**12. Preliminary List of Products Permitted by DCG(I) and considered as Reference Product For BA/BE Studies (2014-2011)**

| YEAR 2014 | | | | |
|---|---|---|---|---|
| 1 | Alogliptin Tablet | Film Coated Tablet | 6.25 mg/ 12.5 mg/ 25 mg | M/s. Takeda Pharmaceutical India Pvt. Ltd |
| 2 | Dimethyl Fumarate | Delayed Release Capsule | 120 mg/240 mg | M/s. Biogen Idec Biotech India Pvt Ltd. |
| | | | | M/s Intas Pharma |
| 3 | Roflumilast | Tablet | 500 mcg | M/s. Takeda Pharmaceutical India Pvt. Ltd |
| | | | | M/s Intas Pharma |
| | | | | M/s Cipla Ltd. |
| 4 | Regorafenib | Tablet | 40mg | M/s. Bayer Pharmaceuticals Pvt. Ltd. |
| 5 | Tulobuterol | Transdermal patch | 0.5 mg/1.0 mg/2.0 mg | M/s. Sparsh Pharmaceuticals Ltd. |
| 6 | Axitinib | Tablet | 1mg/5mg | Pfizer products India Pvt ltd. |
| 7 | Canagliflozin | Tablet | 100mg/300mg | M/s Johnson & Johnson |
| | | | | M/s MSN Laboratories |
| 8 | Afatinib | Tablet | 20 mg/30 mg/40 mg | M/s BoehingerIngelheim |

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| | | - | 50 mg | M/s BoehingerIngelheim |
| 9 | Nevirapine | ER Tablet | 400 mg | M/s Cipla Ltd. |
| | | | | M/s Emcure Pharmaceuticals limited |
| 10 | Indacaterol | Capsule | 150mcg/300mcg | M/s Cipla Ltd. |
| **YEAR 2013** | | | | |
| 1 | Ruxolitinib | Tablet | 5mg/10 mg/15mg/20 mg | M/s Novartis Healthcare Pvt. Ltd. |
| 2 | Cefalonium | Suspension | 250 mg/3G | M/s Intervet India Pvt. Ltd. |
| 3 | GarenoxacinMesylate | Film Coated Tablet | 250 mg/3G | M/s Glenmark Generics Ltd. |
| 4 | Sarogliazar | Tablet | 2 mg/ 4 mg | M/s Cadila Healthcare Limited |
| **YEAR 2012** | | | | |
| 1 | Agomelatine | Tablet | 25 mg | M/s Precise ChemipharmaPvt. Ltd. |
| | | | | M/s Sun Pharmaceuticals Industries Ltd. |
| | | | | M/s MSN Laboratories Ltd |
| 2 | Tolvaptan | Tablets | 15 mg/30 mg | M/s. MSN Laboratories Ltd. |
| | | | | M/s.Cadila |

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| | | | | Healthcare Ltd |
| | | | | M/s. Huve Pharma |
| 3 | ColesevelamHCl | Tablets & Sachets for oral suspension | 625 mg tablet, Sachet..3.75 gm/ 1.875 gm | M/s Ind-Swift Labs Ltd. |
| 4 | Apixaban | Film Coated Tablet | 2.5 mg | M/s Bristol-Myers Squibb India Pvt. Ltd. |
| | | - | 2.5 mg/5 mg | M/s. Pfizer |
| 5 | Seratrodast | Tablet | 40 mg/80 mg | M/s Zuventus Healthcare Ltd. |
| 6 | Choline Fenofibrate | DR capsules | 45 mg/135 mg | M/s Cadila Healthcare Limited |
| | | | | M/s Intas Pharmaceuticals Ltd. |
| | | | | M/s Lupin Ltd. |
| | | | | |
| 7 | Vemurafenib | Film Coated Tablet | 240 mg | M/s Roche Scientific Company Pvt. Ltd. |
| 8 | Almotriptan | Film Coated Tablets | 6.25 mg/12.5 mg | M/s MSN Laboratories Ltd. |
| **YEAR 2011** | | | | |
| 1 | Oxaceprol | Capsule | 200 mg | M/s Lupin Limited |
| 2 | Eslicarbazepine Acetate | Tablet | 200 mg/400 mg/600 mg/800 mg | M/s Torrent Pharmaceuticals Ltd. |
| | | | | M/s. Akums Drugs & Pharmaceuticals |

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| | | | | Ltd. |
| | | | | M/s. Psyco Remedies |
| | | | | M/s. Raven Bhel Healthcare Pvt .ltd. |
| | | | | M/s Sun Pharmaceuticals Industries Ltd. |
| 3 | Iloperidone | Tablet | 1 mg/2 mg/4 mg/ 6 mg/8 mg/10 mg/12 mg | M/s Sun Pharmaceuticals Industries Ltd. |
| | | | | M/s. MSN Laboratories |
| | | | | M/s. Cadila Healthcare Ltd |
| | | | | M/s. Naprod life science Pvt.ltd. |
| | | | | M/s. Hetero Labs Ltd. |
| | | | | M/s. Lupin Ltd. |
| | | | | M/s.Cadila Healthcare |
| 4 | Silodosin | Tablet | 2 mg/4 mg/8 mg | M/s Ajanta Pharma Ltd. |
| | | Capsule | 4 mg/8 mg | M/s MSN Laboratories |
| 5 | Abiraterone Acetate | Tablet | 250 mg | M/s Johnson & Johnson Ltd. |
| | | | 20 mg | M/s.Cipla Ltd. |

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| | | | 250 mg | M/s. BDR Pharmaceuticals Pvt Ltd |
| | | | 500 mg | Dr. Reddy's Laboratories |
| 6 | Revaprazan | Tablet | 100 mg/200 mg | M/s Cadila Healthcare Ltd. |
| 7 | Acrivastine | Capsule | 8 mg | M/s Cadila Healthcare Ltd. |
| 8 | Rivaroxaban | Tablet | 10 mg | M/s Emcure Pharmaceuticals Ltd. |
| | | | 15 mg/20 mg | M/s Torrent Pharmaceuticals Limited. |
| 9 | Maraviroc | Tablet | 150 mg/300 mg | M/s GSK Pharmaceuticals Ltd. |
| | | | - | M/s. Hetero Labs Ltd., |
| 10 | EletriptanHydrobromide | Tablet | 20 mg/40 mg | M/s Intas Pharmaceuticals Ltd. |
| 11 | Udenafil | Tablet | 100 mg/200 mg | M/s Cadila Healthcare Ltd. |
| 12 | Crizotinib | Hard gelatin capsule | 200 mg/250 mg | M/s Pfizer pharma |
| 13 | Diclofenac Colestyramine | Capsule | 75 mg | M/s Novartis India Ltd. |
| 1 | TiaprideHCl | Tablet | 25 mg/50 mg/100 mg | M/s Intas Pharmaceuticals Ltd. |

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| | | | | M/s Macleods Pharmaceutical Ltd. |
| | | | | M/s HeteroLabs Ltd. |
| | | | | M/s Precise Biopharma Ltd. |
| | | | | M/s.Inventia Healthcare Pvt Ltd. |
| | | | | M/s. MSN Laboratories Ltd |
| | | | | M/s.Synokem Pharmaceuticals Ltd |
| 15 | TapentadolHCl | Tablet | 50 mg/75 mg/100 mg | M/s. Biodeal Pharmaceuticals Pvt. Ltd |
| | | | | M/s. Ind-Swift Ltd |
| | | | | M/s. Acme Formulations Pvt Ltd |
| | | | | M/s. Theon Pharmaceuticals Ltd |
| | | | | M/s. Cadila Healthcare Ltd |
| | | | | M/s. Akums Drugs &Pharmaceuticasl ltd |
| | | | | M/s. Gena Pharmaceuticals Ltd |
| 16 | Ilaprazole | Tablet | 5 mg/10 mg | M/s Lupin Limited |
| | | | | M/s Ajanta Pharma |

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| | | | | Ltd. |
| | | | | M/s. Precise Chemipharpma Pvt Ltd |
| 17 | Asenapine Malate | Sublingual Tablet | 5mg/ 10 mg | M/s Sun Pharmaceuticals Industries Ltd. |
| | | | | M/s. Intas Pharmaceuticals |
| | | | | M/s. MSN Lab. Ltd. |
| | | | | M/s. Precise Chemipharma |
| | | | | M/s.Cadila Healthcare Limited |
| | | | | M/s.Alkem Laboratories Ltd. |