

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE
STUDY REPORT FOR YEAR 2000 - 2001**

2ND LIST

Bil (85)dlm.BPFK/007/3.7(14/02/2000)

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.	Enalapril	i) Renitec 10mg Tablet (MAL19940016ARZ)	Merck Sharp & Dohme Ltd, United Kingdom	01/04/2000	31/12/2000	30/06/2001
		ii) Renitec 20mg Tablet (MAL19940017ARZ)	Merck Sharp & Dohme Ltd, United Kingdom			
		iii) Renitec 5mg Tablet (MAL19940015ARZ)	Merck Sharp & Dohme Ltd, United Kingdom			
2.	Lisinopril	i) Zestril 10mg Tablet (MAL19890680AZ)	Astrazeneca, China Astrazeneca UK Ltd, United Kingdom	01/04/2000	31/12/2000	30/06/2001
		ii) Zestril 20mg Tablet (MAL19890681AZ)	Astrazeneca, China Astrazeneca UK Ltd, United Kingdom			
		iii) Zestril 5mg Tablet (MAL19890679AZ)	Astrazeneca, China Astrazeneca UK Ltd, United Kingdom			

3.	Piroxicam	i) Feldene Capsule 10mg (MAL19985517AS) ii) Feldene Capsule 20mg (MAL19985518AS)	Pfizer, France Pfizer, France	01/04/2000	31/12/2000	30/06/2001
		According to circular Bil (51) dlm.BPFK/02/5/1.3, the following generic products have been chosen as new comparators				
		i) Uphaxicam 20 Capsule (MAL19861112AZ) ii) Uphaxicam 10 Capsule (MAL19861109AZ) iii) Felxicam 20 Capsule (MAL19920515AZ) iv) Roxim Capsule 10mg (MAL19950261AZ) v) Roxim Capsule 20mg (MAL19950262AZ) vi) Axcel Piroxicam-10 Capsule (MAL19910832AZ)	Upha Pharmaceutical Mfg. (M) Sdn. Bhd., Malaysia Upha Pharmaceutical Mfg. (M) Sdn. Bhd., Malaysia Hovid Berhad, Malaysia Prime Pharmaceutical Sdn. Bhd., Malaysia Prime Pharmaceutical Sdn. Bhd., Malaysia Kotra Pharma (M) Sdn. Bhd.			

4.	Acyclovir	i) Zovirax Tablet 200mg (MAL19860860A)	The Wellcome Foundation Ltd, UK	01/04/2000	31/12/2000	30/06/2001
		ii) Zovirax Tablet 400mg (MAL19880351A)	The Wellcome Foundation Ltd, UK			
		iii) Zovirax Tablet 800mg (MAL19930258A)	The Wellcome Foundation Ltd, UK			
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 th December 2015, the BE requirement on generic immediate release product containing Acyclovir is re-implemented. This requirement is also applicable for registered products with renewal due date from 1 st July 2017 onwards. The following products are being added to the existing list of comparators:				
i) Acic 200 Tablet (MAL20000724ACZ)	Salutas Pharma, Germany					
ii) Acic 400 Tablet (MAL19986960ACZ)	Salutas Pharma, Germany					
iii) Acic 800 Tablet (MAL19986961ACZ)	Salutas Pharma, Germany					
iv) Acyclovir 200 Stada (MAL19983993AZ)	Stadapharm Gmbh, Germany					
v) Acyclovir 400 Stada (MAL19984318AZ)	Stadapharm Gmbh, Germany					
vi) Ayclovir 800 Stada (MAL19984317AZ)	Stadapharm Gmbh, Germany					
vii) Apo-Acyclovir 200mg (MAL19984321AZ)	Apotex Research Inc, Canada					

		viii) Apo-Acyclovir 400mg (MAL19984322AZ)	Apotex Research Inc, Canada			
		ix) Apo-Acyclovir 800mg (MAL19984323AZ)	Apotex Research Inc, Canada			
		x) Dravyr Tablet 400mg (MAL19983967AZ)	Lisapharm, Italy			
		xi) Medovir 400mg Tablets (MAL09062118AZ)	Medochemie Ltd, Cyprus			

Updated on 28/03/2017