

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE STUDY
REPORT FOR YEAR 2008 - 2009**

7 TH LIST

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.	Atorvastatin	i) Lipitor Tablet 10mg (MAL19985090A) ii) Lipitor Tablet 10mg (MAL20034210ARSZ) iii) Lipitor Tablet 20mg (MAL19985091A) iv) Lipitor Tablet 20mg (MAL20034211ARSZ) v) Lipitor Tablet 40mg (MAL19985092A) vi) Lipitor Tablet 40mg (MAL20034212ARSZ) vii) Lipitor Tablet 80mg (MAL20040226ARZ)	Pfizer Manufacturing Deutschland GmbH., Germany Pfizer Pharmaceutical LLC, United States Godecke GmbH, Germany Pfizer Pharmaceutical LLC, United States Godecke GmbH, Germany Pfizer Pharmaceutical LLC, United States Pfizer Pharmaceutical LLC, United States	01/12/08	01/06/09	31/12/09
		As agreed upon in Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2010 – 8 Disember 2010 : Both parent drug and active metabolite (2-hydroxy-atorvastatin acid) 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.				

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2.	Methotrexate	i) Emthexate Tablet 2.5mg (MAL19920203AZ)	Teva Czech Industries s.r.o. Czech Republic	01/12/08	01/06/09	31/12/09
		ii) Methotrexate Tablet 2.5mg (MAL20000041ACZ)	Pharmachemie B.V, Netherlands Haupt Pharma GMBH,Germany			
As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2013 – 2 September 2013						
3.	Azathioprine	i) Imuran 50mg Tablet (MAL04103439ACZ)	Excella GmbH, Germany	01/12/08	01/06/09	31/12/09
4.	Tacrolimus	i) Prograf Capsule 0.5mg (MAL20031738AZ)	Astellas Ireland Co. Ltd, Ireland	01/12/08	01/06/09	31/12/09
		ii) Prograf Capsule 1mg (MAL19990220AZ)	Astellas Ireland Co. Ltd, Ireland			
		iii) Prograf Capsule 5mg (MAL19990221AZ)	Astellas Ireland Co. Ltd, Ireland			
5.	Sirolimus	i) Rapamune Tablet 1mg (MAL20032403ARZ)	Pfizer Ireland Pharmaceuticals Wyeth Pharma Company, Puerto Rico	01/12/08	01/06/09	31/12/09

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		ii) Rapamune Tablet 2mg (MAL07031064AR)	Wyeth Pharmaceuticals Co., United States			
6.	Mycophenolate Mofetil Mycophenolic Acid	i) Cellcept Capsule 250mg (MAL06030803ARSZ) ii) Cellcept Tablet 500mg (MAL06030804ARSZ) Myfortic 360mg Gastro-Resistant Tablets MAL20040812ARZ Myfortic 180mg Gastro-Resistant Tablets MAL20040811ARZ	Roche S.P.A., Italy Roche S.P.A., Italy Novartis Pharma Stein AG, Switzerland Novartis Pharma Stein AG, Switzerland	01/12/08	01/06/09	31/12/09
7.	Etoposide	i) Vepesid Capsule 50mg (MAL19972952A) ii) Lastet Capsule 50 / MAL19900067AZ iii) Lastet Capsule 100 / MAL19900068AZ	R.P Scherer GMBH & Co. KG, Germany Nippon Kayaku Co. Ltd, Japan Nippon Kayaku Co. Ltd, Japan	01/12/08	01/06/09	31/12/09

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		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2012 – 13 September 2012, Lastet Capsule 50 and Lastet Capsule 100 are being added to the existing list of comparators.				
8.	Flutamide	i) Fugerel Tablet 250mg (MAL19872265A)	Schering Canada Inc, Canada	01/12/08	01/06/09	31/12/09
		ii) FLUTA-cell 250mg Tablets (MAL06021302ACZ)	Rottendorf Pharma GmbH, Germany			
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016 – 16 Jun 2016, FLUTA-cell 250mg Tablet is being added to the existing list of comparator.				
9.	Chlorambucil	i) Leukeran Tablets 2mg (MAL04125474ACZ)	Excella GmbH, Germany	01/12/08	01/06/09	31/12/09
10.	Raloxifene HCl	i) Evista Tablet 60mg (MAL04125481AZ)	Lilly S.A., Spain	01/12/08	01/06/09	31/12/09
11.	Valsartan	i) Diovan 40mg Film-Coated Tablet (MAL06051320A)	Novartis Pharma Stein AG, Switzerland	01/12/08	01/06/09	31/12/09
		ii) Diovan 80mg Film-Coated Tablet (MAL20021002A)	Novartis Pharma Stein AG, Switzerland			

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		iii) Diovan 160mg Film-Coated Tablet (MAL20021003A)	Novartis Pharma Stein AG, Switzerland			
		iv) Diovan 320mg Film-Coated Tablet (MAL07050032ARZ)	Novartis Pharma Stein AG, Switzerland			
		v) Diovan 40mg Film-Coated Tablet (MAL09042429ARSZ)	Novartis Farmaceutica S.A., Spain			
		vi) Diovan 80mg Film-Coated Tablet (MAL09042430ARSZ)	Novartis Farmaceutica S.A., Spain			
		vii) Diovan 160mg Film-Coated Tablet (MAL09042431ARSZ)	Novartis Farmaceutica S.A., Spain			
12.	Irbesartan	i) Aprovel Tablet 75mg (MAL19990970AZ)	Sanofi Winthrop Industrie, France			
		ii) Aprovel Tablet 150mg (MAL19990971AZ)	Sanofi Winthrop Industrie, France	01/12/08	01/06/09	31/12/09
		iii) Aprovel Tablet 300mg (MAL19990972AZ)	Sanofi Winthrop Industrie, France			

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13.	Perindopril	i) Coversyl 2mg Tablet (MAL19900369ARZ)	Les Labs Servier Industrie, France	01/12/08	01/06/09	31/12/09
		ii) Coversyl 4mg Tablet (MAL19900370AZ)	Les Labs Servier Industrie, France			
		iii) Coversyl 4mg Tablet (MAL04103437ACZ)	Kotra Pharma (M) Sdn. Bhd., Malaysia			
		iv) Coversyl 8mg Tablet (MAL05061534AZ)	Les Labs Servier Industrie, France			
		v) Coversyl 8mg Tablet (MAL09062148ACSZ)	Kotra Pharma (M) Sdn. Bhd., Malaysia			
14.	Ramipril	i) Tritace 2.5mg Tablet (MAL19986949AZ)	Sanofi-Aventis S.P.A, Italy	01/12/08	01/06/09	31/12/09
		ii) Tritace 5mg Tablet (MAL19986948AZ)	Sanofi-Aventis S.P.A, Italy			
		iii) Tritace 10mg Tablet (MAL20031929AZ)	Sanofi-Aventis S.P.A, Italy			
15.	Quinapril	i) Accupril 5mg Tablets (MAL19962575A)	Pfizer GmbH, Arzneimittelwerk Godecke, Germany	01/12/08	01/06/09	31/12/09

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		ii) Accupril 10mg Tablets (MAL19962573A)	Pfizer GmbH, Arzneimittelwerk Godecke, Germany			
		iii) Accupril 20mg Tablets (MAL19962574A)	Pfizer GmbH, Arzneimittelwerk Godecke, Germany			
16.	Clopidogrel	i) Plavix Tablet 75mg (MAL19992344AZ)	Sanofi Winthrop Industrie, France	01/12/08	01/06/09	31/12/09
		ii) Plavix Tablet 300mg (MAL10100020AZ)	Sanofi Winthrop Industrie, France			
17.	Valaciclovir	i) Valtrex 250mg Tablet (MAL20020133A)	Glaxo Wellcome Operations UK Ltd, United Kingdom	01/12/08	01/06/09	31/12/09
		ii) Valtrex Tablet 500mg (MAL19962817ARZ)	Glaxo Wellcome S.A, Spain			
18.	Fluconazole	i) Diflucan Capsule 50mg (MAL19913229ACZ)	Fareva Amboise, France Pfizer PGM, France	01/12/08	01/06/09	1/12/09
		ii) Diflucan Capsules 50mg (MAL19984004ASZ)	Pfizer Australia Pty. Ltd, Australia			

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		iii) Diflucan Capsule 100mg (MAL19920034ACZ)	Fareva Amboise, France Pfizer PGM, France			
		iv) Diflucan Capsule 150mg (MAL19913230ACZ)	Fareva Amboise, France Pfizer PGM, France			
		v) Diflucan Capsule 150mg (MAL19984003ASZ)	Pfizer Australia Pty. Ltd, Australia			
19.	Pyrazinamide	i) PZA-CIBA 500mg Tablet (MAL20041254A)	Novartis Bangladesh Ltd, Bangladesh	01/12/08	01/06/09	31/12/09
20.	Isoniazid	i) Isoniazid Tablets 100mg (MAL19961323AZ)	Duopharma (M) Sdn Bhd., Malaysia Pharmaniaga Manufacturing Berhad, Malaysia	01/12/08	01/06/09	31/12/09
		ii) Isoniazid Tablets 400mg (MAL19961322AZ)	Duopharma (M) Sdn Bhd., Malaysia Pharmaniaga Manufacturing Berhad, Malaysia			
As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2009 – 19 Ogos 2009':						

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		For Generic Isoniazid immediate release oral solid dosage form with strength 100mg and 400mg, the above products have been selected as new comparators.				
21.	Topiramate	i) Topamax Tablet 25mg (MAL20013558AZ) ii) Topamax Tablet 50mg (MAL20013560AZ) iii) Topamax Tablet 100mg (MAL20013561AZ) vi) Topamax Tablet 200mg (MAL20013559AZ)	Cilag AG, Switzerland Cilag AG, Switzerland Cilag AG, Switzerland Cilag AG, Switzerland	01/12/08	01/06/09	31/12/09
22.	Alendronate	i) Fosamax 10mg Tablet (MAL19971268AR) ii) Fosamax Tablet 70mg (MAL20013990AR)	Merck Sharp & Dohme (Italia) SPA, Italy Merck Sharp & Dohme (Italia) SPA, Italy	01/12/08	01/06/09	31/12/09
		Fosamax Tablet 70mg can be obtained from Singapore. (Information obtained from Merck Sharp & Dohme (M) Sdn. Bhd dated 8 th January 2016 via an email)				

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23.	Fluvoxamine	i) Luvox 50mg Film Coated Tablet (MAL20021412ACZ)	Mylan Laboratories SAS, France Solvay Pharmaceuticals SAS, France Abbott Healthcare SAS, France	01/12/08	01/06/09	31/12/09
		ii) Luvox 100mg Film Coated Tablet (MAL20021413ACZ)	Mylan Laboratories SAS, France Solvay Pharmaceuticals SAS, France Abbott Healthcare SAS, France			
24.	Fluoxetine	i) Prozac Capsule 20mg (MAL07031127ACSZ)	Patheon France S.A, France	01/12/08	01/06/09	31/12/09
25.	Sertraline	i) Zoloft Tablet 50mg (MAL19971291AZ)	Pfizer Australia Pty Ltd, Australia	01/12/08	01/06/09	31/12/09
		ii) Zoloft Tablet 100mg (MAL19971290A)	Pfizer Pty Ltd, Australia			
		iii) Zoloft Tablet 100mg (MAL19921118A)	Pfizer Ltd, United Kingdom			
		iv) Zoloft Tablet 50mg (MAL19921117A)	Pfizer Ltd, United Kingdom			

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26.	Clozapine	i) Clozaril Tablet 25mg (MAL19992681ARZ)	Novartis Saglik, Turkey Novartis Pharmaceuticals UK Ltd, Horsham, Great Britain.	01/12/08	01/06/09	31/12/09
		ii) Clozaril Tablet 100mg (MAL20000747ARZ)	Novartis Saglik, Turkey Novartis Pharmaceuticals UK Ltd, Horsham, Great Britain.			
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Kajian Bioekuivalens (JKKBE 1/2008) – 23 July 2008 and Drug Control Authority (DCA) at it's 212 meeting (29 January 2009)				

* Amitriptylline and Imipramine have been removed from this list according to circular from DCA : Bil (25) dlm BPFK/PPP/01/03 (10 Mac 2009) 'TAMBAHAN DAN PINDAAN PADA SENARAI KETUJUH KAJIAN BIOEKUIVALENS (BE) BAGI PRODUK GENERIK 'IMMEDIATE RELEASE'

Updated on 28/03/2017