

**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.	<b>Clomipramine</b>	i) Anafranil 25mg Tablet (MAL20000270ACRZ)	Novartis Farma S.p.A, Italy	01/07/2002	31/12/2003	31/12/2003
2.	<b>Lithium Carbonate</b>	<p>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)</p> <p>i) Validation Process Report for 3 consecutive batches ii) Comparative Dissolution Profile for 3 consecutive batches (Time points : 0, 5, 15, 30 &amp; 45 minutes )</p> <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.</p>				
3.	<b>Bromocriptine Mesylate</b>	i) Parlodel Tablet 2.5mg (MAL19870437ARZ)	Novartis Farma S.p.A Italy	01/07/2002	31/12/2003	31/12/2003
4.	<b>Ranitidine</b>	<p>i) Zantac Tablet 150mg (MAL19871471ARZ)</p> <p>ii) Zantac Tablet 300mg (MAL19940613ASZ)</p> <p>iii) Zantac Tablet 75mg (MAL19990987AZ)</p>	<p>GlaxoSmithKline (Tianjin) Co. Ltd, China</p> <p>GlaxoSmithKline Australia Pty Ltd, Australia</p> <p>Glaxo Wellcome Operations UK Ltd, United Kingdom</p>	01/07/2002	31/12/2003	31/12/2003

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		This product can be obtained from Australia, Hong Kong, India, Indonesia, New Zealand, Philippines & Thailand (Information received from GSK Malaysia on 28 February 2014).				
5.	<b>Terbutaline Sulphate</b>	i) Britaline Tablet 2.5mg (MAL19890080AZ)  ii) Pharmaniaga Terbutaline Tablet 2.5mg (MAL19920521AZ)	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.	<b>Digoxin</b>	i) Lanoxin 250micrograms Tablet (MAL19983999AZ)  ii) Lanoxin Pg 62.5mcg Tablets (MAL19973575AZ)	Aspen Bad Oldesloe Gmbh, Germany  GlaxoSmithKline Australia Pty Ltd, Australia  Aspen Bad Oldesloe Gmbh, Germany  GlaxoSmithKline Australia Pty Ltd, Australia	01/07/2002	31/12/2003	31/12/2003

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7.	<b>Sodium Valproate</b>	i) Epilim 200 Enteric Coated Tablet (MAL19860953AZ)	Sanofi Synthelabo Ltd, UK	01/07/2002	31/12/2003	31/12/2003
		ii) Epilim 500 Enteric Coated Tablet (MAL19950223A)	Sanofi Synthelabo Ltd, UK			
8.	<b>Amitriptylline HCl</b>	i) Tryptanol 25mg Tablet (MAL19940012AS)	Merck Sharp & Dohme (Australia) Pty Ltd	01/07/2002	31/12/2003	31/12/2003
		ii) Apo-Amitriptyline 10mg Tablets/MAL19984714ARZ	Apotex Inc, Canada			
		iii) Apo-Amitriptyline 25mg Tablets/MAL19984711ARZ	Apotex Inc, Canada			
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2012 – 13 September 2012				
		"Mesyuarat mencadangkan agar produk Apo-Amitriptyline ditambahkan dalam senarai komparator bagi bahan aktif Amitriptylline pada laman sesawang BPFK di samping komparator asal."				

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9.	<b>Atenolol</b>	i) Tenormin Tablet 100mg (MAL19870056ARZ)	Astrazeneca UK Limited, United Kingdom	01/07/2002	31/12/2003	31/12/2003
		ii) Tenormin Tablet 50mg (MAL19870055ARZ)	Astrazeneca UK Limited, United Kingdom			
10.	<b>Metoprolol</b>	i) Betaloc Tablet 50mg (MAL19988458ACS)	Interphil Laboratories, Inc. Philippines	01/07/2002	31/12/2003	31/12/2003
		ii) Betaloc Tablet 100mg (MAL19988457ACS)	Interphil Laboratories, Inc. Philippines			
		Current approved Manufacturer is as follow:-  <b>AstraZeneca Pharmaceutical Co. Ltd. No 2, Huangshan Road, Wuxi Jiangsu, China</b>  (Information obtained through an email from AstraZeneca dated 11/7/2014)				
11.	<b>Frusemide</b>	i) Lasix Tablet 40mg (MAL19870226AZ)	Sanofi Winthrop Industrie, France	01/07/2002	31/12/2003	31/12/2003
12.	<b>Carbidopa/ L-dopa</b>	i) Sinemet 25/100 Tablet (MAL19913441A)	Merck Sharp & Dohme (Australia) Pty Ltd, Australia			

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		ii) Sinemet 25/250 Tablet (MAL19913442A)	Merck Sharp & Dohme (Australia) Pty Ltd, Australia	01/07/2002	31/12/2003	31/12/2003
13.	<b>Levodopa/ Benserazide</b>	i) Madopar Roche Tablet 250mg (MAL19871099ARZ)  ii) Madopar Roche 125 Capsule (MAL19871097ARZ)	Roche S.P.A., Italy  F. Hoffmann-la Roche Ltd Switzerland  Roche S.P.A., Italy  F. Hoffmann-la Roche Ltd Switzerland	01/07/2002	31/12/2003	31/12/2003
14.	<b>Phenytoin Sodium</b>	i) Dilantin Capsule 100mg (MAL19860935ARZ)  ii) Dilantin Capsule 30mg (MAL19860940ARZ)	Pfizer Australia Pty Ltd, Australia  Pfizer Australia Pty Ltd, Australia	01/07/2002	31/12/2003	31/12/2003
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2010 – 8 December 2010' :				
		i) For Generic immediate release, oral solid dosage form product which follows USP/BP specification and bioequivalence study is not conducted, the label need to				

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		state 'Not interchangeable with Dilantin and other brands of product containing Phenytoin'.				
		ii) For Generic immediate release, oral solid dosage form product which performed BE study and found bioequivalent with Innovator product (Dilantin), there is no requirement to include the statement no.(i).				
15.	<b>Warfarin Sodium</b>	i) Coumadin 1mg Tablet (MAL19992058AS)	Bristol-Myers Squibb Holdings Pharma Ltd, United States			
		ii) Coumadin Tablet 2mg (MAL19880127A)	Bristol-Myers Squibb Holdings Pharma Ltd, United States	01/07/2002	31/12/2003	31/12/2003
		iii) Coumadin Tablet 5mg (MAL19880128A)	Bristol-Myers Squibb Holdings Pharma Ltd, United States			
		iv) Apo-Warfarin 1mg Tablet (MAL20021394AZ)	Apotex Inc, Canada			
		v) Apo- Warfarin 2mg Tablet (MAL20021395AZ)	Apotex Inc, Canada			
		vi) Apo-Warfarin 5mg (MAL20021396AZ)	Apotex Inc, Canada			
		vii) Orfarin Tablet 3mg (MAL19921323AZ)	Orion Corporation, Finland			

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		viii) Orfarin 5mg Tablet (MAL20041004AZ)	Orion Corporation, Finland			
16.	<b>Disopyramide Phosphate</b>	i) Disorythm Capsule 100mg (MAL19861552A)	Royce Pharma Manufacturing Sdn Bhd	01/07/2002	31/12/2003	31/12/2003

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