

LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE
STUDY REPORT FOR YEAR 2006 - 2007

6TH LIST

Bil.(86)dlm.BPFK/007/3.8 (14/08/2006)

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.	Gliclazide	i) Diamicon Tablet 0.08G (MAL19870422AZ)	Les Labs Servier Industrie, France	01/12/2006	01/06/2007	31/12/2007
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2009 – 19 Ogos 2009' :</p> <p>i) Gliclazide remain in BE list requirement.</p> <p>ii) For Generic immediate release, oral solid dosage form product which follows BP specification and bioequivalence study is not conducted, the label need to state 'The dose may need to be titrated if patient has been switched from a different brand of product containing Gliclazide'.</p> <p>iii) For Generic immediate release, oral solid dosage form product which does not follow BP specification and bioequivalence study is also not conducted , the label need to include statement no. (ii).</p> <p>iv) For Generic immediate release, oral solid dosage form product which performed BE study and found bioequivalent with Innovator product (Diamicon), there is no requirement to include the statement no. (ii).</p>				

2.	Glimepiride	i) Amaryl 1.0 (MAL19990961A) ii) Amaryl 2.0 (MAL19990962AZ) iii) Amaryl 3.0 (MAL19990963AZ) iv) Amaryl 4.0 (MAL19990964A) v) Amaryl 6.0 (MAL19990965A)	Aventis Pharma S.P.A., Italy Sanofi-Aventis S.p.A., Italy Sanofi-Aventis S.p.A., Italy Aventis Pharma S.P.A., Italy Aventis Pharma S.P.A., Italy	01/12/2006	01/06/2007	31/12/2007
3.	Cefuroxime Axetil	i) Zinnat Tablet 125mg (MAL19890136AZ) ii) Zinnat Tablet 250mg (MAL19890137ARZ)	Glaxo Wellcome Operations UK Ltd, United Kingdom Glaxo Operations UK Ltd, United Kingdom	01/12/2006	01/06/2007	31 /12/2007
4.	Roxithromycin	i) Rulid Tablet 150 mg (MAL19890574AZ)	Sanofi Winthrop Industrie, France	01/12/2006	01/06/2007	31/12/2007
		This product is available in Thailand and Cambodia. (Information obtained from Sanofi Aventis (M) Sdn. Bhd via an email dated 12th July 2013.)				
5.	Azithromycin	i) Zithromax Tablet 250mg (MAL19985908ACZ)	Haupt Pharma Latina S.r.l., Italy Pfizer Italia S.R.L., Italy			

		ii) Zithromax Tablet 250mg (MAL20040039ASZ) iii) Zithromax Tablet 500mg (MAL19985909ACZ) iv) Zithromax Tablet 500mg (MAL20040036ASZ) v) Zithromax Tablet 250mg (MAL19985908ACZ) vi) Zithromax Tablet 500mg (MAL19985909ACZ) vii) Zithromax Capsules 250mg (MAL19970270AS) viii) Zithromax Capsules 250mg (MAL19921615A)	Pfizer Australia Pty. Ltd, Australia. Haupt Pharma Latina S.r.l., Italy Pfizer Italia S.R.L., Italy Pfizer Australia Pty. Ltd, Australia. Haupt Pharma Latina S.R.L. , Italy Haupt Pharma Latina S.R.L. , Italy Pfizer Pty Ltd, Australia Pfizer Limited, United Kingdom	01/12/2006	01/06/2007	31/12/2007
6.	Metronidazole	As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2008 – 23 July 2008' : Flagyl Tablet from different manufacturer (registered in other country) can also be used as a comparator.		01/12/ 2006	01/06/2007	31/12/2007
7.	Doxycycline	i) Vibramycin Tablet 100 mg (MAL20000043ASZ) ii) Vibramycin Tablet 100 mg (MAL19860578AZ)	Pfizer Australia Pty. Ltd., Australia Pfizer Pharmaceuticals Limited, China	01/12/2006	01/06/2007	31/12/2007

8.	Ketoconazole	i) Nizoral Tablet 200 mg (MAL20002457AR)	Janssen Cilag SPA, Italy	01/12/2006	01/06/2007	31/12/2007
9.	Itraconazole	i) Sporanox Capsule 100mg (MAL05072016AZ)	Janssen Cilag SPA, Italy	01/12/2006	01/06/ 2007	31/12/2007
10.	Ticlopidine	i) Ticlid Film Coated Tablet 250 mg (MAL19930512ARZ)	Sanofi-Aventis, S.AU, Spain	01/12/2006	01/06/2007	31/12/2007
11.	Simvastatin	i) Zocor Tablet 5 mg (MAL19940138AR) ii) Zocor Tablets 10 mg (MAL19921415ARZ) iii) Zocor Tablets 20mg (MAL19921416ARZ) iv) Zocor 40mg Tablet (MAL19985911ARZ) v) Zocor 80mg Tablet (MAL20020352ARZ)	Merck Sharp & Dohme Ltd, United Kingdom Merck Sharp & Dohme Ltd, United Kingdom Merck Sharp & Dohme Ltd, United Kingdom Merck Sharp & Dohme Ltd, United Kingdom Merck Sharp & Dohme Ltd, United Kingdom	01/12/2006	01/06/2007	31/12/2007
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2010 – 8 Disember 2010 : Both parent drug and active metabolite (beta-hydroxyacid simvastatin) need to be analysed in BE study. However, BE study conducted earlier and analysis was only done on parent drug, the report can still be considered for evaluation.				

12.	Lovastatin	i) Medostatin Tablet 20mg (MAL19973311AZ)	Medochemie Ltd, Cyprus	01/12/2006	01/06/2007	31/12/2007
		ii) Medostatin 40mg Tablet (MAL20021411AZ)	Medochemie Ltd, Cyprus			
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2010 – 8 Disember 2010 : Both parent drug and active metabolite (beta-hydroxyacid lovastatin) need to be analysed in BE study However, BE study conducted earlier and analysis was only done on parent drug, the report can still be considered for evaluation.				
13.	Amlodipine	i) Norvasc Tablet 5mg (MAL19970269ASZ)	Pfizer Australia Pty. Ltd., Australia	01/12/2006	01/06/2007	31/12/2007
		ii) Norvasc Tablet 10 mg (MAL19970268ASZ)	Pfizer Australia Pty. Ltd., Australia			
		iii) Norvasc Tablet 5mg (MAL20020266ACZ)	Pharmaniaga Manufacturing Berhad, Malaysia			
		vi) Norvasc Tablet 10mg (MAL20020267ACZ)	Pharmaniaga Manufacturing Berhad, Malaysia			
14.	Losartan	i) Cozaar 100mg Tablet (MAL20021160ARZ)	Merck Sharp & Dohme Ltd., United Kingdom	01/12/2006	01/06/2007	31/12/2007
		ii) Cozaar 50mg Tablet (MAL19963142ARZ)	Merck Sharp & Dohme Ltd., United Kingdom			
15.	Carvedilol	i) Dilatrend Tablet 6.25mg (MAL19991009ARZ)	Roche S.P.A, Italy			

		ii) Dilatrend Tablet 12.5mg (MAL19991010ARZ)	Roche S.P.A, Italy	01/12/2006	01/06/2007	31/12/2007
		iii) Dilatrend Tablet 25mg (MAL19940581ARZ)	Roche S.P.A, Italy			
16.	Tamoxifen	i) Nolvadex-D Tablet 20mg (MAL19870703ARZ)	AstraZeneca UK Limited, United Kingdom	01/12/2006	01/06/2007	31/12/2007
17.	Hydroxyzine	i) Atarax Film-Coated Tablet 10mg (MAL19861218A)	UCB S.A. Sector Pharma, Belgium	01/12/2006	01/06/2007	31/12/2007
		ii) Atarax Film-Coated Tablet 25mg (MAL19861219ARZ)	UCB S.A. Sector Pharma, Belgium			
18.	Lamotrigine	i) Lamictal Tablet 50mg (MAL19930433ARZ)	GlaxoSmithKline Pharmaceuticals SA, Poland	01/12/2006	01/06/2007	31/12/2007
		ii) Lamictal Tablet 100mg (MAL19930435ARZ)	GlaxoSmithKline Pharmaceuticals SA, Poland			
19.	Risperidone	i) Risperdal 1mg Tablet (MAL19963155AZ)	Janssen Pharmaceutica N.V., Belgium	01/12/2006	01/06/2007	31/12/2007
		ii) Risperdal Tablet 1 mg (MAL20002242ASZ)	Janssen Cilag SPA, Italy			

		<p>iii) Risperdal 2mg Tablet (MAL19963156AZ)</p> <p>iv) Risperdal Tablet 2 mg (MAL20002243ASZ)</p> <p>v) Risperdal 3mg Tablet (MAL19963157AZ)</p> <p>vi) Risperdal Tablet 3 mg (MAL20002244ASZ)</p> <p>vii) Risperdal 4mg Tablet (MAL19963158AZ)</p> <p>viii) Risperdal Tablet 4 mg (MAL20002245ASZ)</p>	<p>Janssen Pharmaceutica N.V., Belgium</p> <p>Janssen Cilag SPA, Italy</p> <p>Janssen Pharmaceutica N.V., Belgium</p> <p>Janssen Cilag SPA, Italy</p> <p>Janssen Pharmaceutica N.V., Belgium</p> <p>Janssen Cilag SPA, Italy</p>			
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2009 – 19 Ogos 2009' :</p> <p>Both parent drug and active metabolite (9-hydroxyrisperidone) need to be analysed in BE study based on justification that both parent drug and active metabolite contribute to anti-psychotic activity. However, BE study conducted earlier and analysis was only done on parent drug, the report can still be considered for evaluation.</p>				
20.	Buprenorphine	<p>i) Temgesic Sublingual Tablet 0.2mg (MAL19860975AZ)</p> <p>ii) Subutex Sublingual Tablet 0.4mg (MAL20013545A)</p>	<p>Reckitt Benckiser Healthcare (UK) Ltd, United Kingdom</p> <p>Reckitt Benckiser Healthcare (UK) Ltd, United Kingdom</p>			

		iii) Subutex Sublingual Tablet 2mg (MAL20013546A)	Reckitt Benckiser Healthcare (UK) Ltd, United Kingdom	01/12/2006	01/06/2007	31/12/2007
		iv) Subutex Sublingual Tablet 8mg (MAL20013547A)	Reckitt Benckiser Healthcare (UK) Ltd, United Kingdom			
21.	Cetirizine	i) Zyrtec 10mg Film Coated Tablet (MAL19890575ARZ)	UCB Farchim S.A., Switzerland	01/12/2006	01/06/2007	31/12/2007
22.	Loratadine	i) Clarityne Tablet 10mg (MAL19890576ACZ)	Schering-PL Labo N.V., Belgium	01/12/2006	01/06/2007	31/12/2007
		ii) Clarityne Tablet 10mg (MAL10070583ACSZ)	PT. Merck Sharp Dohme Pharma Tbk, Indonesia P.T Schering-Plough Indonesia TBK, Indonesia			
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2008 – 04 December 2008' : Analytes to measure : loratadine and desloratadine (active metabolite) for study done in 2009 and onward.				
23.	Meloxicam	i) Mobic Capsule 15 mg (MAL19971272A)	Boehringer Ingelheim Pharma KG, Germany			
		ii) Mobic Tablet 15 mg (MAL20000031A)	Boehringer Ingelheim Pharma KG, West Germany	01/12/2006	01/06/2007	31/12/2007

		iii) Mobic Capsule 7.5 mg (MAL19971271A)	Boehringer Ingelheim Pharma KG, Germany				
		iv) Mobic Tablet 7.5 mg (MAL19992696AZ)	Boehringer Ingelheim Pharma KG, West Germany				
		v) Mobic Tablet 7.5 mg (MAL11060027ASZ)	Boehringer Ingelheim Ellas A.E, Greece				
24.	Ibuprofen	i) Nurofen Caplet 200mg (MAL19993015AZ)	Reckitt Benckiser Heathcare Manufacturing (Thailand) Limited, Thailand	01/12/2006	01/06/2007	31/12/2007	
		ii) Nurofen 400 Caplet (MAL19993016AZ)	Reckitt Benckiser Heathcare Manufacturing (Thailand) Limited, Thailand				
		iii) Brufen Tablet 600mg (MAL08031341AZ)	Abbots Lab, Pakistan				
		iv) Brufen Tablet 200mg (MAL19860992A)	The Boots Company Ltd, United Kingdom				
		v) Brufen Tablet 400mg (MAL19861011A)	The Boots Company Ltd, United Kingdom				
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Kajian Bioekuivalens (JKKBE 1/2007) – 02 July 2007					
25.	Naproxen Sodium	i) Synflex Tablet 275mg (MAL20020896ACZ)	Roche Pharma S.A, Spain	01/12/2006	01/06/2007	31/12/2007	

		ii) Synflex Tablet 550mg (MAL20020897ACZ)	Roche Pharma S.A, Spain			
	Naproxen	i) Apo-Naproxen 250mg Tablet (MAL19984792A)	Apotex Inc., Canada	01/12/2006	01/06/2007	31/12/2007
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Kajian Bioekuivalens (JKKBE 1/2008) – 23 July 2008				
26.	Ketoprofen	i) Orudis E-100 Tablet (E/C) (MAL19940625A)	PT Aventis Pharma, Indonesia	01/12/2006	01/06/2007	31/12/2007

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