

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE
STUDY REPORT FOR YEAR 2004 - 2005**

5TH LIST

Bil.(85)dlm.BPFK/007/3.7(18/03/2004)

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.	Stavudine	i) Virostav Capsules 30mg (MAL20033354AZ)	Ranbaxy (Malaysia) Sdn Bhd, Malaysia	01/06/04	31/12/04	30/06/05
		ii) Virostav Capsules 40mg (MAL20033355AZ)	Ranbaxy (Malaysia) Sdn Bhd, Malaysia			
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2008 – 23 July 2008'				
2.	Nevirapine	i) Viramune Tablet 200mg (MAL19992680AZ)	Boehringer Ingelheim Ellas A.E, Greece	01/06/04	31/12/04	30/06/05
		This product can be obtained from Taiwan, Hong Kong, Singapore, Thailand, Germany, Serbia, Switzerland, Saudi Arabia, South Africa, Kenya, Oman, Israel, Turkey, Botswana, Zimbabwe, Germany, Bosnia And Herzegovina, Kazakhstan, Namibia, Cyprus, Slovakia, Iceland, Greece, Portugal, Spain, Austria, Italy, France, Luxembourg, Belgium, Netherlands, Ireland, United Kingdom, Sweden, Finland, Denmark, Norway, Latvia, Malta and Liechtenstein. (Information obtained from Boehringer Ingelheim (M) Sdn Bhd via an email dated 28 June 2016)				

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
3.	Ritonavir	i) Norvir Sec 100mg (MAL20001246ACRZ)	Catalent Pharma Solutions, LLC, United States	01/06/04	31/12/04	30/06/05
		ii) Norvir Tablet 100mg (MAL13015040AZ)	Cardinal Health 409 Inc, United States			
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2008 – 23 July 2008'				
4.	Ciprofloxacin	i) Ciprobay Tablet 250mg (MAL19890115AZ)	Bayer Healthcare AG, Germany	01/06/04	31/12/04	30/06/05
		ii) Ciprobay Tablet 500mg (MAL19890626AZ)	Bayer Healthcare AG, Germany			
		iii) Ciprobay Tablet 750mg (MAL19890627A)	Bayer AG, West Germany			
5.	Ofloxacin	i) Tarivid Tablet 100mg (MAL19890577AZ)	Daiichi Sankyo Propharma Co. Ltd, Shizuoka Plant, Japan	01/06/04	31/12/04	30/06/05
6.	Clarithromycin	i) Klacid 250mg Tablet (MAL19940216A)	Abbott S.P.A., Italy	01/06/04	31/12/04	30/06/05
		ii) Klacid Tablet 500mg (MAL19984348ACZ)	Aesica Queenborough Limited, United Kingdom			

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
			Abbott Labs Ltd, United Kingdom			
7.	Metformin	i) Glucophage 500 mg Tablet (MAL19992047ASZ) ii) Glucophage 850 mg Tablet (MAL19992048ASZ) iii) Glucophage 1000 mg Tablet (MAL06021194AZ)	Merck Sante S.A.S, France Merck Sante S.A.S, France Merck Sante S.A.S, France	01/06/04	31/12/04	30/06/05
8.	Glibenclamide	i) Daonil Tablet 5 mg (MAL19870392AZ)	PT. Aventis Pharma, Indonesia	01/06/04	31/12/04	30/06/05
9.	Diltiazem	i) Herbesser Tablet 30mg (MAL19861581AZ) ii) Herbesser 60 Tablet (MAL19890319AZ)	PT Tanabe Indonesia, Indonesia PT Tanabe Indonesia, Indonesia	01/06/04	31/12/04	30/06/05
10.	Salbutamol	i) Ventolin Tablet 4mg (MAL19962831ACRZ)	Aspen Bad Oldesloe GmbH, Germany Glaxo Wellcome GMBH & Co, Germany	01/06/04	31/12/04	30/06/05

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
		ii) Ventolin Tablet 2mg (MAL19961269ACRZ)	Aspen Bad Oldesloe GmbH, Germany			
		iii) Ventolin Rotacaps 200mcg (MAL19870729A)	Glaxo Wellcome GMBH & Co, Germany			
		iv) Ventolin Rotacaps 400mcg (MAL19870730A)	Glaxo Wellcome Operations, United Kingdom			
11.	Rifampicin	i) Rimactane 150 Capsule (MAL19860792AZ)	Novartis Sandoz, India	01/12/04	30/06/05	31/12/05
12.	Sulpiride	i) Dogmatil 50mg Capsule (MAL19930596AZ)	Sanofi Winthrop Industrie, France	01/12/04	30/06/05	31/12/05
		ii) Dogmatil 200mg Tablet (MAL19913453AZ)	Sanofi Winthrop Industrie, France			
13.	Dexamethasone	<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</p> <p>ii) Comparative Dissolution Profile for 3 consecutive batches (Time points : 0, 5, 15, 30 & 45 minutes)</p>				

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	
		This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on BPFK website for more information.					
14.	Verapamil	<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> <ul style="list-style-type: none"> i) Validation Process Report for 3 consecutive batches ii) Comparative Dissolution Profile for 3 consecutive batches (Time points : 0, 5, 15, 30 & 45 minutes) <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on BPFK website for more information.</p>					
15.	Omeprazole	i) Losec Mups 10mg Tablet (MAL19992064AZ) ii) Losec Mups 20mg Tablet (MAL19992065AZ)	AstraZeneca AB, Sweden AstraZeneca AB, Sweden	01/12/04	30/06/05	31/12/05	
		<p>However, as agreed upon in ‘ Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2008 – 04 December 2008 :</p> <p>For Omeprazole tablet, label claim need to state ‘not interchangeable with capsule form’ and for Omeprazole capsule, label claim need to state ‘not interchangeable with tablet form’ (Comparator : Losec 10mg Capsule or Losec 20mg Capsule, manufactured by Astrazeneca AB, Sweden)</p>					

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	
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2014, 15 December 2014, the following products are being added to the existing list of comparator:					
		(i) Omezole 20mg capsule (MAL20000377AZ)	Hovid Berhad				
		(ii) Omilock Capsule 20mg (MAL19993078AZ)	SM Pharmaceutical Sdn Bhd				
		(iii) Probitor 20mg Capsule (MAL09122031AZ)	Lek Pharmaceuticals Slovenia				
		(iv) Romesec Capsule 20mg (MAL19992760AZ)	Ranbaxy (M) Sdn Bhd				
16.	Prednisolone	<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> <ul style="list-style-type: none"> i) Validation Process Report for 3 consecutive batches ii) Comparative Dissolution Profile for 3 consecutive batches (Time points : 0, 5, 15, 30 & 45 minutes) <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on BPFK website for more information.</p>					

Updated on 28/03/2017