

F.No. 12-32/2019-DC(Pt-Misc-SND)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

FDA Bhawan, New Delhi

Dated: 22/11/2020

Notice

Sub: List of Reference Products for conduct of BE Study- regarding.

Drugs & Cosmetics Rules, 1945 have been amended vide G.S.R. 327(E) dated 03.04.2017, providing that the applicant shall submit the result of bioequivalence study along with the application for grant of a licence of oral dosage form of drugs specified under category II and IV of the biopharmaceutical classification system.

In order to have proper understanding about the BCS classification, requirement of BE study and reference product to be used in such studies, earlier CDSCO had issued guidelines vide letter dated 13.10.2017. Further the matter was also deliberated in meeting held on 02.06.2018 with State Drugs Controllers and various experts with CDSCO officers.

Further, 12 workshops for providing training on conduct of BA/BE studies for BCS Class II & BCS Class IV drugs were conducted in different parts of the country in collaboration with the State Drugs Controllers & the Indian Drugs/Pharmaceutical Association Forum between 03.08.2019 to 21.09.2019.

In order to streamline further, in respect of conduct of BE study, list of a number of drugs falling under BCS II & IV along with list of their reference products have been prepared taking information from various sources. The list will be expanded by including more drugs based on further available information in this regard.

It is expected that reference product for BA/BE studies should normally be the innovator's product, to which all generic versions should be shown to be bioequivalent. If, in case, innovator product is not available, applicant may use Indian product approved by CDSCO as Reference product.

A copy of the list of drug formulations along-with list of products that could be used as reference product in BE study is enclosed.

Discrepancies in the list, if any, may please be forwarded to this office for updating the list.



(Dr. V.G. Somani)
Drugs Controller General (India)

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|---------------|----------------------|--|--|
| 1 | Aceclofenac | BCS CLASS-II (Two) | Aceclofenac Tablets 100 mg | 1. Aceclofenac Tablet 100 mg PRESERVEX® (M/s. Almirall Limited, (UK)) 2. M/s Abbot 3. M/s Intas Pharma |
| 2 | Acetazolamide | BCS CLASS-IV (Four) | Acetazolamide Tablets 250 mg | 1. Acetazolamide Tablets 250 mg (M/s Taro Pharma Industries Ltd. US) 2. M/s. Intas Pharma |
| 3 | Acitretin | BCS CLASS-II (Two) | Acitretin Capsules 10/25 mg | 1. Acitretin Capsules 10 mg SORIATANE® (M/s Stiefel Laboratories Inc.) 2. Acitretin Capsules 10/25mg (M/s Glenmark pharma ltd.) |
| 4 | Acyclovir | BCS CLASS-IV (Four) | Acyclovir Tablets 200 mg | 1. Acyclovir Tablets 200mg ACHIPHERPIN® (M/s Agio) 2. M/s ZEE lab |
| 5 | Albendazole | BCS CLASS-II (Two) | Albendazole Tablets 400 mg | Albendazole Tablets 400 mg ZENTEL® (M/s.GSK Pharma) |
| 6 | Allopurinol | BCS CLASS-IV (Four) | Allopurinol Tablets 100 mg | 1. Allopurinol Tablets 100 mg (ZYLOPRIM®) (M/s. Casper Pharma Llc) 2. Allopurinol Tablets 100 mg ZYLORIC® (M/s GSK Pharma) |
| 7 | Altretamine | BCS CLASS-II (Two) | Altretamine Capsules 50 mg | Altretamine Capsules 50 mg CANTRET® (M/s Natco Pharma) |
| 8 | Amiodarone | BCS CLASS-II (Two) | Amiodarone HCl Tablets 100/200 mg | 1. Amiodarone Hydrochloride Tablets 100/200 mg CORDARONE® (M/s Wyeth Pharmaceuticals Llc) 2. M/s Torrent Pharma 3. M/s Lupin Pharma |
| 9 | Amisulpride | BCS CLASS-IV (Four) | Amisulpride Tablets 50/100/200/300/400 mg | 1. Amisulpride Tablets 50/100 mg SOLIAN® (M/s Sanofi Aventis) 2. M/s Intas Pharma 3. M/s Emcure Pharma 4. M/s Torrent Pharma |
| 10 | Amoxicillin | BCS CLASS-IV (Four) | Amoxicillin Capsules 250/500mg | 1. Amoxicillin Capsules 250/500mg MOX® (M/s. Sun Pharma) 2. M/s Cipla Ltd. |
| 11 | Aprepitant | BCS CLASS-II (Two) | Aprepitant Capsules 80/125 mg | 1. Aprepitant Capsules 125 mg EMEND® (M/s Merck and Co Inc) 2. M/s Sun Pharma |
| 12 | Aripiprazole | BCS CLASS-II (Two) | Aripiprazole Tablets 10/15/20/30 mg | Aripiprazole Tablets 10/15/20/30 mg ARIP-MT® (M/s Torrent Pharma) |
| 13 | Armodafinil | BCS CLASS-II (Two) | Armodafinil Tablets 50/150/250 mg | Armodafinil Tablets 50/150 mg WAKLERT® (M/s. Sun Pharma) |
| 14 | Artesunate | BCS CLASS-II (Two) | Artesunate Tablets 50mg | 1. Artesunate Tablets 50 mg A-KEFTAL® (M/s Healthcare) 2. M/s. IPCA |
| 15 | Atazanavir | BCS CLASS-II (Two) | Atazanavir Capsules 100/150/200/300 mg | 1. Atazanavir Capsules 100/150/200/300mg REYATAZ® (M/s Bristol Myers Squibb Co, USA) 2. M/s Emcure Pharma |
| 16 | Atorvastatin | BCS CLASS-II (Two) | Atorvastatin calcium Tablets 5/10/20/40/80 | 1. Atorvastatin calcium Tablets 80 mg CADUET® (M/s Pfizer) 2. M/s Dr. Reddy's Lab 3. M/s Sun Pharma 4. M/s Cadila Healthcare Ltd |
| 17 | Azathioprine | BCS CLASS- IV (Four) | Azathioprine Tablets 50 mg | 1. Azathioprine Tablets 50mg AZASAN® (M/s AAIPHARMA LLC) 2. M/s Sebela Ireland Ltd 3. M/s Sun Pharma 4. M/s Alkem Lab |
| 18 | Azithromycin | BCS CLASS-II (Two) | Azithromycin Tablets 250/500 mg | 1. Azithromycin Tablets 250/500 mg ZITHROMAX® (M/s Pfizer Inc) 2. Azithromycin Tablet 250/500 mg ZITHROLIDE® (M/s Pharmaniaga Manufacturing Berhad) 3. M/s Cipla Ltd |
| 19 | Bezafibrate | BCS CLASS-II (Two) | Bezafibrate Tablets 200 mg | 1. Bezafibrate Tablets 200 mg BIZALIP® (M/s NPIL (Actis)) 2. M/s Abbot |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|-----------------------|---------------------|---|--|
| 20 | Bicalutamide | BCS CLASS-II (Two) | Bicalutamide Tablets 50/150 mg | 1. Bicalutamide Tablets 50 mg CASODEX® (M/s ANI Pharma Inc, USA) 2. Bicalutamide Tablets 150 mg CASODEX® (M/s AstraZeneca) |
| 21 | Bisacodyl | BCS CLASS-II (Two) | Bisacodyl Tablets 5 mg | 1. Bisacodyl Tablets 5 mg BIDLAX-5® (M/s GSK Pharma) 2. M/s Sanofi Aventis 3. M/s Cipla Ltd |
| 22 | Cabergoline | BCS CLASS-II (Two) | Cabergoline Tablets 0.5/1 mg | 1. Cabergoline Tablets 0.5 mg (M/s PAR Pharma Inc) 2. M/s Sun Pharma 3. M/s Svizera 4. M/s Sereum |
| 23 | Calcitriol | BCS CLASS-II (Two) | Calcitriol Capsules 0.5/0.25 mcg | 1. Calcitriol Capsules 0.25/0.5 mcg ROCALTROL® (M/s Validus Pharmaceuticals Llc) 2. M/s Macleods Pharma |
| 24 | Candesartan cilexetil | BCS CLASS-II (Two) | Candesartan cilexetil Tablets 4/8/16 mg | 1. Candesartan Cilexetil Tablets 4/8/16 mg ATACAND® (M/s ANI Pharmaceuticals Inc) 2. M/s Bal Pharma |
| 25 | Carbamazepine | BCS CLASS- II (Two) | Carbamazepine Tablets 100/200/300 mg | 1. M/s Shire Develeppment LLC 2. M/s Zydus cadila 3. M/s Torrent lab 4. M/s Sun laboratories |
| 26 | Carvedilol | BCS CLASS-II (Two) | Carvedilol Tablet 3.125/6.25/12.5/25 mg | 1. Carvedilol Tablets 3.125/6.25/12.5/25 mg COREG® (M/s Smithkline Beecham Ltd) 2. Ms Intas Pharma 3. M/s Sun Pharma |
| 27 | Cefixime | BCS CLASS-IV (Four) | Cefexime Capsules/Tablets 100/200/400 mg | 1. Cefexime Capsules 100/200/400 mg RAXIM® (M/s Zydus Cadilla) 2. M/s Lupin Pharma 3. M/s Novartis Healthcare Ltd. 4. M/s Macleods Pharma |
| 28 | Cefpodoxime proxetil | BCS CLASS-IV (Four) | Cefpodoxime proxetil Tablets 100/200 mg | 1. Cefpodoxime proxetil Tablets 100/200 mg (M/s Sandoz Inc 2. M/s Aurobindo Pharma Ltd |
| 29 | Ceftibuten | BCS CLASS-IV (Four) | Ceftibuten Capsules 200/400 mg | Ceftibuten Capsules 400mg (M/s Fulford India) |
| 30 | Cefuroxime axetil | BCS CLASS-IV (Four) | Cefuroxime axetil Tablets 125/250/500 mg | 1. Cefuroxime axetil 125/250/500mg tablets (M/s Lupin Ltd) 2. M/s GlaxosmithKline Pharma |
| 31 | Celecoxib | BCS CLASS-II (Two) | Celecoxib Capsules 100/200 mg | 1. Celecoxib Capsules 50/100/200/400 mg CELEBREX® M/s GD Searle Llc. 2. M/s Sun Pharma, 3. M/s Cadila, 4. M/s Dr.Reddy's Lab 5.M/s Lupin Lab |
| 32 | Cephalexin | BCS CLASS-IV (Four) | Cephalexin Capsules 250/500mg and Cephalexin Tablets 1000mg | 1. Cephalexin 250/500 mg Capsules, KEFLEX® (M/s Pragma Pharma Llc) 2. Cephalexin Tablets 500 mg (Teva Pharma Inc) 3. M/s Sun Pharma |
| 33 | Cilostazol | BCS CLASS-II (Two) | Cilostazol Tablets 50/100 mg | 1. Cilostazol Tablet 50/100 mg M/s Teva Pharma USA Inc 2. M/s Glenmark Pharma (M/s IPCA Lab) 3. M/s Cipla Ltd 4. M/s Sandoz |
| 34 | Cinacalcet | BCS CLASS-IV (Four) | Cinacalcet (as HCl) Tablets 30/60/90 mg | 1. Cinacalcet 30/60/90 mg Tablets SENSIPAR® (M/s Amgen Inc) 2.M/s Biocon 3.M/s Intas Pharma |
| 35 | Cisapride | BCS CLASS-II (Two) | Cisapride Tablets 5/10/20 mg | Cisapride Monohydrate Tablets 10/20 mg , PROPULSID® (M/s. Janssen Pharma Inc) |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|-----------------------|---------------------|--|---|
| 36 | Clarithromycin | BCS CLASS-II (Two) | Clarithromycin Tablets 250/500 mg | 1. Clarithromycin Tablets 250/500 mg (M/s Aurobindo Pharma Ltd) 2. M/s Emcure 3. M/s GSK 4. M/s Abbott |
| 37 | Clofazimine | BCS Class IV (Four) | Clofazimine Capsule 50/100 mg | 1. Clofazimine Capsules 50/100 mg (M/s Novartis Pharmaceuticals corp) 2. M/s AstraZeneca |
| 38 | Clofibrate | BCS CLASS-II (Two) | Clofibrate Capsules 250 mg | Clofibrate Capsules 500 mg ATROMID-S® (M/s. Wyeth- Ayerst Laboratories) |
| 39 | Clopidogrel bisulfate | BCS CLASS-II (Two) | Clopidogrel bisulphate Tablets 75/150/300 mg | 1. Clopidogrel bisulphate Tablets 75/300 mg PLAVIX® (M/s. Sanofi Aventis US Llc) 2. M/s Sun Pharma 3. M/s Abbott |
| 40 | Clozapine | BCS CLASS-II (Two) | Clozapine Tablets 25/100/200 mg | 1. Clozapine Tablets 25/100/200 mg CLOZARIL® (M/s. Heritage Life Sci. barbados Inc) 2. M/s Intas Pharma 3. M/s Sun Pharma 4. M/s Sandoz Pvt Ltd. |
| 41 | Danazol | BCS CLASS-II (Two) | Danazol Capsules 100/200 mg | 1. Danazol Capsule 100/200 mg (M/s Barr Lab Inc) 2. M/s Cipla Ltd 3. M/s Sun Pharma |
| 42 | Dapsone | BCS CLASS- II (Two) | Dapsone Tablets 25/50/100 mg | 1. Dapsone Tablets 25/100 mg (M/s Virtus) 2. M/s GSK Pharma Ltd. |
| 43 | Darunavir | BCS CLASS-II (Two) | Darunavir Tablets 300/600/800 mg | 1. Darunavir Tablets 600/800 mg PREZISTA® (M/s Janssen) 2. M/s Cipla Ltd 3. M/s Emcure Lab |
| 44 | Dasatinib | BCS CLASS-II (Two) | Dasatinib Tablets 20/50/70/100 mg | 1. Dasatinib Tablet 20/50/70mg SPRYCEL® (M/s.Bristol Myers Squibb co.) 2. M/s. Natco Pharma Ltd |
| 45 | Desloratadine | BCS CLASS-II (Two) | Desloratadine Tablets 5 mg | 1. Desloratadine Tablets 5 mg CLARINEX® (M/s Merck Sharp and Dohme Corp) 2. M/s SUN Pharma 3. M/s Ajanta |
| 46 | Dexamethasone | BCS CLASS-II (Two) | Dexamethasone Tablets 4/8 mg | 1. Dexamethasone Tablets 4/8 mg (M/s Sun Pharma) 2. M/s Dr. Reddy's Lab 3. M/s Wockhardt Ltd |
| 47 | Diclofenac | BCS CLASS-II (Two) | Diclofenac Potassium Tablets 25/50 mg Diclofenac Sodium Tablets 25/50/75/100/150 mg | 1. Diclofenac Sodium Tablet 50/75mg (M/s Mylan Pharms INC) 2. Diclofenac Sodium Tablet 25/50 mg (M/s Unique Pharma Labs) 3. Diclofenac Sodium Tablet 100 mg (M/s Dexcel) 4. Diclofenac Potassium Tablets 50 mg (M/s Teva) 5. M/s Novartis |
| 48 | Dipyridamole | BCS CLASS-II (Two) | Dipyridamole Tablets 12.5 mg | 1. Dipyridamole Tablets 12.5 mg (M/s Torrent Pharma) 2. M/s Intas Pharma 3. M/s Zydus Healthcare 4. M/s Sun Pharma |
| 49 | Dronedarone | BCS CLASS-II (Two) | Dronedarone Tablets 400 mg | Dronedarone Tablet 400 mg MULTAQ® (M/s. Sanofi Aventis US Llc) |
| 50 | Ebastine | BCS CLASS-II (Two) | Ebastine Tablets 10mg | 1. Ebastine Tablets 10mg (M/s Abbott Pharma) 2. M/s Micro Labs |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|-------------------------|---------------------|--|---|
| 51 | Efavirenz | BCS CLASS-II (Two) | Efavirenz Capsules 50/100/200 mg | 1. Efavirenz Capsules 50 mg SUSTIVA® (M/s. Bristol Myers Squibb Co.) 2. M/s Cipla Ltd. 3. M/s Sun Pharma |
| | | | Efavirenz Tablet 600 mg | 1. Efavirenz Tablets 600 mg SUSTIVA®, (M/s Bristol Myers Squibb Co.) 2. M/s Mylan Lab 3. M/s Cipla Ltd |
| 52 | Entacapone | BCS CLASS-II (Two) | Entacapone Tablets 200 mg | 1. Entacapone Tablets 200 mg COMTAN® 200 mg(M/s Orion Pharma) 2. M/s Intas Pharma 3. M/s Sun Pharma |
| 53 | Erlotinib hydrochloride | BCS CLASS-II (Two) | Erlotinib hydrochloride Tablet 25/100/150 mg | 1. Erlotinib Hydrochloride Tablets, TARCEVA® 25 mg (M/s Osi Pharma Llc) 2. M/s Glenmark Pharma 3. M/s Cipla Ltd |
| 54 | Etodolac | BCS CLASS-II (Two) | Etodolac Tablet 200/400 mg | Etodolac Tablet 200/400 mg (M/s IPCA Lab) |
| | | | Etodolac Tablets 400 mg | 1. M/s Sandoz 2. M/s Teva Pharma, 3. M/s Torrent Pharma |
| | | | Etodolac Capsules 300 mg | 1. M/s M/s Taro Pharma Industries ltd 2. M/s ANI Pharma Inc 3. M/s Lupin Ltd |
| 55 | Etoposide | BCS CLASS-IV (Four) | Etoposide Capsules 50 mg | 1. Etoposide Capsules 50 mg ACTITOP® (M/s Khandelwal) 2. M/s Cipla Ltd 3. M/s Mylan Lab |
| 56 | Exemestane | BCS CLASS-II (Two) | Exemestane Tablets 25 mg | 1. Exemestane Tablets 25 mg AROMASIN® (M/s Pharmacia and Upjohn co.) 2. M/s Alkem Lab 3. M/s Natco Pharma |
| 57 | Ezetimibe | BCS CLASS-II (Two) | Ezetimibe Tablets 10 mg | 1. Ezetimibe Tablets 10 mg ZETIA® (M/s. MSD International GMBH) 2. M/s Sun Pharma 3. M/s Lupin Lab 4. M/s Cadila healthcare Ltd. |
| 58 | Febuxostat | BCS CLASS-II (Two) | Febuxostat Tablets 80/120 mg | 1. Febuxostat Tablets 80/120 mg ULORIC® (M/s Takeda Pharma USA Inc) 2. M/s Ajanta Pharma 3. M/s Intas Pharma |
| 59 | Felbamate | BCS CLASS-II (Two) | Felbamate Tablets 400/600 mg | Felbamate Tablets 400/600 mg FELBATOL® (M/s Mylan Specialty LP) |
| 60 | Fenofibrate | BCS CLASS-II (Two) | Fenofibrate Tablets 145 mg | 1. Fenofibrate Tablet 145 mg (M/s Abbvie Inc) 2. M/s Cipla Ltd 3. M/s Troikaa Pharma Ltd 4. M/s Sun Pharma |
| | | | Fenofibrate Capsules 200 mg | M/s USV Ltd |
| 61 | Flecainide acetate | BCS CLASS-II (Two) | Flecainide acetate Tablets 100 mg | 1. Flecainide acetate Tablets 100 mg TAMBOCOR® (M/s. County Line Pharma Line) 2. M/s Torrent Pharma |
| 62 | Flunarizine | BCS CLASS-II (Two) | Flunarizine Capsule 5/10 mg Flunarizine Tablets 10 mg | 1. Flunarizine Capsule 5/10 mg NOMIGRAIN® (M/s Torrent) 2. Flunarizine Tablets 10 mg MIGARID® (M/s Cipla) |
| 63 | Flutamide | BCS CLASS-II (Two) | Flutamide Tablets 250 mg | 1. Flutamide Tablets 250 mg Euflex® (M/s Merck Canada Inc.) 2. M/s Cipla Ltd |
| 64 | Folic acid | BCS CLASS-IV (Four) | Folic acid Tablets 5 mg | Folic acid Tablets 5 mg FOLVITE®, (M/s Wyeth Pharmaceuticals Limited) |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|--------------------|---------------------|---|---|
| 65 | Furosemide | BCS CLASS-IV (Four) | Furosemide Tablets 40 mg | 1. Furosemide Tablets 40 mg LASIX® (M/s US Pharm Holdings) 2. M/s Sandoz |
| 66 | Gefitinib | BCS CLASS-II (Two) | Gefitinib Tablets 250 mg | 1. Gefitinib Tablets 250 mg IRESAA® (M/s AstraZeneca Pharmaceuticals LP UK) 2. M/s Natco Pharma |
| 67 | Gemfibrozil | BCS CLASS-II (Two) | Gemfibrozil Capsules 300 mg | 1. M/s Cadila 2. M/s Pfizer 3. M/s Sun Pharma |
| | | | Gemfibrozil Tablets 600 mg | Gemfibrozil Tablets 600 mg LOPID® (M/s. Pfizer) |
| 68 | Glimepiride | BCS CLASS-II (Two) | Glimepiride Tablets 1/2/3/4 mg | 1. Glimepiride Tablets, AMARYL® (M/s. Sanofi-aventis U.S. Llc) 2. M/s Torrent Pharma 3. M/s IPCA |
| 69 | Griseofulvin | BCS CLASS-II (Two) | Griseofulvin Tablets 125/ 500 mg | 1. Griseofulvin Tablets 250/500 mg GRISOVIN-FP® (M/s GSK) |
| 70 | Haloperidol | BCS CLASS-IV (Four) | Haloperidol Tablets 1.5/5/10 mg | 1. M/s Johnson & Johnson 2. M/s Sun Pharma 3. M/s Intas |
| 71 | Hydroxychloroquine | BCS CLASS-II (Two) | Hydroxychloroquine Tablets 400 mg | 1. Hydroxychloroquine Tablets 400 mg PLAQUENIL® (M/s Sanofi-aventis Canada Inc) 2. M/s IPCA 3. M/s Zydus 4. M/s Torrent Pharma |
| 72 | Ibrutinib | BCS CLASS-II (Two) | Ibrutinib Hard Gelatin Capsules 140 mg | 1. Ibrutinib Hard Gelatin Capsules 140 mg IMBRUVICA® (M/s Pharmacyclics Inc.) 2. M/s Johnson & Johnson |
| 73 | Ibuprofen | BCS CLASS-II (Two) | Ibuprofen Tablets 200 mg | 1. M/s Abott Labs 2. M/s Cipla Ltd 3. M/s Intas |
| 74 | Imatinib | BCS CLASS-II (Two) | Imatinib Capsules 100 mg | 1. M/s Sun Pharma 2. M/s Cipla Ltd |
| | | | Imatinib Tablets 100/400 mg | 1. Imatinib Tablets 100/400 mg GLEEVEC® (M/s Novartis Pharma) 2. M/s Natco Pharma 3. M/s Glenmark Pharma |
| 75 | Irbesartan | BCS CLASS-II (Two) | Irbesartan Tablets 150/300 mg | 1. Irbesartan Tablets 150/300 mg AVAPRO® (M/s Sanofi Aventis US Llc) 2. M/s Sun Pharma 3. M/s Abbot |
| 76 | Isotretinoin | BCS CLASS-II (Two) | Isotretinoin soft gelatin Capsules 10/20 mg | 1. Isotretinoin soft gelatin Capsules 10/20 mg ABSORICA® (M/s Sun Pharma) 2. Cipla Ltd. 3. M/s IPCA Lab |
| 77 | Itraconazole | BCS CLASS-II (Two) | Itraconazole Capsules 100 mg | 1. Itraconazole Capsules 100 mg SPORANOX® (M/s Janssen Pharma Inc) 2. M/s Johnson & Johnson 3. M/s Glenmark Pharma 4. M/s Intas Pharma |
| 78 | Lacidipine | BCS CLASS-II (Two) | Lacidipine Tablets 2/4 mg | 1. M/s Glaxo India Ltd 2. M/s Sun Pharma |
| 79 | Lafutidine | BCS CLASS-II (Two) | Lafutidine Tablets 5/10mg | 1. M/s. Macleods Ltd 2. M/s. Ajanta Pharma |
| 80 | Lamotrigine | BCS CLASS-II (Two) | Lamotrigine-25/50/100 mg Tablets | 1. Lamotrigine Tablets 25/100 mg LAMICTAL (M/s GlaxoSmithKline Llc) 2. M/s Sun Pharma 3. M/s Torrent Pharma |
| 81 | Lapatanib | BCS CLASS-IV (Four) | Lapatanib film coated Tablets 250 mg | Lapatanib film coated Tablets 250 mg (M/s GlaxoSmithKline) |
| 82 | Leflunomide | BCS CLASS-II (Two) | Leflunomide Tablets 10/20/100 mg | 1. Leflunomide Tablets 10/20/100 mg ARAVA® (M/s Sanofi Aventis US Llc) 2. M/s. Zydus Cadila 3. M/s Torrent |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|---------------------|---------------------|--|---|
| 83 | Lenalidomide | BCS CLASS-IV (Four) | Lenalidomide Capsules 5/10/15/25 mg | 1. Lenalidomide Capsule 5/10/15/25 mg REVLIMID® (Celgene Corp) 2. M/s Ranbaxy 3. M/s Natco Pharma Ltd 4. M/s Dr. Reddy's Lab |
| 84 | Losartan Potassium | BCS CLASS-II (Two) | Losartan Potassium Tablets 25/50/100 mg | 1. Losartan Potassium Tablets 25/50/100 mg COZAAR® (M/s Merck Sharp and Dohme Corp) 2. M/s. Cadila 3. M/s Torrent Pharma |
| 85 | Lovastatin | BCS CLASS-II (Two) | Lovastatin Tablets 10/20 mg | 1. Lovastatin Tablets 10/20 mg AZTATIN® (M/s Sun Pharma) 2. M/s Glenmark 3. M/s Intas |
| 86 | Mebendazole | BCS CLASS-II (Two) | Mebendazole Tablets 100 mg | 1. Mebendazole Tablets 100 mg EMVERM® (M/s IMPAX LABS INC) 2. M/s Cipla Ltd 3. M/s Cadila |
| 87 | Meclizine | BCS CLASS-II (Two) | Meclizine Tablets 25 mg | 1. Meclizine Tablets 25 mg ANTIVERT® (M/s CASPER PHARMA LLC) 2. M/s UCB |
| 88 | Mefloquine | BCS CLASS-II (Two) | Mefloquine Tablets 250 mg | 1. Mefloquine Hydrochloride Tablets 250 mg (M/s BARR) 2. M/s Lupin 3. M/s Sun |
| 89 | Meloxicam | BCS CLASS-II (Two) | Meloxicam Tablets 7.5/15 mg | 1. Meloxicam Tablets 7.5/15 mg MOBIC® (M/s Boehringer Ingelheim) 2. M/s Cadila 3. M/s Sun Pharma |
| 90 | Mercaptopurine | BCS CLASS-IV (Four) | Mercaptopurine Tablets 50 mg | 1. Mercaptopurine Tablets 50 mg PURINETHOL® (M/s Stason Pharms) 2. M/s GSK 3. M/s Mylan Lab |
| 91 | Mifepristone | BCS CLASS-IV (Four) | Mifepristone Tablets 200 mg | 1. Mifepristone Tablets 200 mg MIFEPREX® (M/s Danco Lab Llc) 2. M/s Sun Pharma 3. M/s Abbott Healthcare Pvt. Ltd. 4. Cipla Limited |
| 92 | Nateglinide | BCS CLASS-II (Two) | Nateglinide Tablets 60/120 mg | 1 Nateglinide Tablets 60/120 mg NATEGLINIDE® (M/s Dr. Reddy's Lab) 2. M/s Glenmark Pharma 3. IPCA |
| 93 | Nelfinavir Mesylate | BCS CLASS-II (Two) | Nelfinavir Tablets 250mg | 1. Nelfinavir Tablets 250mg VIRACEPT® (M/s Agouron Pharms) 2. M/s Cipla |
| 94 | Nevirapine | BCS CLASS-II (Two) | Nevirapine Tablets 200mg | 1. Nevirapine Tablets 200 mg (M/s Aurobindo Pharma) 2. M/s Cipla Ltd |
| 95 | Nifedipine | BCS CLASS-II (Two) | Nifedipine Capsules 5/10 mg | 1. Nifedipine Capsules 10 mg PROCARDIA® (M/s Pfizer) 2. M/s. Merck 3. M/s Torrent Pharma 4. M/s Alkem Laboratories Ltd |
| 96 | Nimesulide | BCS CLASS-II (Two) | Nimesulide Tablets 100mg | 1. Nimesulide Tablets 100 mg ANTIPEN® (M/s Dr. Reddy's Lab) 2. M/s Sun Pharma |
| 97 | Nitrazepam | BCS CLASS-II (Two) | Nitrazepam Tablets 5/10 mg | 1. Nitrazepam 5 mg Tablets, M/s Accord- UK Ltd 2. Nitrazepam Tablets 5/10 mg NITROSUN® (M/s Sun Pharma) 3. M/s Lupin Laboratories Ltd |
| 98 | Nitrofurantoin | BCS CLASS-II (Two) | Nitrofurantoin Tablets 50mg | 1. Nitrofurantoin Tablets 50 mg FURADANTIN® (M/s Procter and Gamble) 2. M/s Glaxo SmithKline Pharma Ltd. |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|-------------------------|--------------------|--|--|
| 99 | Norfloxacin | BCS CLASS-IV(Four) | Norfloxacin Tablets 200/400/800mg | 1. Norfloxacin Tablets 200/400 mg NORFLOX® (M/s Cipla Limited) 2. M/s Alembic Chemical Works Co. Ltd. 3. M/s Sun Pharma |
| 100 | Olanzapine | BCS CLASS-II (Two) | Olanzapine Tablets 2.5/5/7.5/10/15/20 mg | 1. Olanzapine Tablets 2.5/5/7.5/10/15/20mg ZYPREXA® (M/s Eli Lilly & Co.) 2. M/s Sun Pharma |
| 101 | Orlistat | BCS CLASS-II (Two) | Orlistat Capsules 60/120 mg | 1. Orlistat Capsules 120 mg XENICAL® (M/s Cheplapharm Arzneimittel GMBH) Orlistat Capsules 60mg ALLI® (M/s GSK) 2. M/s Sun Pharma 3. M/s Meyer Organics Ltd |
| 102 | Oxcarbazepine | BCS CLASS-IV(Four) | Oxcarbazepine Tablets 150/300/600 mg | 1. Oxcarbazepine Tablets 150/300/600 mg TRILEPTAL® (M/s Novartis Pharma) 2. M/s Sun Pharma |
| 103 | Pioglitazone | BCS CLASS-II(Two) | Pioglitazone Tablets 15/30/45 mg | 1. Pioglitazone Tablets 15/30/45 mg ACTOS® (M/s Takeda Pharmaceuticals USA INC) 2. M/s Sun Pharma 3. M/s Dr Reddys |
| 104 | Praziquantel | BCS CLASS-II (Two) | Praziquantel Tablets 600 mg | 1. Praziquantel Tablets 600 mg BILTRICIDE® (M/s Bayer Healthcare) |
| 105 | Primidone | BCS CLASS-II(Two) | Primidone Tablets 250 mg | 1. Primidone Tablets 250 mg MYSOLINE® (M/s Valeant Pharma) 2. M/s Abbott Healthcare Pvt. Ltd |
| 106 | Quetiapen fumarate | BCS CLASS-II (Two) | Quetiapine Tablets 25/50/100/200/300 mg | 1. Quetiapine fumarate, SEROQUEL® (M/s Astrazeneca Pharmaceuticals) 2. M/s Sun Pharma |
| 107 | Quinapril Hydrochloride | BCS CLASS-II (Two) | Quinapril Tablets 5/10/20 mg | 1. Quinapril Tablets 5/10/20 mg ACCUPRIL® (M/s Pfizer Pharmaceuticals) 2. M/s Macleods Pharmaceuticals |
| 108 | Raloxifene | BCS CLASS-II (Two) | Raloxifene Tablets 60 mg | 1. Raloxifene Tablets 60 mg EVISTA® (M/s Eli Lilly & Co.) 2. M/s Dr. Reddys |
| 109 | Raltegravir | BCS CLASS-II (Two) | Raltegravir Film coated tablets 400 mg | 1. Raltegravir Film coated tablets 400 mg ISENTRESS® (M/s MSD) 2. M/s Cipla |
| 110 | Rebamipide | BCS CLASS-II (Two) | Rebamipide Tablets 100mg | 1. Rebamipide Tablets 100mg OXALIS® (M/s Macleods Pharmaceuticals) 2. M/s Ajanta Pharma |
| 111 | Rifabutin | BCS CLASS-II (Two) | Rifabutin Capsules 150mg | 1. Rifabutin Capsules 150mg MYCOBUTIN® (M/s Pharmacia & Upjohn co.) 2. M/s Lupin |
| 112 | Rifampicin | BCS CLASS-II (Two) | Rifampicin Capsules 150/300/450 mg | 1. Rifampicin Capsules 150/300 mg RIFADIN® (M/s Sanofi Aventis) 2. M/s Sandoz 3. M/s Lupin |
| 113 | Risperidone | BCS CLASS-II (Two) | Risperidone Tablets 1/2/3/4 mg | 1. M/s Johnson & Johnson 2. M/s Torrent 2. M/s Sun Pharma |
| 114 | Ritonavir | BCS CLASS-II (Two) | Ritonavir Capsules 100 mg | 1. Ritonavir Capsules 100 mg NORVIR® (M/s Abbvie INC) 2. M/s Cipla |
| 115 | Saquinavir | BCS CLASS-II (Two) | Saquinavir Tablets 500mg | 1. Saquinavir Tablets 500mg INVIRASE® (M/s Hoffmann-la Roche Inc.) 2. M/s Hetero Healthcare 3. M/s Cipla |
| 116 | Simvastatin | BCS CLASS-II (Two) | Simvastatin Tablets 5/10/20/40 mg | 1. Simvastatin Tablets 5/10/20/40 mg ZOCOR® (M/s Merck Sharp & Dohme Corp.) 2. M/s Sun Pharma |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|-------------------------|---------------------|---|--|
| 117 | Sirolimus | BCS CLASS-II (Two) | Sirolimus Tablets 0.5/1/2 mg | 1. Sirolimus Tablets 0.5/1/2 mg RAPAMUNE® (M/s PF PRISM CV) 2. M/s Wyeth Limited |
| 118 | Spironolactone | BCS CLASS-II (Two) | Spironolactone Tablets 50 mg | 1. Spironolactone Tablets 50 mg ALDACTONE® (M/s GD SEARLE LLC) 2. M/s Sun Pharma |
| 119 | Sulfadiazine | BCS CLASS-IV (Four) | Sulfadiazine Tablets 500 mg | 1. Sulfadiazine Tablets 500 mg SULFADIAZINE® (M/s Eli Lilly & Co.) 2. M/s Sandoz |
| 120 | Sulpiride | BCS CLASS-IV (Four) | Sulpiride Tablets 50/100/200/300 mg | Sulpiride 200/400 mg Tablet (M/s Wockhardt UK Ltd.) |
| 121 | Tacrolimus | BCS CLASS-II (Two) | Tacrolimus Capsules 0.25/0.5/1/3/4/5 mg | 1. Tacrolimus Capsules 0.5/ 1/5 mg PROGRAF® (M/s Astellas Pharma US INC) 2. Tacrolimus Capsule 0.25/0.5/1/5mg PANGRAF® (M/s Panacea Biotec Ltd.) 3. M/s Torrent Pharmaceuticals Ltd. |
| 122 | Tadalafil | BCS CLASS-IV(Four) | Tadalafil Tablets 2.5/5/10/20 mg | 1. Tadalafil Tablets 10/20 mg FORZEST® (M/s Sun Pharma) 2. M/s Astellas Pharma 2. M/s Lupin Ltd. |
| 123 | Telmisartan | BCS CLASS-II (Two) | Telmisartan Tablets 20/40/80 mg | 1. Telmisartan Tablets 20/40/80 mg TELMA® (M/s Glenmark) 2. M/s Cipla |
| 124 | Terbinafine | BCS CLASS-II (Two) | Terbinafine Tablets 250 mg | 1. Terbinafine Tablets 250 mg LAMISIL® (M/s Novartis Pharmaceuticals) 2. M/s Dr. Reddy's |
| 125 | Tiagabine hydrochloride | BCS CLASS-II (Two) | Tiagabine HCl USP Tablets 2/4/12/16 mg | 1. Tiagabine HCl USP Tablets 2/4/12/16 mg GABITRIL® (M/s Cephalon Inc. USA) 2. M/s Sun Pharma |
| 126 | Tibolone | BCS CLASS-II (Two) | Tibolone Tablets 2.5 mg | 1. Tibolone Tablets 2.5 mg MAXTIB® (M/s Sun Pharma) 2. M/s Cipla Limited 3. M/s Zydus Cadila Healthcare Ltd 4. M/s Organon |
| 127 | Ticlopidine | BCS CLASS-II (Two) | Ticlopidine HCl Tablets 250 mg | 1. Ticlopidine HCl Tablets 250 mg (M/s Teva Pharmaceuticals) 2. M/s Cipla Limited 3. M/s Torrent Pharmaceuticals 4. M/s Emcure Pharmaceuticals |
| 128 | Tolvaptan | BCS CLASS-II (Two) | Tolvaptan Tablets 15/30 mg | 1. Tolvaptan Tablets 15/30 mg SAMSCA® (M/s Otsuka America Pharmaceutical Inc) 2. M/s Glenmark Pharmaceuticals 3. M/s Sun Pharma |
| 129 | Torsemide | BCS CLASS-II (Two) | Torsemide Tablets 5/10/20/100 mg | 1. Torsemide Tablets 5/10/20/100 mg DEMADEx® (M/s Mylan Speciality LP) 2. M/s Cipla Limited 3. M/s Lupin Ltd 4. M/s Torrent Pharmaceuticals Ltd. |
| 130 | Tranexamic acid | BCS CLASS-II (Two) | Tranexamic acid Tablets 250/500 mg | 1. Tranexamic acid Tablets 250/500 mg TRANAREST® (M/s Zydus Cadila) 2. M/s Pfizer |
| 131 | Trimethoprim | BCS CLASS-IV (Four) | Trimethoprim Tablets 100 mg | 1. Trimethoprim Tablets 100 mg (M/s Mayne Pharma) 2. M/s IPCA Laboratories Ltd. |
| 132 | Ursodeoxycholic Acid | BCS CLASS-II (Two) | Ursodeoxycholic acid Tablets 300/600 mg | 1. Ursodeoxycholic acid Tablets 300/600 mg UDILIV® (M/s Abbott) 2. M/s Cadila Healthcare |
| 133 | Valsartan | BCS CLASS-II (Two) | Valsartan Tablets & Capsuels 40/80/160 mg | 1. Valsartan Tablets & Capsuels 40/80/160mg VALZAAR® (M/s Torrent Pharma) 2. M/s Novartis Pharma (India) Ltd 3. M/s Lupin Laboratories Ltd |

| Sr. No. | Name of Drug | BCS (Class II/IV) | Product | Name of drug/ Company/Trade Name/Manufacturer) |
|---------|--------------|---------------------|---|---|
| 134 | Vardenafil | BCS CLASS-II (Two) | Vardenafil Hydrochloride Trihydrate Tablets 5 mg | 1. Vardenafil Hydrochloride Trihydrate Tablets 5 mg LEVITRA® (M/s Ajanta Pharma) 2. M/s Bayer plc, UK 3. M/s Macleods |
| 135 | Vemurafenib | BCS CLASS-IV (Four) | Vemurafenib Tablets 240 mg | 1. Vemurafenib Tablets 240 mg ZELBORAF® (M/s Hoffmann La Roche Inc.) 2. M/s Roche Products Limited, UK |
| 136 | Verapamil | BCS CLASS-II (Two) | Verapamil Tablets 40/80/120/160 mg | 1. Verapamil Tablets 40/80/120 mg VASOPTEN® (M/s Torrent) 2. M/s Themis Medicare |
| 137 | Zafirlukast | BCS CLASS-II (Two) | Zafirlukast Tablets 10/20 mg | 1. Zafirlukast Tablets 10/20 mg ACCOLATE® (M/s AstraZeneca Pharmaceuticals LP, USA) 2. M/s Dr. Reddy's Lab |
| 138 | Zaleplon | BCS CLASS-II (Two) | Zaleplon Capsules 5/10 mg | 1. Zaleplon Capsules 5/10 mg STILNITE® (M/s Zydus Cadila Healthcare Ltd) 2. M/s Sonata and PFIZER INC, USA 3. M/s Zydus Cadila Healthcare 4. M/s Cipla 5. M/s Torrent Pharmaceuticals |
| 139 | Ziprasidone | BCS CLASS-II (Two) | Ziprasidone HCl Monohydrate Capsules 20/40/60/80 mg | 1. Ziprasidone HCl Monohydrate Capsules 20/40/60/80 mg GEODON® (M/s Pfizer Inc, USA) 2. M/s Torrent Pharma 3. M/s Sun Pharma |