

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

		-	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	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