

LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE
STUDY REPORT FOR YEAR 1999 - 2000

1ST LIST

Bil (50)dlm.BPFK/007/3.7(23/02/1999)

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products		Effective Date for Submission of BE Study Report	Closing Date for Submission of BE Study Report of Registered Products	
		Trade Mark/Registration No.	Manufacturer	New Application	Imported Products	Local Products
1.	Nifedipine	i) Adalat 5 Capsule (MAL19880105AZ)	Bayer Schering Pharma AG, Leverkusen, Germany	01/03/1999	31/12/1999	30/06/2000
		ii) Adalat Capsule 10mg (MAL19880104AZ)	Bayer Schering Pharma AG, Leverkusen, Germany			
2.	Cyclosporin	i) Sandimmun Neoral 10mg Capsule (MAL20001791ACRZ)	Catalent Germany Eberbach GmbH, Germany R.P. Scherer GMBH & Co KG, Germany	01/03/1999	31/12/1999	30/06/2000
		ii) Sandimmun Neoral Capsule 100mg (MAL19962140ACRZ)	Catalent Germany Eberbach GmbH, Germany R.P. Scherer GMBH & Co KG, Germany			
		iii) Sandimmun Neoral Capsule 25mg (MAL19962142ACRZ)	Catalent Germany Eberbach GmbH, Germany			

		iv) Sandimmun Neoral Capsule 50mg (MAL19962141AC)	R.P. Scherer GMBH & Co KG, Germany R.P. Scherer GMBH & Co KG, Germany			
3.	Captopril	i) Apo-Capto 12.5mg Tablet (MAL19987341ARZ) ii) Apo-Capto 25mg Tablet (MAL19987340ARZ) iii) Kimafan Tablet 12.5mg (MAL19985970A) iv) Kimafan Tablet 25mg (MAL19985969AZ)	Apotex Inc., Canada Apotex Inc., Canada Duopharma (M) Sdn Bhd Duopharma (M) Sdn Bhd	01/03/1999	31/12/1999	30/06/2000
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2009 – 19 Ogos 2009'				

Updated on 28/03/2017