

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

		-	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

				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	Seratrodist	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

				Ltd.
				M/s. Psyc 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.

			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.

15	TapentadolHCl	Tablet	50 mg/75 mg/100 mg	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
				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

				Ltd.
				M/s. Precise Chemipharma 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.