

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 Develepmnt 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