefore, decided to remind RA to furnish application. Accordingly, case was deferred for four weeks.</p> |                                            |                                            |                           |
| 2 | Case No.:61/24/87-ALC1/2007                                                                                                                                                                                                                                                                                                                                                              | Party Name:ALEMBIC LIMITED                 | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn     |
|   | HQ File :<br>01/87/050/00084/AM06/                                                                                                                                                                                                                                                                                                                                                       | RLA File :<br>34/24/040/00007/AM06/        | Lic.No/Date:34100132<br>61<br>27.04.2005   |                           |
|   | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Modafinil under para 4.7 of HBP.</p>                                                                                                                                                                                                                                                  |                                            |                                            |                           |

Committee decided to withdraw case as case has been considered in its 43/08 meeting held on 04.03.2008.

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| 3 | Case No.:205/21/82-ALC4/2007                                                                                                                                                                                                                                                                                                       | Party Name:IGOR PHARMACHEM LIMITED  | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|   | HQ File :<br>01/82/050/00268/AM06/                                                                                                                                                                                                                                                                                                 | RLA File :<br>09/24/040/00086/AM06/ | Lic.No/Date:0910023219<br>21.06.2005       |                       |
|   | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2-Aminomethyl-7-Chloro-2,3-Dihydro-5-(2-Fluorophenyl)-1H-1,4-Benzodiazepine Dimaleate under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered in its 44/08 meeting held on 04.03.2008.</p> |                                     |                                            |                       |

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| 4 | Case No.:579/21/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                    | Party Name:KUMAR ORGANIC PRODUCTS LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|   | HQ File :<br>01/82/050/01174/AM07/                                                                                                                                                                                                                                                                                                                                                              | RLA File :<br>07/24/040/00449/AM07/        | Lic.No/Date:0710047985<br>19.10.2006       | Defer Date:<br>08.04.2008 |
|   | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Zinc Pyrithione under para 4.7 of HBP.</p> <p>Committee observed that application was called for from RA vide letter dated 01.03.2008, but same has not been received. Committee, therefore, decided to remind RA to furnish application. Accordingly, case was deferred for four weeks.</p> |                                            |                                            |                           |

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| 5 | Case No.:3/44/83-ALC1/2006                                                                                                                                                                                                                                                                       | Party Name:SRINI PHARMACEUTICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case withdrawn |
|   | HQ File :<br>01/83/050/00905/AM07/                                                                                                                                                                                                                                                               | RLA File :<br>09/24/040/00292/AM07/    | Lic.No/Date:0910028194<br>14.11.2006       |                       |
|   | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Lebetalol Hydrochloride under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 44/08 meeting held on 04.03.2008.</p> |                                        |                                            |                       |

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| 6 | Case No.:6/44/83-ALC1/2006 | Party Name:SRINI PHARMACEUTICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
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| HQ File :<br>01/83/050/00948/AM07/                                                                                                                                                                                                                                                                                          | RLA File :<br>09/24/040/00337/AM07/ | Lic.No/Date:09100283<br>60<br>23.11.2006 |  |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2-(1-H-Tetrazol-5-YL)Phenyl Boronic Acid Dihydrate under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 44/08 meeting held on 04.03.2008.</p> |                                     |                                          |  |

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| Case No.:16/49/82-<br>ALC1/2006    | Party Name:LUPIN LIMITED                                                                                                                                                                                                                                                                                           | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Withdrawn |
| 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       |                          |
| 7                                  | <p>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.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 43/08 meeting held on 04.03.2008.</p> |                                                |                          |

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| Case No.:858/21/82-<br>ALC4/2007   | Party Name:KUMAR<br>ORGANIC PRODUCTS<br>LIMITED,                                                                                                                                                                                                      | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Deferred      |
| HQ File :<br>01/82/050/01685/AM07/ | RLA File :<br>07/24/040/00761/AM07/                                                                                                                                                                                                                   | Lic.No/Date:07100502<br>36<br>22.02.2007       | Defer<br>Date:<br>22.04.2008 |
| 8                                  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Zinc Pyrithione under para 4.7 of HBP.</p> <p>Committee decided to call for application from RA. Accordingly, case was deferred for six weeks.</p> |                                                |                              |

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| Case No.:852/21/82-<br>ALC4/2007   | Party Name:METROCHEM<br>API PVT. LTD.                                                                                                                    | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Withdrawn |
| 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       |                          |
| 9                                  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Lansoprazole Pellets 11.2% under para 4.7 of HBP.</p> |                                                |                          |

Committee decided to withdraw case as case has already been approved in its 16/08 meeting held on 21.08.2007.

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| 10 | Case No.:879/21/82-ALC4/2007                                                                                                                                                                                                                               | Party Name:LAKE CHEMICALS PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|    | HQ File :<br>01/82/050/01714/AM07/                                                                                                                                                                                                                         | RLA File :<br>07/24/040/00780/AM07/       | Lic.No/Date:07100503<br>14<br>27.02.2007   |                       |
|    | <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 withdraw case as case has been approved in its 43/08 meeting held on 04.03.2008.</p> |                                           |                                            |                       |

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| 11 | Case No.:7/2/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                      | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|    | HQ File :<br>01/82/050/01804/AM07/                                                                                                                                                                                                                                                                                                                                                             | RLA File :<br>03/94/040/01443/AM07/ | Lic.No/Date:03104229<br>72<br>13.03.2007   |                       |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Triomune 30/Lamivudine, Stavudine and Nevirapine Tablets, (2) Triomune40/Lamivudine, Stavudine and Nevirapine Tablets under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 43/08 meeting held on 04.03.2008.</p> |                                     |                                            |                       |

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| 12 | Case No.:17/9/82-ALC4/2007                                                                                                                                                                                                                            | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|    | HQ File :<br>01/82/050/01837/AM07/                                                                                                                                                                                                                    | RLA File :<br>03/94/040/01468/AM07/ | Lic.No/Date:03104237<br>77<br>21.03.2007   |                       |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Exemestate under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been rejected in its 43/08 meeting held on 04.03.2008.</p> |                                     |                                            |                       |

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| 13 | Case No.:25/14/83-ALC1/2007 | Party Name:ALCHYMARS ICM SM PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|    | HQ File :                   | RLA File :                                  | Lic.No/Date:04100887                       |                       |
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| 01/83/050/00016/AM08/                                                                                                                                                                                                                                                                 | 04/24/040/00501/AM07/ | 27<br>02.04.2007 |  |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Allylestrenol under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for six weeks in its 44/08 meeting held on 04.03.2008.</p> |                       |                  |  |

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| Case No.:19/19/83-ALC1/2007        | Party Name:GRANULES INDIA LIMITED                                                                                                                                                                                                                                                                                         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status: Case Withdrawn |
| 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   |                        |
| 14                                 | <p>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.</p> <p>Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                            |                        |

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| Case No.:27/19/83-ALC1/2007        | Party Name:GRANULES INDIA LIMITED                                                                                                                                                                                                              | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case 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 Date:<br>08.04.2008 |
| 15                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Phenazopyridine Hydrochloride 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.:20/21/82-ALC4/2007        | Party Name:RANBAXY LABORATORIES LTD                                                                                                                                                                                                          | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status: Case Withdrawn |
| 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   |                        |
| 16                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Clarithromycin Carbomer Granules 44% under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and</p> |                                            |                        |

deferred for four weeks in its 40/08 meeting held on 03.03.2008.

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| 17                                                                                                                                                                                                                                                                                                  | Case No.:614/24/83-ALC1/2007       | Party Name:NICHOLAS PIRAMAL INDIA LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                     | 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   |                              |
| <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 decided to withdraw case as case has been approved in its 41/08 meeting held on 03.03.2008.</p> |                                    |                                        |                                            |                              |

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| 18                                                                                                                                                                                                                                                                                                       | Case No.:622/24/83-ALC1/2007       | Party Name:SHODHANA LABORATORIES LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                          | 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   |                              |
| <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 decided to withdraw case as case has been considered and deferred for six weeks in its 40/08 meeting held on 03.03.2008.</p> |                                    |                                       |                                            |                              |

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| 19                                                                                                                                                                                                                                                                                                          | Case No.:730/24/83-ALC1/2007       | Party Name:SUVEN LIFE SCIENCES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                             | HQ File :<br>01/83/050/00623/AM08/ | RLA File :<br>09/24/040/00120/AM08/    | Lic.No/Date:09100306<br>86<br>29.06.2007   |                              |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product (S)-3-Hydroxy-N-Benzyl Pyrrolidine under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                        |                                            |                              |

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| 20 | Case No.:731/24/83-ALC1/2007 | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
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| HQ File :<br>01/83/050/00624/AM08/                                                                                                                                                                                                                              | RLA File :<br>09/24/040/00425/AM07/ | Lic.No/Date:09100306<br>91<br>29.06.2007 |  |
| <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 withdraw case as case has been approved in its 41/08 meeting held on 03.03.2008.</p> |                                     |                                          |  |

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| Case No.:95/21/82-<br>ALC4/2007    | Party Name:NICHOLAS<br>PIRAMAL INDIA LTD.                                                                                                                                                                                                                                                    | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
| HQ File :<br>01/82/050/00144/AM08/ | RLA File :<br>03/95/040/00389/AM08/                                                                                                                                                                                                                                                          | Lic.No/Date:03104375<br>08<br>26.07.2007       |                              |
| 21                                 | <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 decided to withdraw case as case has been approved in its 41/08 meeting held on 03.03.2008.</p> |                                                |                              |

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| Case No.:113/21/82-<br>ALC4/2007   | Party Name:NECTAR<br>LIFESCIENCES LIMITED,                                                                                                                                                                                                                      | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
| HQ File :<br>01/82/050/00157/AM08/ | RLA File :<br>22/24/040/00030/AM08/                                                                                                                                                                                                                             | Lic.No/Date:22100069<br>84<br>20.08.2007       |                              |
| 22                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been rejected in its 43/08 meeting held on 04.03.2008.</p> |                                                |                              |

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| Case No.:7/25/83-<br>ALC1/2007     | Party Name:ASTRIX<br>LABORATORIES LTD.,                                                                                                                                                                            | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
| HQ File :<br>01/83/050/01032/AM08/ | RLA File :<br>09/24/040/00231/AM08/                                                                                                                                                                                | Lic.No/Date:09100313<br>14<br>29.08.2007       |                              |
| 23                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Didanosine under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and</p> |                                                |                              |



deferred for six weeks in its 43/08 meeting held on 04.03.2008.

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| 24 | Case No.:42/25/83-ALC1/2007                                                                                                                                                                                                                             | Party Name:AARTI DRUGS LIMITED      | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|    | 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   |                              |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Nitazoxanide under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been approved in its 40/08 meeting held on 03.03.2008.</p> |                                     |                                            |                              |

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| 25 | Case No.:12/27/83-ALC1/2007                                                                                                                                                                                                                                                                                              | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|    | 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   |                              |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Saquinavir 200mg Capsules/Saqvir 200mg Capsules under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 43/08 meeting held on 04.03.2008.</p> |                                     |                                            |                              |

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| 26 | Case No.:5/27/83-ALC1/2007                                                                                                                                                                                                                             | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|    | 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   |                              |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Florfenicol under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been approved in its 40/08 meeting held on 03.03.2008.</p> |                                     |                                            |                              |

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| 27 | Case No.:9/27/83-ALC1/2007         | Party Name:OM SHREE PHARMACHEM PVT.LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|    | 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   |                              |
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Decision : Committee considered case as per agenda for ratification of norms for export product Iso Sorbide-5-Mononitrate under para 4.7 of HBP.

Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.

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| 28                                                                                                                                                                                                                                                      | Case No.:33/27/83-ALC1/2007        | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                         | 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   |                              |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product GCLE-Stage-I under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been approved in its 41/08 meeting held on 03.03.2008.</p> |                                    |                                     |                                            |                              |

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| 29                                                                                                                                                                                                                                                                                 | Case No.:54/27/83-ALC1/2007        | Party Name:GLENMARK PHARMACEUTICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                    | 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   |                              |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Aprepitant under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                           |                                            |                              |

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| 30                                                                                                                                                                                                                                                                                                                                                           | Case No.:69/27/83-ALC1/2007        | Party Name:CODEXIS LABORATORIES INDIA PVT.LTD, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                                                                              | 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   |                              |
| <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) under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                                |                                            |                              |

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| 31 | Case No.:72/27/83-ALC1/2007 | Party Name:LUPIN LIMITED | Meet No/Date:45/82-ALC4/2007 | Status:<br>Case |
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|  |                                                                                                                                                                                                                                                                                                                    |                                     | 11.03.2008                               | Withdrawn |
|  | 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 |           |
|  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Sterile Ceftriazone Sodium Non Infringing under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for four weeks in its 44/08 meeting held on 04.03.2008.</p> |                                     |                                          |           |

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|    | Case No.:10/22/82-<br>ALC4/2007                                                                                                                                                                                                                                                                         | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|    | 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       |                              |
| 32 | <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 withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                     |                                                |                              |

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|    | Case No.:189/27/83-<br>ALC1/2007                                                                                                                                                                                                                                                               | Party Name:KESHAVA<br>ORGANICS PVT. LTD., | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Cas<br>e Deferred     |
|    | HQ File :<br>01/83/050/01263/AM08/                                                                                                                                                                                                                                                             | RLA File :<br>03/94/040/00595/AM08/       | Lic.No/Date:03104447<br>05<br>01.10.2007       | Defer<br>Date:<br>22.04.2008 |
| 33 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Chlorpheniramine Base under para 4.7 of HBP.</p> <p>Committee decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for six weeks.</p> |                                           |                                                |                              |

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|    | Case No.:1/25/82-<br>ALC4/2007                                                                                                                               | Party Name:AMOL<br>PHARMACEUTICALS PVT.<br>LTD. | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|    | HQ File :<br>01/82/050/00195/AM08/                                                                                                                           | RLA File :<br>13/24/040/00019/AM08/             | Lic.No/Date:13100250<br>71<br>01.10.2007       |                              |
| 34 | <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> |                                                 |                                                |                              |

Committee decided to withdraw case as case has been approved in its 41/08 meeting held on 03.03.2008.

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| 35                                                                                                                                                                                                                                                                                                      | Case No.:2/25/82-ALC4/2007         | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                         | HQ File :<br>01/82/050/00196/AM08/ | RLA File :<br>03/94/040/00664/AM08/ | Lic.No/Date:03104450<br>42<br>03.10.2007   |                              |
| <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 withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                     |                                            |                              |

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| 36                                                                                                                                                                                                                                                                                                                                                          | Case No.:7/29/83-ALC1/2007         | Party Name:CODEXIS LABORATORIES INDIA PVT.LTD, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                                                                             | 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   |                              |
| <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) under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                                |                                            |                              |

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| 37                                                                                                                                                                                                                                                                                                      | Case No.:53/30/83-ALC1/2007        | Party Name:MANTENA LABORATORIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
|                                                                                                                                                                                                                                                                                                         | 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   |                              |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cyclopropyl Diol Cyclic Sulfite under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                         |                                            |                              |

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| 38 | Case No.:51/30/83-ALC1/2007 | Party Name:HETERO DRUGS LIMITED, | Meet No/Date:45/82-ALC4/2007 | Status:<br>Case |
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|                                                                                                                                                                                                                                                                                            |                                     | 11.03.2008                               | Withdrawn |
| HQ File :<br>01/83/050/01420/AM08/                                                                                                                                                                                                                                                         | RLA File :<br>09/24/040/00276/AM08/ | Lic.No/Date:09100318<br>79<br>24.10.2007 |           |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Indinavir Sulphate under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                     |                                          |           |

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| Case No.:81/32/83-<br>ALC1/2007    | Party Name:METROCHEM<br>API PVT. LTD.                                                                                                                                                                                                                                                                                                              | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Deferred      |
| HQ File :<br>01/83/050/01503/AM08/ | RLA File :<br>09/24/040/00240/AM08/                                                                                                                                                                                                                                                                                                                | Lic.No/Date:09100319<br>88<br>05.11.2007       | Defer<br>Date:<br>22.04.2008 |
| 39                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2-Chloro Methyl-3-Methyl-4-(2,2,2-Trifloro Ethoxy)-Pyridine hydrochloride under para 4.7 of HBP.</p> <p>Committee decided to forward a copy of application to PI Division for their comments. Accordingly, case was deferred for six weeks.</p> |                                                |                              |

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| Case No.:82/32/83-<br>ALC1/2007    | Party Name:AUROBINDO<br>PHARMA LIMITED                                                                                                                                                                                                                                | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
| 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       |                              |
| 40                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cefepime Hcl for Injection under para 4.7 of HBP.</p> <p>Committee decided to withdraw case as case has been approved in its 43/08 meeting held on 04.03.2008.</p> |                                                |                              |

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| Case No.:32/33/83-<br>ALC1/2007    | Party Name:ASTRIX<br>LABORATORIES LTD.,                                                                                                                                                                                  | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:<br>Case<br>Withdrawn |
| HQ File :<br>01/83/050/01561/AM08/ | RLA File :<br>09/24/040/00256/AM08/                                                                                                                                                                                      | Lic.No/Date:09100320<br>90<br>14.11.2007       |                              |
| 41                                 | <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 withdraw case as case has been considered and</p> |                                                |                              |

deferred for six weeks in its 43/08 meeting held on 04.03.2008.

| 42                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Case No.:32/39/83-ALC1/2007        | Party Name:VANI CHEMICALS & INTERMEDIATES LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved                    |                |             |        |              |                                         |                     |      |    |               |            |    |              |           |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | HQ File :<br>01/83/050/01611/AM08/ | RLA File :<br>09/24/040/00219/AM08/            | Lic.No/Date:0910032233<br>27.11.2007       |                                         |                |             |        |              |                                         |                     |      |    |               |            |    |              |           |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Metformin Hcl BP/EP under para 4.7 of HBP.</p> <p>Committee in line with revised SION No. A-290 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> <tr> <th>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> <tr> <td rowspan="2">Metformin Hcl BP/EP</td><td rowspan="2">1kg.</td><td>1.</td><td>Dicyandiamide</td><td>0.567kg/kg</td></tr> <tr> <td>2.</td><td>Ortho-xylene</td><td>0.75kg/kg</td></tr> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                    |                                                |                                            |                                         | Export product | Export Qty. | Sl.No. | Import items | Qty. allowed per unit of export product | Metformin Hcl BP/EP | 1kg. | 1. | Dicyandiamide | 0.567kg/kg | 2. | Ortho-xylene | 0.75kg/kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Export Qty.                        | Sl.No.                                         | Import items                               | Qty. allowed per unit of export product |                |             |        |              |                                         |                     |      |    |               |            |    |              |           |
| Metformin Hcl BP/EP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 1kg.                               | 1.                                             | Dicyandiamide                              | 0.567kg/kg                              |                |             |        |              |                                         |                     |      |    |               |            |    |              |           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                    | 2.                                             | Ortho-xylene                               | 0.75kg/kg                               |                |             |        |              |                                         |                     |      |    |               |            |    |              |           |

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| 43                                                                                                                                                                                                                                                                                                                              | Case No.:34/39/83-ALC1/2007        | Party Name:SRINI PHARMACEUTICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|                                                                                                                                                                                                                                                                                                                                 | HQ File :<br>01/83/050/01613/AM08/ | RLA File :<br>09/24/040/00385/AM08/    | Lic.No/Date:0910032245<br>28.11.2007       |                       |
| <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 withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.</p> |                                    |                                        |                                            |                       |

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| 44 | Case No.:74/45/82-ALC4/2007        | Party Name:SHREE BANKEY BEHARI LAL BOARD MILLS | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00537/AM08/ | RLA File :<br>05/24/040/00727/AM08/            | Lic.No/Date:0510213720<br>18.12.2007       | Defer Date:<br>01.04.2008 |

Decision : Committee considered case as per agenda for ratification of norms for export product Thymol above 98.5% Pure under para 4.7 of HBP.

Committee decided to defer case for three weeks for comments of Chemical Division.

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| Case No.:77/45/82-ALC4/2007        | Party Name:ANJAN DRUGS PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
| HQ File :<br>01/82/050/00540/AM08/ | RLA File :<br>04/24/040/00058/AM08/    | Lic.No/Date:04100928<br>18<br>19.12.2007   |                      |

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2004-PI-III dated 11.03.2008 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

| Export product    | Export Qty. | Sl.No . | Import items      | Qty. allowed per unit of export product |
|-------------------|-------------|---------|-------------------|-----------------------------------------|
| Divalproex Sodium | 1kg.        | 1.      | Sodium Metal      | 0.52kg/kg                               |
|                   |             | 2.      | N-Propyl Bromide  | 2.69kg/kg                               |
|                   |             | 3.      | T-Butanol         | 0.69kg/kg                               |
|                   |             | 4.      | Sodium Hydroxide  | 0.13kg/kg                               |
|                   |             | 5.      | Di-ethyl malonate | 1.43kg/kg                               |

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

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| Case No.:63/45/82-ALC4/2007        | Party Name:PUNJAB CHEMICALS AND CROP PROTECTION LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00526/AM08/ | RLA File :<br>03/95/040/00918/AM08/                   | Lic.No/Date:03104549<br>61<br>20.12.2007   | Defer Date:<br>01.04.2008 |

Decision : Committee considered case as per agenda for ratification of norms for export product 2[(Chloro Methyl) Mercapto] Benzo Thiazole (CMBT) under para 4.7 of HBP.

Committee decided to defer case for three weeks for comments of Chemical Division.

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| 47 | Case No.:33/45/82-ALC4/2007                                                                                                                                                                                                             | Party Name:AARTI DRUGS LIMITED      | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00496/AM08/                                                                                                                                                                                                      | RLA File :<br>03/94/040/00644/AM08/ | Lic.No/Date:0310455127<br>26.12.2007       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Clopidogrel Bisulphate 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.:85/45/82-ALC4/2007                                                                                                                                                                                                                           | Party Name:YASHO INDUSTRIES PVT.LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00548/AM08/                                                                                                                                                                                                                    | RLA File :<br>03/95/040/00947/AM08/  | Lic.No/Date:0310455179<br>26.12.2007       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Copper Dibutyl Dithiocarbamate under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                      |                                            |                           |

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| 49 | Case No.:64/45/82-ALC4/2007                                                                                                                                                                                                                | Party Name:NANDOLIA ORGANIC CHEMICALS PVT.LTD | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00527/AM08/                                                                                                                                                                                                         | RLA File :<br>03/95/040/00872/AM08/           | Lic.No/Date:0310455396<br>27.12.2007       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Para Anisyl Alcohol under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                               |                                            |                           |

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| 50 | Case No.:9/40/83-ALC1/2007                                             | Party Name:KUDUES CHEMIE LTD.,      | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Withdrawn |
|    | HQ File :<br>01/83/050/01774/AM08/                                     | RLA File :<br>22/24/040/00059/AM08/ | Lic.No/Date:2210007329<br>27.12.2007       |                       |
|    | Decision : Committee considered case as per agenda for ratification of |                                     |                                            |                       |



norms for export product Caffeine under para 4.7 of HBP.

Committee decided to withdraw case as case has been considered and deferred for six weeks in its 43/08 meeting held on 04.03.2008.

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| 51                                                                                                                                                                                                                         | Case No.:2/45/82-ALC4/2007         | Party Name:ASTRIX LABORATORIES LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                            | HQ File :<br>01/82/050/00465/AM08/ | RLA File :<br>09/24/040/00420/AM08/  | Lic.No/Date:09100324<br>92<br>28.12.2007   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Stavudine 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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| 52                                                                                                                                                                                                                                                      | Case No.:66/45/82-ALC4/2007        | Party Name:HILDOSE                  | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                         | HQ File :<br>01/82/050/00529/AM08/ | RLA File :<br>03/94/040/00984/AM08/ | Lic.No/Date:0310455668<br>28.12.2007       | Defer Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Methyl 2,2 Dimethyl Cyanoacetate under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                     |                                            |                           |

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| 53                                                                                                                                                                                                                                                                               | Case No.:1/45/82-ALC4/2007         | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                                                  | HQ File :<br>01/82/050/00464/AM08/ | RLA File :<br>09/24/040/00246/AM08/ | Lic.No/Date:0910032496<br>31.12.2007       | Defer Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Piperacillin Sodium Sterile and Tazobactam Sodium Sterile (8:1) 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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| 54                                                                                                                                                                                                                                                                                                                            | Case No.:5/45/82-ALC4/2007         | Party Name:AUCTUS PHARMA PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                                                                                               | HQ File :<br>01/82/050/00468/AM08/ | RLA File :<br>09/24/040/00361/AM08/      | Lic.No/Date:0910032497<br>31.12.2007       | Defer Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product 4-Amino-2-oxo-Pyrimidinyl-Oxathiolane-2-Carboxylic acid-Isopropyl-Methyl-Cyclohexyl Ester (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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|----|-----------------------------|--------------------------------------|------------------------------|----------------------|
| 55 | Case No.:75/45/82-ALC4/2007 | Party Name:VIDA LABORATORIES (P) LTD | Meet No/Date:45/82-ALC4/2007 | Status:Case Deferred |
|----|-----------------------------|--------------------------------------|------------------------------|----------------------|

|                                                                                                                                                                                                                                                                                                                                                                             |                                     |                                          |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                             |                                     | 11.03.2008                               |                              |
| HQ File :<br>01/82/050/00538/AM08/                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>07/24/040/00686/AM08/ | Lic.No/Date:07100551<br>40<br>31.12.2007 | Defer<br>Date:<br>22.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cefuroxime Sodium for Injection, Piperacillin Sodium + Tazobactam Sodium Sterile for injection and Amoxicillin Sodium + Clavulanate Potassium for Injection under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                     |                                          |                              |

|                                                                                                                                                                                                                                          |                                    |                                        |                                                |                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------------------------|------------------------------------------------|------------------------------|
| 56                                                                                                                                                                                                                                       | Case No.:65/45/82-<br>ALC4/2007    | Party Name:KAJAY<br>REMEDIES PVT. LTD. | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Deferred      |
|                                                                                                                                                                                                                                          | HQ File :<br>01/82/050/00528/AM08/ | RLA File :<br>03/94/040/00993/AM08/    | Lic.No/Date:03104558<br>79<br>01.01.2008       | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Para nitro phenol under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                        |                                                |                              |

|                                                                                                                                                                                                                                                                    |                                    |                                          |                                                |                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------------|------------------------------------------------|------------------------------|
| 57                                                                                                                                                                                                                                                                 | Case No.:25/45/82-<br>ALC4/2007    | Party Name:AROMA<br>AROMATICS & FLAVOURS | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Deferred      |
|                                                                                                                                                                                                                                                                    | HQ File :<br>01/82/050/00488/AM08/ | RLA File :<br>05/24/040/00766/AM08/      | Lic.No/Date:05102143<br>92<br>03.01.2008       | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Propenyl Guaethol above 99% pure (Crystals) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                          |                                                |                              |

|                                                                                                                                                           |                                    |                                     |                                                |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------|------------------------------------------------|------------------------------|
| 58                                                                                                                                                        | Case No.:14/45/82-<br>ALC4/2007    | Party Name:ALKALOIDS<br>CORPORATION | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Deferred      |
|                                                                                                                                                           | HQ File :<br>01/82/050/00477/AM08/ | RLA File :<br>02/24/040/00270/AM08/ | Lic.No/Date:02101078<br>30<br>04.01.2008       | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Digoxin (Dititalis Extract) under para 4.7 of HBP.</p> |                                    |                                     |                                                |                              |

Committee decided to forward a copy of application to Department of MSME for their comments. Accordingly, case was deferred for four weeks.

|                                    |                                     |                                            |                      |
|------------------------------------|-------------------------------------|--------------------------------------------|----------------------|
| Case No.:19/45/82-ALC4/2007        | Party Name:ALKALOIDS CORPORATION    | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
| HQ File :<br>01/82/050/00482/AM08/ | RLA File :<br>02/24/040/00269/AM08/ | Lic.No/Date:02101078<br>28<br>04.01.2008   |                      |

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

Committee in light of its earlier decision taken in its 24/82 meeting held on 16.10.2007 in the case of Indo Phytochem Pharmaceuticals and in consultation with representative of 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:-

| Export product              | Export Qty. | Import item                                                  | Qty. allowed per unit of export product |
|-----------------------------|-------------|--------------------------------------------------------------|-----------------------------------------|
| Yohimbine Hydrochloride USP | 1kg.        | Yohimbine Bark (containing Yohimbine Content maximum 1-1.2%) | 133.44kg/kg                             |

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

|                                    |                                     |                                            |                           |
|------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| Case No.:20/45/82-ALC4/2007        | Party Name:ALKALOIDS CORPORATION    | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00483/AM08/ | RLA File :<br>02/24/040/00272/AM08/ | Lic.No/Date:02101078<br>33<br>04.01.2008   | Defer Date:<br>22.04.2008 |

Decision : Committee considered case as per agenda for ratification of norms for export product Artesunate Int PH3 under para 4.7 of HBP.

Committee decided to call for complete description of export and import items, copy of DML and technical details as per Appendix 33 from firm. Accordingly, case was deferred for six weeks.

|    |                                                                                                                                                                                                                          |                                      |                                            |                           |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|---------------------------|
| 61 | Case No.:24/45/82-ALC4/2007                                                                                                                                                                                              | Party Name:ALCHEM INTERNATIONAL LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00487/AM08/                                                                                                                                                                                       | RLA File :<br>05/24/040/00740/AM08/  | Lic.No/Date:0510214522<br>04.01.2008       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Digoxin under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of PI Division.</p> |                                      |                                            |                           |

|    |                                                                                                                                                                                                                                                                           |                                                 |                                            |                           |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------------------------------------|---------------------------|
| 62 | Case No.:57/45/82-ALC4/2007                                                                                                                                                                                                                                               | Party Name:NAVIN FLUORINE INTERNATIONAL LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00520/AM08/                                                                                                                                                                                                                                        | RLA File :<br>03/95/040/00956/AM08/             | Lic.No/Date:0310456685<br>07.01.2008       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Para Fluoro Bromo Benzene (4 Fluoro Bromo Benzene) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                                 |                                            |                           |

|    |                                                                                                                                                                                                                                                                                                    |                                     |                                            |                           |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 63 | Case No.:15/45/82-ALC4/2007                                                                                                                                                                                                                                                                        | Party Name:ANUH PHARMA LTD.         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00478/AM08/                                                                                                                                                                                                                                                                 | RLA File :<br>03/94/040/00916/AM08/ | Lic.No/Date:0310456983<br>08.01.2008       | Defer Date:<br>22.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Mometasone Furoate under para 4.7 of HBP.</p> <p>Committee decided to call for complete details of import item alongwith chemistry from firm. Accordingly, case was deferred for six weeks.</p> |                                     |                                            |                           |

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|----|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 64 | Case No.:16/45/82-ALC4/2007                                                                                                                             | Party Name:AARTI INDUSTRIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00479/AM08/                                                                                                                      | RLA File :<br>03/94/040/00980/AM08/ | Lic.No/Date:0310456999<br>08.01.2008       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product N,Ethyl Ortho Toluidine (NEOT) under para 4.7 of</p> |                                     |                                            |                           |

HBP.

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

|    |                                                                                                                                                                                                                               |                                     |                                            |                              |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 65 | Case No.:18/45/82-ALC4/2007                                                                                                                                                                                                   | Party Name:ANUH PHARMA LTD.         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/82/050/00481/AM08/                                                                                                                                                                                            | RLA File :<br>03/94/040/00917/AM08/ | Lic.No/Date:03104569<br>85<br>08.01.2008   | Defer<br>Date:<br>22.04.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product Clobetasone Butyrate under para 4.7 of HBP.<br><br>Committee decided to defer case for six weeks for comments of PI Division. |                                     |                                            |                              |

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|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------|------------------------------|
| 66 | Case No.:84/45/82-ALC4/2007                                                                                                                                                                                                               | Party Name:SALVI CHEMICAL INDUSTRIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/82/050/00547/AM08/                                                                                                                                                                                                        | RLA File :<br>03/95/040/00997/AM08/          | Lic.No/Date:03104569<br>69<br>08.01.2008   | Defer<br>Date:<br>22.04.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product 3,5 Di-Iodo Salicylic Acid under para 4.7 of HBP.<br><br>Committee decided to defer case for six weeks for comments of Chemical Division. |                                              |                                            |                              |

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|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| 67 | Case No.:44/45/82-ALC4/2007                                                                                                                                                                                                                  | Party Name:HEMA DYE CHEM PVT. LTD.  | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/82/050/00507/AM08/                                                                                                                                                                                                           | RLA File :<br>03/94/040/00971/AM08/ | Lic.No/Date:03104571<br>90<br>09.01.2008   | Defer<br>Date:<br>08.04.2008 |
|    | Decision : Committee considered case as per agenda for ratification of norms for export product 2 Chloro 14 Dimethoxybenzene under para 4.7 of HBP.<br><br>Committee decided to defer case for four weeks for comments of Chemical Division. |                                     |                                            |                              |

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|----|-----------------------------|---------------------------------------------------|--------------------------------------------|----------------------|
| 68 | Case No.:28/45/82-ALC4/2007 | Party Name:ARKEMA PEROXIDES INDIA PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred |
|----|-----------------------------|---------------------------------------------------|--------------------------------------------|----------------------|

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|------------------------------|
| HQ File :<br>01/82/050/00491/AM08/                                                                                                                                                                                                                                                                                   | RLA File :<br>04/24/040/00335/AM08/ | Lic.No/Date:04100931<br>38<br>10.01.2008 | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product 1,1-Di-Methyl 3 Hydroxy Butyl Peroxy neodecanoate 50% Non Frozen Emulsion (Luperox 610 EN 50) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                     |                                          |                              |

|                                    |                                                                                                                                                                                                                                                                            |                                                |                              |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------------|
| Case No.:70/45/82-<br>ALC4/2007    | Party Name:SOUTHERN<br>PETROCHEMICAL IND.<br>CORPN. LIMITED                                                                                                                                                                                                                | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Deferred      |
| HQ File :<br>01/82/050/00533/AM08/ | RLA File :<br>04/24/040/00337/AM08/                                                                                                                                                                                                                                        | Lic.No/Date:04100931<br>39<br>10.01.2008       | Defer<br>Date:<br>08.04.2008 |
| 69                                 | <p>Decision : Committee considered case as per agenda for ratification of norms for export product N-(2-Hydroxyethyl) Pyrrolidine Pyrrolidine - Liquid under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                                |                              |

| 70             | Case No.:90/45/82-<br>ALC4/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Party Name:DIVIS<br>LABORATORIES LTD., | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Approved                 |                |             |        |              |                                         |  |  |  |  |  |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|------------------------------------------------|-----------------------------------------|----------------|-------------|--------|--------------|-----------------------------------------|--|--|--|--|--|
|                | HQ File :<br>01/82/050/00553/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | RLA File :<br>09/24/040/00433/AM08/    | Lic.No/Date:0910032<br>640<br>10.01.2008       | :                                       |                |             |        |              |                                         |  |  |  |  |  |
|                | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cyclopentadecanolide (Recrystallised) under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 23/82 meeting held on 09.10.2007 vide Case No.6/11/82 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>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> |                                        |                                                |                                         | Export product | Export Qty. | Sl.No. | Import items | Qty. allowed per unit of export product |  |  |  |  |  |
| Export product | Export Qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Sl.No.                                 | Import items                                   | Qty. allowed per unit of export product |                |             |        |              |                                         |  |  |  |  |  |
|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                        |                                                |                                         |                |             |        |              |                                         |  |  |  |  |  |

|                                                                          |      |    |                                                          |           |
|--------------------------------------------------------------------------|------|----|----------------------------------------------------------|-----------|
| Cyclopentadecanolide<br>(Recrystallised)<br>(Purity not less than 99.5%) | 1kg. | 1. | Cyclopentadecanolide (Tech. Grade)<br>(Purity NMT 90.5%) | 1.20kg/kg |
|                                                                          |      | 2. | Methanol                                                 | 3.95kg/kg |

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

71

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|-----------------------------|-----------------------------------------|
| Case No.:91/45/82-ALC4/2007                                                                                                                                                                                                                             | Party Name:DIVIS LABORATORIES LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved        |                                         |
| HQ File :<br>01/82/050/00554/AM08/                                                                                                                                                                                                                      | RLA File :<br>09/24/040/00432/AM08/ | Lic.No/Date:0910032641<br>10.01.2008       |                             |                                         |
| Decision : Committee considered case as per agenda for ratification of norms for export product Levetiracetam under para 4.7 of HBP.                                                                                                                    |                                     |                                            |                             |                                         |
| Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/218/2006-PI-III dated 11.03.2008 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- |                                     |                                            |                             |                                         |
| Export product                                                                                                                                                                                                                                          | Export Qty.                         | Sl.No.                                     | Import items                | Qty. allowed per unit of export product |
| Levetiracetam                                                                                                                                                                                                                                           | 1kg.                                | 1.                                         | 2-Pyrrolidone               | 2.57kg/kg                               |
|                                                                                                                                                                                                                                                         |                                     | 2.                                         | D(+ )Alpha Phenylethylamine | 0.87kg/kg                               |
|                                                                                                                                                                                                                                                         |                                     | 3.                                         | Ethyl-2-Bromo Butyrate      | 5.89kg/kg                               |
|                                                                                                                                                                                                                                                         |                                     | 4.                                         | Methanol                    | 3.22kg/kg                               |
|                                                                                                                                                                                                                                                         |                                     | 5.                                         | Iso Propyl Alcohol          | 4.90kg/kg                               |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                             |                                     |                                            |                             |                                         |

|    |                                    |                                          |                                            |                           |
|----|------------------------------------|------------------------------------------|--------------------------------------------|---------------------------|
| 72 | Case No.:4/45/82-ALC4/2007         | Party Name:AUCTUS PHARMA PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00467/AM08/ | RLA File :<br>09/24/040/00411/AM08/      | Lic.No/Date:0910032646<br>11.01.2008       | Defer Date:<br>08.04.2008 |



Decision : Committee considered case as per agenda for ratification of norms for export product {1 R,2 S,5R}-Methyl-5S-(Cytosine-1-YL)-1-3-Oxathiolane-2R-Carboxylate under para 4.7 of HBP.

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

|                                    |                                                   |                                            |                              |
|------------------------------------|---------------------------------------------------|--------------------------------------------|------------------------------|
| Case No.:12/45/82-ALC4/2007        | Party Name:BENZO CHEM INDUSTRIES PRIVATE LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
| HQ File :<br>01/82/050/00475/AM08/ | RLA File :<br>03/94/040/00999/AM08/               | Lic.No/Date:03104574<br>07<br>11.01.2008   | Defer<br>Date:<br>08.04.2008 |

73 Decision : Committee considered case as per agenda for ratification of norms for export product 2,5-Dimethyl Phenyl Acetyl Chloride under para 4.7 of HBP.

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

|                                    |                                     |                                            |                              |
|------------------------------------|-------------------------------------|--------------------------------------------|------------------------------|
| Case No.:13/45/82-ALC4/2007        | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
| HQ File :<br>01/82/050/00476/AM08/ | RLA File :<br>03/94/040/01028/AM08/ | Lic.No/Date:03104575<br>08<br>11.01.2008   | Defer<br>Date:<br>08.04.2008 |

74 Decision : Committee considered case as per agenda for ratification of norms for export product Lamivir 150mg Tablets etc. under para 4.7 of HBP.

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

|                                    |                                     |                                            |                      |
|------------------------------------|-------------------------------------|--------------------------------------------|----------------------|
| Case No.:21/45/82-ALC4/2007        | Party Name:AARTI INDUSTRIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
| HQ File :<br>01/82/050/00484/AM08/ | RLA File :<br>03/94/040/00979/AM08/ | Lic.No/Date:03104575<br>14<br>11.01.2008   |                      |

75 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.35011/150/2005-PI-III dated 11.03.2008 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as

applied by firm whichever is lower:-

| Export product         | Export Qty. | Sl.No. | Import items              | Qty. allowed per unit of export product |
|------------------------|-------------|--------|---------------------------|-----------------------------------------|
| Fluticasone Propionate | 1kg.        | 1.     | Flumethasone              | 2.50kg/kg                               |
|                        |             | 2.     | Bromo Fluro Methane       | 0.68kg/kg                               |
|                        |             | 3.     | N,N-carboxyl Di-imidazole | 1.62kg/kg                               |

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

|                                    |                                         |                                            |                           |
|------------------------------------|-----------------------------------------|--------------------------------------------|---------------------------|
| Case No.:47/45/82-ALC4/2007        | Party Name:MANTENA LABORATORIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00510/AM08/ | RLA File :<br>09/24/040/00371/AM08/     | Lic.No/Date:0910032645<br>11.01.2008       | Defer Date:<br>08.04.2008 |

76 Decision : Committee considered case as per agenda for ratification of norms for export product 1,2-Epoxy-2(2,4-Difluorophenyl)-3-(1-(H)-1,2,4-Triazole,1 Propane Methane Sulphonate under para 4.7 of HBP.

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

|                                    |                                                    |                                            |                           |
|------------------------------------|----------------------------------------------------|--------------------------------------------|---------------------------|
| Case No.:49/45/82-ALC4/2007        | Party Name:INVENTIS DRUG DELIVERY SYSTEMS PVT LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00512/AM08/ | RLA File :<br>09/24/040/00222/AM08/                | Lic.No/Date:0910032644<br>11.01.2008       | Defer Date:<br>22.04.2008 |

77 Decision : Committee considered case as per agenda for ratification of norms for export product Lansoprazole Pellets 8.5% under para 4.7 of HBP.

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

|                                    |                                                  |                                            |                           |
|------------------------------------|--------------------------------------------------|--------------------------------------------|---------------------------|
| Case No.:61/45/82-ALC4/2007        | Party Name:HINDUSTAN POLYAMIDES & FIBRES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00524/AM08/ | RLA File :<br>03/94/040/01014/AM08/              | Lic.No/Date:0310457513<br>11.01.2008       | Defer Date:<br>08.04.2008 |

Decision : Committee considered case as per agenda for ratification of

norms for export product Hamber under para 4.7 of HBP.

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

Case No.:48/45/82-  
ALC4/2007

Party  
Name:METROPOLITAN  
EXIMCHEM LTD.

Meet No/Date:45/82-  
ALC4/2007  
11.03.2008

Status:Case  
Deferred

HQ File :  
01/82/050/00511/AM08/

RLA File :  
03/95/040/00974/AM08/

Lic.No/Date:03104576  
22  
14.01.2008

Defer  
Date:  
08.04.2008

79 Decision : Committee considered case as per agenda for ratification of norms for export product 5 Amino 6 Methyl Benzimidazolone under para 4.7 of HBP.

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

Case No.:80/45/82-  
ALC4/2007

Party Name:SUVEN LIFE  
SCIENCES LIMITED

Meet No/Date:45/82-  
ALC4/2007  
11.03.2008

Status:Case  
Deferred

HQ File :  
01/82/050/00543/AM08/

RLA File :  
09/24/040/00450/AM08/

Lic.No/Date:09100326  
59  
15.01.2008

Defer  
Date:  
08.04.2008

80 Decision : Committee considered case as per agenda for ratification of norms for export product (2-Chloro-5-Iodo Phenyl)-(4-Fluoro Phenyl) Methanone under para 4.7 of HBP.

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

Case No.:87/45/82-  
ALC4/2007

Party Name:SUVEN LIFE  
SCIENCES LIMITED

Meet No/Date:45/82-  
ALC4/2007  
11.03.2008

Status:Case  
Deferred

HQ File :  
01/82/050/00550/AM08/

RLA File :  
09/24/040/00452/AM08/

Lic.No/Date:09100326  
58  
15.01.2008

Defer  
Date:  
08.04.2008

81 Decision : Committee considered case as per agenda for ratification of norms for export product (2-Chloro-5-Iodophenyl)-[4-(Tetrahydrofuran-3-Yloxy) Phenyl]-Methanone under para 4.7 of HBP.

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

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| 82                                                                                                                                                                                                                                                                     | Case No.:8/45/82-ALC4/2007         | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                                                                        | HQ File :<br>01/82/050/00471/AM08/ | RLA File :<br>03/94/040/01041/AM08/ | Lic.No/Date:03104578<br>81<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Nevimine 200mg Tablets and Nevirapine Oral Sulpension 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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| 83                                                                                                                                                                                                                                   | Case No.:9/45/82-ALC4/2007         | Party Name:GALAXY LABORATORIES PVT LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                                      | HQ File :<br>01/82/050/00472/AM08/ | RLA File :<br>03/94/040/01004/AM08/      | Lic.No/Date:03104577<br>55<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Furfurylamine under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                          |                                            |                              |

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| 84                                                                                                                                                                                                                                      | Case No.:10/45/82-ALC4/2007        | Party Name:GEMINI EXPORTS.,         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                                         | HQ File :<br>01/82/050/00473/AM08/ | RLA File :<br>03/94/040/01035/AM08/ | Lic.No/Date:03104578<br>91<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Ferrous Fumarate under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                     |                                            |                              |

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| 85                                                                                                                                                     | Case No.:23/45/82-ALC4/2007        | Party Name:FINE ORGANIC INDUSTRIES(MUMBAI) PVT. LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                        | HQ File :<br>01/82/050/00486/AM08/ | RLA File :<br>03/94/040/01026/AM08/                  | Lic.No/Date:03104578<br>84<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Sodium Stearyl Lactylate under para 4.7 of HBP.</p> |                                    |                                                      |                                            |                              |

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

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| 86                                                                                                                                                                                                                                                                      | Case No.:45/45/82-ALC4/2007        | Party Name:LAFFANS PETROCHEMICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                                                                         | HQ File :<br>01/82/050/00508/AM08/ | RLA File :<br>03/95/040/01003/AM08/     | Lic.No/Date:03104578<br>33<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Laffsolve MEB (Ethylene Glycol mono butyl Ether) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                         |                                            |                              |

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| 87                                                                                                                                                                                                                                                                                                                          | Case No.:46/45/82-ALC4/2007        | Party Name:MANGALAM DRUGS & ORGANICS LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                                                                                                                             | HQ File :<br>01/82/050/00509/AM08/ | RLA File :<br>03/95/040/01017/AM08/          | Lic.No/Date:03104577<br>18<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product N Acetoxy Ethyl N Cyano Ethyl Meta Amino Acetanilide (1-Acetylamino-3-N(2 Acetoxy Ethyl-3-N(2 Cyano Ethyl) 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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| 88                                                                                                                                                                                                                                                                             | Case No.:50/45/82-ALC4/2007        | Party Name:KALPSUTRA CHEMICALS PVT. LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|                                                                                                                                                                                                                                                                                | HQ File :<br>01/82/050/00513/AM08/ | RLA File :<br>03/94/040/01020/AM08/      | Lic.No/Date:03104577<br>97<br>16.01.2008   | Defer<br>Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Timberfleur (1-(2,2,6-Trimethyl Cyclohexyl)-Hexan-3-01) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                          |                                            |                              |

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| 89 | Case No.:51/45/82-ALC4/2007                                                                                                                                                                                                | Party Name:IPCA LABORATORIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/82/050/00514/AM08/                                                                                                                                                                                         | RLA File :<br>03/94/040/00996/AM08/  | Lic.No/Date:03104578<br>11<br>16.01.2008   | Defer<br>Date:<br>22.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Nabumetone under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                      |                                            |                              |

| 90             | Case No.:52/45/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Party Name:IPCA LABORATORIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved                    |                |             |        |              |                                         |             |      |    |                          |           |    |                        |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|-----------------------------------------|----------------|-------------|--------|--------------|-----------------------------------------|-------------|------|----|--------------------------|-----------|----|------------------------|
|                | HQ File :<br>01/82/050/00515/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | RLA File :<br>03/94/040/00974/AM08/  | Lic.No/Date:03104578<br>05<br>16.01.2008   |                                         |                |             |        |              |                                         |             |      |    |                          |           |    |                        |
|                | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Testosterone under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/88/2007-PI-III dated 11.03.2008 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>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td rowspan="2">Testosteron</td><td rowspan="2">1kg.</td><td>1.</td><td>Androst-4-ene-3,17 dione</td><td>1.33kg/kg</td></tr> <tr> <td>2.</td><td>Triethyl Ortho Formate</td><td>0.36kg/kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                      |                                            |                                         | Export product | Export Qty. | Sl.No. | Import items | Qty. allowed per unit of export product | Testosteron | 1kg. | 1. | Androst-4-ene-3,17 dione | 1.33kg/kg | 2. | Triethyl Ortho Formate |
| Export product | Export Qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Sl.No.                               | Import items                               | Qty. allowed per unit of export product |                |             |        |              |                                         |             |      |    |                          |           |    |                        |
| Testosteron    | 1kg.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1.                                   | Androst-4-ene-3,17 dione                   | 1.33kg/kg                               |                |             |        |              |                                         |             |      |    |                          |           |    |                        |
|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 2.                                   | Triethyl Ortho Formate                     | 0.36kg/kg                               |                |             |        |              |                                         |             |      |    |                          |           |    |                        |

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| 91 | Case No.:27/45/82-ALC4/2007                                                                                                                        | Party Name:GEMINI EXPORTS.,         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|    | HQ File :<br>01/82/050/00490/AM08/                                                                                                                 | RLA File :<br>03/94/040/00812/AM08/ | Lic.No/Date:03104580<br>56<br>17.01.2008   | Defer<br>Date:<br>22.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Metoprolol Succinate under para 4.7 of HBP.</p> |                                     |                                            |                              |

Committee decided to defer case for six weeks for comments of PI/Chem. Division.

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| 92                                                                                                                                                                                                                                                    | Case No.:79/45/82-ALC4/2007        | Party Name:DR REDDYS LABORATORIES LTD | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                       | HQ File :<br>01/82/050/00542/AM08/ | RLA File :<br>09/24/040/00434/AM08/   | Lic.No/Date:0910032665<br>17.01.2008       | Defer Date:<br>22.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Spironolactone Tablets 25mg and 100mg under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                    |                                       |                                            |                           |

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| 93                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Case No.:53/45/82-ALC4/2007        | Party Name:METROPOLITAN OVERSEAS LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | HQ File :<br>01/82/050/00516/AM08/ | RLA File :<br>03/95/040/01030/AM08/       | Lic.No/Date:0310458166<br>18.01.2008       | Defer Date:<br>22.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product N-[1-(S)-Ethoxy Carbonyl-3-Phenyl Propyl]-L-Alanine under para 4.7 of HBP.</p> <p>Committee observed that norms applied by firm are not as per chemistry furnished by them. Committee, therefore, decided to call from firm the technical justification alongwith calculations for working out the quantative requirement as applied by them. Accordingly, case was deferred for six weeks.</p> |                                    |                                           |                                            |                           |

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| 94                                                                                                                                                                                                                                   | Case No.:58/45/82-ALC4/2007        | Party Name:LUPIN LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                      | HQ File :<br>01/82/050/00521/AM08/ | RLA File :<br>03/95/040/01026/AM08/ | Lic.No/Date:0310458300<br>18.01.2008       | Defer Date:<br>22.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cefpodoxime Proxetil under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                    |                                     |                                            |                           |

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| 95                                                                                                                                                                                                                                                         | Case No.:8/44/83-ALC1/2007         | Party Name:SHIVA PHARMACHEM PVT. LTD, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                            | HQ File :<br>01/83/050/01802/AM08/ | RLA File :<br>34/24/040/00208/AM08/   | Lic.No/Date:3410020655<br>21.01.2008       | Defer Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product n-Butyryl Chloride/Butyryl Chloride under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                    |                                       |                                            |                           |

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| 96                                                                                                                                                                                                                                                             | Case No.:62/45/82-ALC4/2007        | Party Name:NICHOLAS PIRAMAL INDIA LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                                | HQ File :<br>01/82/050/00525/AM08/ | RLA File :<br>03/95/040/01007/AM08/    | Lic.No/Date:0310458373<br>21.01.2008       | Defer Date:<br>08.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Oxysept Tablets (9081X) Contact Lens Cleaning Tablets under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of DBT.</p> |                                    |                                        |                                            |                           |

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| 97                                                                                                                                                                                                                                                                                                                    | Case No.:86/45/82-ALC4/2007        | Party Name:VIJAYASRI ORGANICS LTD   | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|                                                                                                                                                                                                                                                                                                                       | HQ File :<br>01/82/050/00549/AM08/ | RLA File :<br>09/24/040/00469/AM08/ | Lic.No/Date:0910032688<br>21.01.2008       | Defer Date:<br>22.04.2008 |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2-Butyl-5-Chloro-3H-Imidazole-4-Carbaldehyde (IMAL) (Or) (2-N-Butyl-4-Chloro-5-Formylimidazole (BCFI) under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                    |                                     |                                            |                           |

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| 98 | Case No.:89/45/82-ALC4/2007        | Party Name:VIJAYASRI CHEMICALS      | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00552/AM08/ | RLA File :<br>09/24/040/00470/AM08/ | Lic.No/Date:0910032689<br>21.01.2008       | Defer Date:<br>22.04.2008 |



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|  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2-Butyl-5-Chloro-3H-Imidazole-4-Carbaldehyde (IMAL) (Or) (2-N-Butyl-4-Chloro-5-Formylimidazole (BCFI) under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |  |  |
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| 99 | Case No.:56/45/82-ALC4/2007                                                                                                                                                                                                       | Party Name:OLEOFINE ORGANICS (INDIA)PVT.LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|    | HQ File :<br>01/82/050/00519/AM08/                                                                                                                                                                                                | RLA File :<br>03/95/040/01050/AM08/           | Lic.No/Date:0310458576<br>22.01.2008       | Defer Date:<br>08.04.2008 |
|    | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Behenamide under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                               |                                            |                           |

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| 100 | Case No.:59/45/82-ALC4/2007                                                                                                                                                                                                                                                                        | Party Name:MANGALAM DRUGS & ORGANICS LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00522/AM08/                                                                                                                                                                                                                                                                 | RLA File :<br>03/95/040/01022/AM08/          | Lic.No/Date:0310458669<br>22.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Amodiaquine hydrochloride under para 4.7 of HBP.</p> <p>Committee decided to call for All Industry Data from Pharmexcil for revision of SION. Accordingly, case was deferred for six weeks.</p> |                                              |                                            |                           |

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| 101 | Case No.:3/45/82-ALC4/2007                                                                                                                                                                                      | Party Name:AUROBINDO PHARMA LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00466/AM08/                                                                                                                                                                              | RLA File :<br>09/24/040/00405/AM08/ | Lic.No/Date:0910032711<br>23.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Lopinavir under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI</p> |                                     |                                            |                           |

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| 102 | Case No.:68/45/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                                                            | Party Name:SHASUN CHEMICALS & DRUGS LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
|     | HQ File :<br>01/82/050/00531/AM08/                                                                                                                                                                                                                                                                                                                                                                                                     | RLA File :<br>04/24/040/00309/AM08/         | Lic.No/Date:0410093423<br>23.01.2008       |                      |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Sulfasalazine Tablets (500mg) under para 4.7 of HBP.</p> <p>I was decided to ratify the subject Advance Authorisation with 2% wastage or as applied for whichever is less subject to verification of DML and other relevant documents by RA.</p> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                             |                                            |                      |

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| 103 | Case No.:69/45/82-ALC4/2007                                                                                                                                                                                                                                                        | Party Name:SHASUN CHEMICALS & DRUGS LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00532/AM08/                                                                                                                                                                                                                                                 | RLA File :<br>04/24/040/00318/AM08/         | Lic.No/Date:0410093428<br>23.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 1,4-Dithia 7-Azaspiro(4,4) nonane-8(S)-Carbolylicacid Hydrobromide under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                             |                                            |                           |

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| 104 | Case No.:60/45/82-ALC4/2007                                                                                                                                                                                               | Party Name:LUPIN LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00523/AM08/                                                                                                                                                                                        | RLA File :<br>03/95/040/01054/AM08/ | Lic.No/Date:0310458992<br>24.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>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.</p> <p>Committee decided to examine case on file.</p> |                                     |                                            |                           |

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| 105 | Case No.:76/45/82-ALC4/2007                                                                                                                                                                                                                                                                          | Party Name:CODEXIS LABORATORIES INDIA PVT.LTD, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00539/AM08/                                                                                                                                                                                                                                                                   | RLA File :<br>05/24/040/00787/AM08/            | Lic.No/Date:0510215390<br>24.01.2008       | Defer Date:<br>08.04.2008 |
|     | <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) 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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|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------------|---------------------------|
| 106 | Case No.:82/45/82-ALC4/2007                                                                                                                                                                                                                                    | Party Name:SUDERSHAN LABORATORIES LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00545/AM08/                                                                                                                                                                                                                             | RLA File :<br>09/24/040/00476/AM08/    | Lic.No/Date:0910032726<br>24.01.2008       | Defer Date:<br>08.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product N Butyl Lithium (1.6 M Solution As 100% under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                        |                                            |                           |

|     |                                                                                                                                                                                                                                             |                                     |                                            |                           |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 107 | Case No.:11/45/82-ALC4/2007                                                                                                                                                                                                                 | Party Name:AARTI INDUSTRIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00474/AM08/                                                                                                                                                                                                          | RLA File :<br>03/94/040/01078/AM08/ | Lic.No/Date:0310459141<br>25.01.2008       | Defer Date:<br>08.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2,4 Dichloro Aniline under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                     |                                            |                           |

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| 108 | Case No.:40/45/82-ALC4/2007 | Party Name:HALDIA PETROCHEMICALS LTD. | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred |
|     | HQ File :                   | RLA File :                            | Lic.No/Date:02101085                       | Defer                |

|  |                                                                                                                                                                                                                                |                       |                  |                     |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------|---------------------|
|  | 01/82/050/00503/AM08/                                                                                                                                                                                                          | 02/24/040/00285/AM08/ | 51<br>25.01.2008 | Date:<br>08.04.2008 |
|  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Benzene under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                       |                  |                     |

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|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|------------------------------|
| 109 | Case No.:54/45/82-ALC4/2007                                                                                                                                                                                                                                                                | Party Name:LAFFANS PETROCHEMICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|     | HQ File :<br>01/82/050/00517/AM08/                                                                                                                                                                                                                                                         | RLA File :<br>03/95/040/01046/AM08/     | Lic.No/Date:0310459172<br>25.01.2008       | Defer<br>Date:<br>08.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Lafftol DEB (Di Ethylene Glycol Mono Butyl Ether) (Butyl Di Glycol) under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                         |                                            |                              |

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| 110 | Case No.:6/45/82-ALC4/2007                                                                                                                                                                                                                                                         | Party Name:JOCIL LTD.,              | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|     | HQ File :<br>01/82/050/00469/AM08/                                                                                                                                                                                                                                                 | RLA File :<br>09/24/040/00417/AM08/ | Lic.No/Date:0910032743<br>28.01.2008       | Defer<br>Date:<br>08.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Pink/Yellow/Green Soap Noodles Sodium Salt of Palmitic Acid under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                     |                                            |                              |

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| 111 | Case No.:7/45/82-ALC4/2007                                                    | Party Name:METROCHEM API PVT. LTD.  | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred         |
|     | HQ File :<br>01/82/050/00470/AM08/                                            | RLA File :<br>09/24/040/00456/AM08/ | Lic.No/Date:0910032740<br>28.01.2008       | Defer<br>Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of</p> |                                     |                                            |                              |

norms for export product Rabeprazole Sodium under para 4.7 of HBP.

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

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| Case No.:17/45/82-ALC4/2007 | Party Name:ANJAN DRUGS PRIVATE LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
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| HQ File :<br>01/82/050/00480/AM08/ | RLA File :<br>04/24/040/00213/AM08/ | Lic.No/Date:0410093497<br>29.01.2008 |  |
|------------------------------------|-------------------------------------|--------------------------------------|--|

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/207/2004-PI-III dated 11.03.2008 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

| Export product    | Export Qty. | Sl.No . | Import items      | Qty. allowed per unit of export product |
|-------------------|-------------|---------|-------------------|-----------------------------------------|
| Divalproex Sodium | 1kg.        | 1.      | Sodium Metal      | 0.52kg/kg                               |
|                   |             | 2.      | N-Propyl Bromide  | 2.69kg/kg                               |
|                   |             | 3.      | T-Butanol         | 0.69kg/kg                               |
|                   |             | 4.      | Sodium Hydroxide  | 0.13kg/kg                               |
|                   |             | 5.      | Di-ethyl malonate | 1.43kg/kg                               |

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

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| Case No.:22/45/82-ALC4/2007 | Party Name:GLOBAL CALCIUM PRIVATE LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred |
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| HQ File :<br>01/82/050/00485/AM08/ | RLA File :<br>07/24/040/00725/AM08/ | Lic.No/Date:0710055635<br>29.01.2008 | Defer Date:<br>01.04.2008 |
|------------------------------------|-------------------------------------|--------------------------------------|---------------------------|

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

Committee decided to defer case for three weeks for comments of PI/Chemical Division.

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| 114 | Case No.:83/45/82-ALC4/2007                                                                                                                                                                                                           | Party Name:DUJODWALA PAPER CHEMICALS LTD | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00546/AM08/                                                                                                                                                                                                    | RLA File :<br>03/94/040/00956/AM08/      | Lic.No/Date:0310459419<br>29.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Polyamide Resin under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of Chemical Division.</p> |                                          |                                            |                           |

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| 115 | Case No.:88/45/82-ALC4/2007                                                                                                                                                                                                                                                      | Party Name:VIVIMED LABS LIMITED     | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00551/AM08/                                                                                                                                                                                                                                               | RLA File :<br>09/24/040/00422/AM08/ | Lic.No/Date:0910032808<br>29.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Benzophenone-3/2-Hydroxy-4-Methoxy Benzophenone/Oxybenzone under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of Chemical Division.</p> |                                     |                                            |                           |

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| 116 | Case No.:30/45/82-ALC4/2007                                                                                                                                                                                                              | Party Name:ANUH PHARMA LTD.         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00493/AM08/                                                                                                                                                                                                       | RLA File :<br>03/94/040/01047/AM08/ | Lic.No/Date:0310459539<br>30.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Clobetasol Propionate BP under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                     |                                            |                           |

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| 117 | Case No.:26/45/82-ALC4/2007        | Party Name:GLOBAL CALCIUM PRIVATE LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred |
|     | HQ File :<br>01/82/050/00489/AM08/ | RLA File :<br>07/24/040/00593/AM08/        | Lic.No/Date:0710055673                     | Defer Date:          |

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|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|------------|------------|
|  |                                                                                                                                                                                                                                                                                                   |  | 31.01.2008 | 01.04.2008 |
|  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Calcium Lactobionate, Calcium Glubionate and Calcium Bromolactobionate under para 4.7 of HBP.</p> <p>Committee decided to defer case for three weeks for comments of PI/Chemical Division.</p> |  |            |            |

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|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 118 | Case No.:32/45/82-ALC4/2007                                                                                                                                                                                                                                                   | Party Name:AARTI DRUGS LIMITED      | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00495/AM08/                                                                                                                                                                                                                                            | RLA File :<br>03/94/040/01031/AM08/ | Lic.No/Date:0310459714<br>31.01.2008       | Defer Date:<br>08.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 1-(4 Methyl Phenyl)-4,4,4 Trifluorobutane-3-Dione (Diketone) 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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| 119 | Case No.:73/45/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                | Party Name:WIN-MEDICARE PVT. LTD    | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00536/AM08/                                                                                                                                                                                                                                                                                                                                                         | RLA File :<br>05/24/040/00267/AM08/ | Lic.No/Date:0510215725<br>31.01.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Betadine Standardised Microbicidal Solution 10% USP/IP 100ml, 500ml and 50ml, Betadine Surgical Scrub 7.5% USP/IP 50ml and 500ml, Betadine Gargle 1% USP/IP 50ml and 100ml under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                     |                                            |                           |

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|-----|------------------------------------|--------------------------------------------------|--------------------------------------------|---------------------------|
| 120 | Case No.:38/45/82-ALC4/2007        | Party Name:NANAVATI SPECIALITY CHEMICALS PVT LTD | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00501/AM08/ | RLA File :<br>03/95/040/01002/AM08/              | Lic.No/Date:0310459796<br>01.02.2008       | Defer Date:<br>08.04.2008 |

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|  | <p>Decision : Committee considered case as per agenda for ratification of norms for export product 2 Nitro Dimethyl Terephthalate Chemical under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |  |  |  |
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| 12<br>1 | Case No.:41/45/82-ALC4/2007                                                                                                                                                                                                                   | Party Name:MAKAM PHARMACHEM         | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|         | HQ File :<br>01/82/050/00504/AM08/                                                                                                                                                                                                            | RLA File :<br>07/24/040/00741/AM08/ | Lic.No/Date:0710055677<br>01.02.2008       | Defer Date:<br>08.04.2008 |
|         | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Fluometrin 1% W/V Pour under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                     |                                            |                           |

|         |                                                                                                                                                                                                                                       |                                     |                                            |                           |
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| 12<br>2 | Case No.:71/45/82-ALC4/2007                                                                                                                                                                                                           | Party Name:SKY LIFE SCIENCE.        | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|         | HQ File :<br>01/82/050/00534/AM08/                                                                                                                                                                                                    | RLA File :<br>34/24/040/00214/AM08/ | Lic.No/Date:3410020757<br>01.02.2008       | Defer Date:<br>22.04.2008 |
|         | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Clobetasol Propionate under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                     |                                            |                           |

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|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------|---------------------------|
| 12<br>3 | Case No.:72/45/82-ALC4/2007                                                                                                                                                                                                                             | Party Name:TATVA CHINTAN PHARMA CHEM PVT LTD | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|         | HQ File :<br>01/82/050/00535/AM08/                                                                                                                                                                                                                      | RLA File :<br>34/24/040/00216/AM08/          | Lic.No/Date:3410020758<br>01.02.2008       | Defer Date:<br>08.04.2008 |
|         | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Methyl Tributyl Ammonium Chloride Cas No.56375-79-2 under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of</p> |                                              |                                            |                           |



Chemical Division.

|     |                                                                                                                                                                    |                                                   |                                            |                           |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------------|---------------------------|
| 124 | Case No.:31/45/82-ALC4/2007                                                                                                                                        | Party Name:BENZO CHEM INDUSTRIES PRIVATE LIMITED, | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00494/AM08/                                                                                                                                 | RLA File :<br>03/94/040/01086/AM08/               | Lic.No/Date:0310459938<br>04.02.2008       | Defer Date:<br>08.04.2008 |
|     | Decision : Committee considered case as per agenda for ratification of norms for export product Protectol DA or 2,4-Dichloro Benzyl Alcohol under para 4.7 of HBP. |                                                   |                                            |                           |
|     | Committee decided to defer case for four weeks for comments of Chemical Division.                                                                                  |                                                   |                                            |                           |

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| Case No.:55/45/82-ALC4/2007                                                                                                                                                                                                            | Party Name:CIPLA LIMITED            | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved                     |                                              |
| HQ File :<br>01/82/050/00518/AM08/                                                                                                                                                                                                     | RLA File :<br>03/94/040/01098/AM08/ | Lic.No/Date:0310459956<br>04.02.2008       |                                          |                                              |
| Decision : Committee considered case as per agenda for ratification of norms for export product Tenofovir Disoproxil Fumarate Tablets 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 23.10.2007 decided to ratify norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:- |                                     |                                            |                                          |                                              |
| Export product                                                                                                                                                                                                                         | Export Qty.                         | Sl.No.                                     | Import items                             | Qty. allowed per unit of export product      |
| Tenofovir Disoproxil Fumerate Tablets 300mg/Tenvir Tablets                                                                                                                                                                             | 2349180Nos.                         | 1.                                         | 9-[2-(Phosphonyl Methoxy)Propyl] Adenine | 0.8026kg/kg of Tenofovir Disoproxil Fumerate |

|  |                                                                                                                |  |    |                                     |                                                            |
|--|----------------------------------------------------------------------------------------------------------------|--|----|-------------------------------------|------------------------------------------------------------|
|  | Total weight of<br>Tenofovir<br>Disoproxil<br>Fumerate—<br>704.754kgs.                                         |  | 2. | Chloromethyl<br>Isopropyl carbonate | 2.08670kg/<br>kg of<br>Tenofovir<br>Disoproxil<br>Fumerate |
|  | RA concerned may take further necessary action under para 4.7 of HBP as per above decision of Norms committee. |  |    |                                     |                                                            |

|         |                                                                                                                                                                                                                                              |                                     |                                                |                                  |
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| 12<br>6 | Case No.:34/45/82-<br>ALC4/2007                                                                                                                                                                                                              | Party Name:HILDOSE                  | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Cas<br>e Deferred         |
|         | HQ File :<br>01/82/050/00497/AM08/                                                                                                                                                                                                           | RLA File :<br>03/94/040/01100/AM08/ | Lic.No/Date:03104602<br>75<br>06.02.2008       | Defer<br>Date:<br>08.04.200<br>8 |
|         | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Dichloro Meta Xylenol under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                     |                                                |                                  |

|         |                                                                                                                                                                                                                                       |                                                    |                                                |                                  |
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| 12<br>7 | Case No.:36/45/82-<br>ALC4/2007                                                                                                                                                                                                       | Party Name:MANGALAM<br>DRUGS & ORGANICS<br>LIMITED | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Cas<br>e Deferred         |
|         | HQ File :<br>01/82/050/00499/AM08/                                                                                                                                                                                                    | RLA File :<br>03/95/040/01065/AM08/                | Lic.No/Date:03104602<br>71<br>06.02.2008       | Defer<br>Date:<br>22.04.200<br>8 |
|         | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Chloroquine Phosphate under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                                    |                                                |                                  |

|         |                                                                                                                                             |                                     |                                                |                                  |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------------|----------------------------------|
| 12<br>8 | Case No.:39/45/82-<br>ALC4/2007                                                                                                             | Party Name:KORES (INDIA)<br>LTD.    | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Cas<br>e Deferred         |
|         | HQ File :<br>01/82/050/00502/AM08/                                                                                                          | RLA File :<br>03/94/040/01071/AM08/ | Lic.No/Date:03104602<br>46<br>06.02.2008       | Defer<br>Date:<br>22.04.200<br>8 |
|         | Decision : Committee considered case as per agenda for ratification of norms for export product 2(7 Theophylline Methyl)1,3 Dioxolane under |                                     |                                                |                                  |

para 4.7 of HBP.

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

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|------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| Case No.:121/42/82-ALC4/2007       | Party Name:BODAL CHEMICALS LTD      | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
| HQ File :<br>01/82/050/00457/AM08/ | RLA File :<br>08/24/040/00251/AM08/ | Lic.No/Date:0810069963<br>06.02.2008       | Defer Date:<br>08.04.2008 |

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

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

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|------------------------------------|--------------------------------------|--------------------------------------------|----------------------|
| Case No.:35/45/82-ALC4/2007        | Party Name:IPCA LABORATORIES LIMITED | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
| HQ File :<br>01/82/050/00498/AM08/ | RLA File :<br>03/94/040/01104/AM08/  | Lic.No/Date:0310460532<br>11.02.2008       |                      |

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

Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/259/2006-PI-III dated 11.03.2008 decided to ratify norms on repeat basis under para 4.7 of HBP as per details below or as applied by firm whichever is lower:-

| Export product   | Export Qty. | Sl.No. | Import items        | Qty. allowed per unit of export product |
|------------------|-------------|--------|---------------------|-----------------------------------------|
| Morantel Citrate | 1kg.        | 1.     | 3-Methyl Thiophene  | 0.330kg/kg                              |
|                  |             | 2.     | Acetonitrile        | 0.180kg/kg                              |
|                  |             | 3.     | Dimethyl Formamide  | 0.270kg/kg                              |
|                  |             | 4.     | Citric Acid         | 0.640kg/kg                              |
|                  |             | 5.     | Ethylene dichloride | 0.165kg/kg                              |
|                  |             | 6.     | Iso Propyl Alcohol  | 0.225kg/kg                              |

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

|         |                                                                                                                                                                                                                                    |                                     |                                            |                           |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 13<br>1 | Case No.:37/45/82-ALC4/2007                                                                                                                                                                                                        | Party Name:PRIVI ORGANICS LTD       | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|         | HQ File :<br>01/82/050/00500/AM08/                                                                                                                                                                                                 | RLA File :<br>03/95/040/01082/AM08/ | Lic.No/Date:0310460511<br>11.02.2008       | Defer Date:<br>08.04.2008 |
|         | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Amber Fleur under para 4.7 of HBP.</p> <p>Committee decided to defer case for four weeks for comments of Chemical Division.</p> |                                     |                                            |                           |

| 13<br>2                                                                                                              | Case No.:42/45/82-ALC4/2007                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Party Name:KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved                    |                |             |        |              |                                         |                                                                                                                      |        |    |                           |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------------------|-----------------------------------------|----------------|-------------|--------|--------------|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------|----|---------------------------|
|                                                                                                                      | HQ File :<br>01/82/050/00505/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | RLA File :<br>07/24/040/00745/AM08/                      | Lic.No/Date:0710055784<br>11.02.2008       |                                         |                |             |        |              |                                         |                                                                                                                      |        |    |                           |
|                                                                                                                      | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Cefuroxime 750mg Inj. USP under para 4.7 of HBP.</p> <p>Committee in light of written comments forwarded by PI Division vide their U.O. No.35011/266/2006-PI-III dated 11.03.2008 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>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td>Cefuroxime 750mg Injection USP, each vial containing Cefuroxime Sodium USP equivalent to Cefuroxime 750mg, 10ml vial</td><td>1 Vial</td><td>1.</td><td>Cefuroxime Sodium Sterile</td><td>817.50mg/vial</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                                          |                                            |                                         | Export product | Export Qty. | Sl.No. | Import items | Qty. allowed per unit of export product | Cefuroxime 750mg Injection USP, each vial containing Cefuroxime Sodium USP equivalent to Cefuroxime 750mg, 10ml vial | 1 Vial | 1. | Cefuroxime Sodium Sterile |
| Export product                                                                                                       | Export Qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Sl.No.                                                   | Import items                               | Qty. allowed per unit of export product |                |             |        |              |                                         |                                                                                                                      |        |    |                           |
| Cefuroxime 750mg Injection USP, each vial containing Cefuroxime Sodium USP equivalent to Cefuroxime 750mg, 10ml vial | 1 Vial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1.                                                       | Cefuroxime Sodium Sterile                  | 817.50mg/vial                           |                |             |        |              |                                         |                                                                                                                      |        |    |                           |

|         |                             |                                    |                              |             |
|---------|-----------------------------|------------------------------------|------------------------------|-------------|
| 13<br>3 | Case No.:43/45/82-ALC4/2007 | Party Name:KARNATAKA ANTIBIOTICS & | Meet No/Date:45/82-ALC4/2007 | Status:Case |
|---------|-----------------------------|------------------------------------|------------------------------|-------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     | PHARMACEUTICALS LTD.,                    | 11.03.2008              | Approved                                |                |             |        |              |                                         |                                   |          |    |                         |             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|-------------------------|-----------------------------------------|----------------|-------------|--------|--------------|-----------------------------------------|-----------------------------------|----------|----|-------------------------|-------------|
| HQ File :<br>01/82/050/00506/AM08/                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | RLA File :<br>07/24/040/00746/AM08/ | Lic.No/Date:07100557<br>83<br>11.02.2008 |                         |                                         |                |             |        |              |                                         |                                   |          |    |                         |             |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Kanamycin Acid Sulphate for Inj BP 1gm under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 2/82 meeting held on 16.05.2005 vide Case No.42/28/82 in the case of M/S Brawn Laboratories Ltd 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>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td>Kanamycin acid sulphate Injection</td><td>1gm vial</td><td>1.</td><td>Kanamycin acid sulphate</td><td>1.39gm/vial</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                     |                                          |                         |                                         | Export product | Export Qty. | Sl.No. | Import items | Qty. allowed per unit of export product | Kanamycin acid sulphate Injection | 1gm vial | 1. | Kanamycin acid sulphate | 1.39gm/vial |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Export Qty.                         | Sl.No.                                   | Import items            | Qty. allowed per unit of export product |                |             |        |              |                                         |                                   |          |    |                         |             |
| Kanamycin acid sulphate Injection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 1gm vial                            | 1.                                       | Kanamycin acid sulphate | 1.39gm/vial                             |                |             |        |              |                                         |                                   |          |    |                         |             |

| 134                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Case No.:67/45/82-<br>ALC4/2007    | Party Name:SHREYA LIFE<br>SCIENCES PRIVATE LIMITED | Meet No/Date:45/82-<br>ALC4/2007<br>11.03.2008 | Status:Case<br>Approved                 |                |             |        |              |                                         |  |  |  |  |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------------------------------------|------------------------------------------------|-----------------------------------------|----------------|-------------|--------|--------------|-----------------------------------------|--|--|--|--|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | HQ File :<br>01/82/050/00530/AM08/ | RLA File :<br>03/95/040/01035/AM08/                | Lic.No/Date:03104605<br>08<br>11.02.2008       |                                         |                |             |        |              |                                         |  |  |  |  |  |
| <p>Decision : Committee considered case as per agenda for ratification of norms for export product Prednisolone Sodium Phosphate Injection 30mg/ml, 1ml under para 4.7 of HBP.</p> <p>Committee in light of its earlier decision taken in its 46/83 meeting held on 28.02.2007 vide case No.45/23/83 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>Export product</th><th>Export Qty.</th><th>Sl.No.</th><th>Import items</th><th>Qty. allowed per unit of export product</th></tr> </thead> <tbody> <tr> <td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table> |                                    |                                                    |                                                |                                         | Export product | Export Qty. | Sl.No. | Import items | Qty. allowed per unit of export product |  |  |  |  |  |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Export Qty.                        | Sl.No.                                             | Import items                                   | Qty. allowed per unit of export product |                |             |        |              |                                         |  |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                    |                                                    |                                                |                                         |                |             |        |              |                                         |  |  |  |  |  |

|  |                                                                             |       |    |                               |               |
|--|-----------------------------------------------------------------------------|-------|----|-------------------------------|---------------|
|  | Prednisolone Sodium Phosphate Injection 30mg/ml, 1ml.                       | 1vial | 1. | Prednisolone Sodium Phosphate | 42.628mg/vial |
|  | RA concerned may take further necessary action as per above decision of NC. |       |    |                               |               |

|     |                                                                                                                                                                                                                                                |                                         |                                            |                           |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|---------------------------|
| 135 | Case No.:29/45/82-ALC4/2007                                                                                                                                                                                                                    | Party Name:CENTAUR CHEMICALS PVT. LTD., | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00492/AM08/                                                                                                                                                                                                             | RLA File :<br>03/94/040/01129/AM08/     | Lic.No/Date:0310460671<br>12.02.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Rivastigmine Hydrogen Tartrate under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                         |                                            |                           |

|     |                                                                                                                                                                                                                               |                                     |                                            |                           |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------------|---------------------------|
| 136 | Case No.:78/45/82-ALC4/2007                                                                                                                                                                                                   | Party Name:BAL PHARMA LTD           | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Deferred      |
|     | HQ File :<br>01/82/050/00541/AM08/                                                                                                                                                                                            | RLA File :<br>07/24/040/00742/AM08/ | Lic.No/Date:0710055799<br>12.02.2008       | Defer Date:<br>22.04.2008 |
|     | <p>Decision : Committee considered case as per agenda for ratification of norms for export product Amiloride Hcl under para 4.7 of HBP.</p> <p>Committee decided to defer case for six weeks for comments of PI Division.</p> |                                     |                                            |                           |

|     |                                    |                                     |                                            |                      |
|-----|------------------------------------|-------------------------------------|--------------------------------------------|----------------------|
| 137 | Case No.:81/45/82-ALC4/2007        | Party Name:VASUDHA PHARMA CHEM LTD  | Meet No/Date:45/82-ALC4/2007<br>11.03.2008 | Status:Case Approved |
|     | HQ File :<br>01/82/050/00544/AM08/ | RLA File :<br>09/24/040/00497/AM08/ | Lic.No/Date:0910032935<br>12.02.2008       |                      |
|     |                                    |                                     |                                            |                      |

Decision : Committee considered case as per agenda for ratification of norms for export product Tert-N-Boc-4-Piperidone (OR) N-BOC-4-Piperidone under para 4.7 of HBP.

Committee in light of its earlier decision taken in its 7/83 meeting held on 17.05.2006 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. | Sl.N o. | Import items               | Qty. allowed per unit of export product |
|-----------------------------------------------------|-------------|---------|----------------------------|-----------------------------------------|
| Tertiary-N-BOC-4-Piperidone (OR) N-Boc-4-Piperidone | 1kg.        | 1.      | Methanol                   | 5.95kg/kg                               |
|                                                     |             | 2.      | Methyl Acrylate            | 2.74kg/kg                               |
|                                                     |             | 3.      | Sodium Methoxide           | 1.04kg/kg                               |
|                                                     |             | 4.      | Ethyl Chloro Formate       | 1.73kg/kg                               |
|                                                     |             | 5.      | Trimethyl Ortho Formate    | 0.64kg/kg                               |
|                                                     |             | 6.      | Phosphoric Acid            | 0.98kg/kg                               |
|                                                     |             | 7.      | Iso Propyl Alcohol         | 0.39kg/kg                               |
|                                                     |             | 8.      | Di Tert Butyl di carbonate | 1.08kg/kg                               |

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

