LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE STUDY REPORT FOR YEAR 2002 - 2003

4TH LIST

Bil.(85)dlm.BPFK/007/3.8 (14/06/2002)

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.	**Clomipramine**	i) Anafranil 25mg Tablet (MAL 20000270AC)	Novartis Farma S.p.A, Italy	01/07/2002	31/12/2003	31/12/2003
2.	**Lithium Carbonate**	However , as according to circular Bil (51) dlm.BPFK/02/5/1.3, the following requirement to be submitted in place of Bioequivalence report (effective date – 01 December 2005) i) Validation Process Report for 3 consecutive batches ii) Comparative Dissolution Profile for 3 consecutive batches (Time points : 0, 5, 15, 30 & 45 minutes)				
3.	**Bromocriptine Mesylate**	i) Parlodel Tablet 2.5mg (MAL 19870437A)	Novartis Farma S.p.A Italy	01/07/2002	31/12/2003	31/12/2003
4.	**Ranitidine**	i) Zantac Tablet 150mg (MAL 19871471A) ii) Zantac Tablet 300mg (MAL 19940613AS) iii) Zantac Tablet 75mg (MAL 19990987A)	GlaxoSmithKline (Tianjin) Co. Ltd, China GlaxoSmithKline Australia Pty Ltd, Australia Glaxo Wellcome Operations UK Ltd, United Kingdom	01/07/2002	31/12/2003	31/12/2003

5.	**Terbutaline Sulphate**	i) Britaline Tablet 2.5mg (MAL 19890080A) ii) Pharmaniaga Terbutaline Tablet 2.5mg (MAL 19920521A)	Duopharma (M) Sdn Bhd, Malaysia Pharmaniaga Manufacturing Sdn Bhd, Malaysia	01/07/2002	31/12/2003	31/12/2003
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2008 – 23 July 2008'				
6.	**Digoxin**	i) Lanoxin 250micrograms Tablet (MAL 19983999AS) ii) Lanoxin Pg 62.5mcg Tablets (MAL 19973575A)	GlaxoSmithKline Australia Pty Ltd, Australia GlaxoSmithKline Australia Pty Ltd, Australia	01/07/2002	31/12/2003	31/12/2003
7.	**Sodium Valproate**	i) Epilim 200 Enteric Coated Tablet (MAL 19860953A) ii) Epilim 500 Enteric Coated Tablet (MAL 19950223A)	Sanofi Synthelabo Ltd, UK Sanofi Synthelabo Ltd, UK	01/07/2002	31/12/2003	31/12/2003
8.	**Amitriptylline HCl**	i) Tryptanol 25mg Tablet (MAL 19940012AS)	Merck Sharp & Dohme (Australia) Pty Ltd	01/07/2002	31/12/2003	31/12/2003
9.	**Atenolol**	i) Tenormin Tablet 100mg (MAL 19870056A)	Astrazeneca UK Limited, United Kingdom			

		ii) Tenormin Tablet 50mg (MAL 19870055A)	Astrazeneca UK Limited, United Kingdom	01/07/2002	31/12/2003	31/12/2003
10.	**Metoprolol**	i) Betaloc Tablet 50mg (MAL 19988458ACS) ii) Betaloc Tablet 100mg (MAL 19988457ACS)	Interphil Laboratories, Inc. Philipines Interphil Laboratories, Inc. Philipines	01/07/2002	31/12/2003	31/12/2003
11.	**Frusemide**	i) Lasix Tablet 40mg (MAL 19870226A)	Aventis Pharma Deutschland Gmbh, Germany	01/07/2002	31/12/2003	31/12/2003
12.	**Carbidopa/ L-dopa**	i) Sinemet 25/100 Tablet (MAL 19913441A) ii) Sinemet 25/250 Tablet (MAL 19913442A)	Merck Sharp & Dohme (Australia) Pty Ltd, Australia Merck Sharp & Dohme (Australia) Pty Ltd, Australia	01/07/2002	31/12/2003	31/12/2003
13.	**Levodopa/ Benserazide**	i) Madopar Roche Tablet 250mg (MAL 19871099A) ii) Madopar Roche 125 Capsule (MAL 19871097A)	F. Hoffmann-la Roche Ltd Switzerland F. Hoffmann-la Roche Ltd Switzerland	01/07/2002	31/12/2003	31/12/2003
14.	**Phenytoin Sodium**	i) Dilantin Capsule 100mg (MAL19860935AR) ii) Dilantin Capsule 30mg (MAL19860940AR)	Pfizer Australia Pty Ltd, Australia Pfizer Australia Pty Ltd, Australia	01/07/2002	31/12/2003	31/12/2003

15.	**Warfarin Sodium**	i) Coumadin 1mg Tablet (MAL 19992058AS) ii) Coumadin Tablet 2mg (MAL 19880127A) iii)Coumadin Tablet 5mg (MAL 19880128A)	Bristol-Myers Squibb Holdings Pharma Ltd, United States Bristol-Myers Squibb Holdings Pharma Ltd, United States Bristol-Myers Squibb Holdings Pharma Ltd, United States	01/07/2002	31/12/2003	31/12/2003
16.	**Disopyramide Phosphate**	i) Disorythm Capsule 100mg (MAL 19861552A)	Royce Pharma Manufacturing Sdn Bhd	01/07/2002	31/12/2003	31/12/2003