

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE STUDY
REPORT FOR YEAR 2011**

9 TH LIST

Bil (8)dlm.BPFK/PPP/01/03 Jilid 1 (10/01/2011)

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./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
1.	Letrozole	i) Femara 2.5mg Film-Coated Tablet (MAL19973303ARZ)	Novartis Pharma Stein AG, Switzerland	01/07/2011	01/07/2011	01/07/2011
2.	Anagrelide	i) Agrylin 0.5mg Capsules (MAL20051337ACR) ii) Agrylin 0.5mg Capsules (MAL13055062ACRZ)	Mallinckrodt Inc, United States DSM Pharmaceuticals, Inc., United States	01/07/2011	01/07/2011	01/07/2011
3.	Chlorpromazine	i) Largactil Tablet 25mg (PBKD861335A) ii) Largactil Tablet 100mg (PBKD8631345A)	May & Baker Ltd, United Kingdom May & Baker Ltd, United Kingdom	01/07/2011	01/07/2011	01/07/2011
		Products are available in East Europe, Tunisia and Africa. (Information obtained from Sanofi-Aventis (Malaysia) Sdn Bhd through an email dated 19 September 2011) and Australia (According to				

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
		<p>information provided during upon Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013)</p> <p>However, as agreed upon Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013, Largactil® manufactured from other sites which are Sanofi Aventis, Spain and Famar Lyon, France can also be used as the comparator.</p>				
4.	Haloperidol	i) Serenace Tablet 0.5mg (PBKD861361A) ii) Serenace Tablet 1.5mg (PBKD861365A) iii) Serenace Tablet 5mg (PBKD861368A)	Searle Labs, Australia Searle Labs, Australia Searle Labs, Australia	01/07/2011	01/07/2011	01/07/2011
		<p>Products are available in Aruba, Bahrain, Iran, Kuwait, Macau, Oman, Philippines, Qatar, South Africa, UAE (Information obtained from Pfizer through an email dated 14/7/2011)</p> <p>As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: Serenace Tablet from Piramal Healthcare UK Limited & Sigma Australia can also be used as a comparator.</p>				

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
5.	Perphenazine	Trilafon Tablet 2mg (1986043353A)	Schering-Plough Pty. Ltd., Australia	01/07/2011	01/07/2011	01/07/2011
		Trilafon Tablet 4mg (1986043352A)	Schering-Plough Pty. Ltd., Australia			
6.	Trifluoperazine	i) Stelazine Tablet 1mg (PBKD861375A)	Smith Kline & French (Aust) Ltd, Australia	01/07/2011	01/07/2011	01/07/2011
		ii) Stelazine Tablet 5mg (PBKD861379A)	Smith Kline & French (Aust) Ltd, Australia			
		iii) Stelazine Capsule 2mg (MAL19871465A)	Smith Kline & French Labs, United Kingdom			
		Products are available in Singapore (Information obtained during Mesyuarat JKKBE 02/2011)				
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2017”, 24 May 2017, the following product is being added to the existing list of comparator:-				
		i) Apo-Trifluoperazine 5mg (MAL19984755AZ)	Apotex Inc, Canada			

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7.	Aripiprazole	Abilify Tablet 10mg (MAL07021401ARS)	Otsuka Pharmaceutical Co Ltd., Japan	01/07/2011	01/07/2011	01/07/2011
		Abilify Tablet 15mg (MAL07021403ARS)	Otsuka Pharmaceutical Co Ltd., Japan			
		Abilify Tablets 10mg (MAL05023433AR)	Bristol-Myers Squibb Manufacturing Company, United States			
		Abilify Tablets 15mg (MAL05023434AR)	Bristol-Myers Squibb Manufacturing Company, United States			
		Products are available in Singapore, Australia and New Zealand (Information obtained through an email from Bristol-Myers Squibb, Korea dated 22/6/2011)				
8.	Olanzapine	i) Zyprexa 5mg Tablet (MAL19986933AZ)	Lilly Del Caribe Inc., Puerto Rico Basingstoke UK	01/07/2011	01/07/2011	01/07/2011
		ii) Zyprexa Tablet 5mg (MAL08061564ARSZ)	Lilly S.A., Spain			

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
		iii) Zyprexa 10mg Tablet (MAL19986935AZ)	Lilly Del Caribe Inc., Puerto Rico			
			Basingstoke UK			
		iv) Zyprexa Tablet 10mg (MAL08061565ARSZ)	Lilly S.A., Spain			
		v) Zyprexa Tablet 15mg (MAL04125528AR)	Lilly Del Caribe Inc., United States			
		vi) Zyprexa Tablet 20mg (MAL04125532AR)	Lilly Del Caribe Inc., United States			
		Products are available in Canada, USA, Denmark and Sweden (Information obtained from Eli Lilly dated 23rd January 2013 via email)				
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013, 2 nd September 2013, the following products are being added to the existing list of comparator:				

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
		i) Oleanz 5 Tablet (MAL10100139AZ) ii) Oleanz 10 Tablet (MAL10100143AZ) iii) Olenza 5mg Tablet (MAL10100149AZ) iv) Olenza 10mg Tablet (MAL10100148AZ)	Sun Pharmaceutical, India Sun Pharmaceutical, India Noripharma Sdn. Bhd. Noripharma Sdn. Bhd.			
9	Quetiapine	i) Seroquel Tablet 25mg (MAL20000261AZ) ii) Seroquel Tablet 100mg (MAL20000262AZ) iii) Seroquel Tablet 200mg (MAL20000263AZ) iv) Seroquel Tablet 300mg (MAL06041484AZ)	Astra Zeneca Pharmaceutical Co. Ltd., China Astra Zeneca Pharmaceutical Co. Ltd., China Astra Zeneca Pharmaceutical Co. Ltd., China Astra Zeneca Pharmaceutical Co. Ltd., China	01/07/2011	01/07/2011	01/07/2011

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10.	Ziprasidone	i) Zeldox Capsule 20mg (MAL20032622A)	Pfizer Australia Pty Ltd, Australia	01/07/2011	01/07/2011	01/07/2011
		ii) Zeldox Capsule 40mg (MAL20032623AZ)	Pfizer Australia Pty Ltd, Australia			
		iii) Zeldox Capsule 60mg (MAL20032624AZ)	Pfizer Australia Pty Ltd, Australia			
		iv) Zeldox Capsule 80mg (MAL20032625AZ)	Pfizer Australia Pty Ltd, Australia			
11.	Citalopram	i) Cipram Tablets 10mg (MAL19950393A)	H. Lundbeck A/S, Denmark	01/07/2011	01/07/2011	01/07/2011
		ii) Cipram Tablets 20mg (MAL19950394AZ)	H. Lundbeck A/S, Denmark			
		iii) Cipram Tablets 40mg (MAL19950392A)	H. Lundbeck A/S, Denmark			
12.	Escitalopram	i) Lexapro 5mg Tablet (MAL20041159AZ)	H. Lundbeck A/S, Denmark	01/07/2011	01/07/2011	01/07/2011
		ii) Lexapro 10mg Tablet (MAL20041160AZ)	H. Lundbeck A/S, Denmark			

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		iii) Lexapro 15mg Tablet (MAL20041161AZ)	H. Lundbeck A/S, Denmark			
		iv) Lexapro 20mg Tablet (MAL20041162AZ)	H. Lundbeck A/S, Denmark			
13.	Paroxetine	i) Seroxat 20mg Tablet (MAL19930146A)	Glaxo Wellcome Production, France	01/07/2011	01/07/2011	01/07/2011
		Product is available in Hong Kong, Thailand and Philippines (Information obtained via an email from GSK dated 5th October 2015)				
14.	Duloxetine	i) Cymbalta Capsule 30mg (MAL05092473AZ)	Lilly del Caribe Inc., Puerto Rico Lilly S.A, Spain	01/07/2011	01/07/2011	01/07/2011
		ii) Cymbalta Capsule 60mg (MAL05092474AZ)	Lilly del Caribe Inc., Puerto Rico Lilly S.A, Spain			
15.	Venlafaxine	i) Efexor Tablets 37.5mg (MAL19973300A)	Wyeth Canada, Canada	01/07/2011	01/07/2011	01/07/2011

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
		ii) Efexor Tablets 50mg (MAL19973301A)	Wyeth Canada, Canada			
		iii) Efexor Tablets 75mg (MAL19973302A)	Wyeth Canada, Canada			
		<p>Products are available from Ireland, Italy, Spain, Malta, Ireland, France (Information obtained through an email from Pfizer Malaysia dated 3rd October 2012)</p> <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on NPRA website for more information.</p>				
16.	Mirtazapine	i) Remeron 15mg Tablet (MAL19990905A)	N.V. Organon, Netherlands			
		ii) Remeron 30mg Tablet (MAL19990903A)	N.V. Organon, Netherlands	01/07/2011	01/07/2011	01/07/2011
		iii) Remeron 45mg Tablet (MAL19990904A)	N.V. Organon, Netherlands			
17.	Imipramine	i) Tofranil Tablet 25mg (PBKD861457A)	Novartis Pharma Stein AG., Switzerland	01/07/2011	01/07/2011	01/07/2011

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		<p>Product is available in Afghanistan, Argentina Aruba, Bahrain, Bangladesh, Bolivia, Brazil, Cameroon, Colombia, Costa Rica, Curacao, Dominican Republic, El Salvador Ethiopia, Guatemala, Honduras, Indonesia, Iraq, Israel, Jamaica, Jordan, Kenya, Kuwait, Madagascar, Mauritius, Mexico, Nicaragua, Oman, Pakistan, Palestine, Palestine, Panama, Paraguay, Qatar, Saudi Arabia, Senegal, Sudan, Switzerland, Trinidad and Tobago, Turkey, United Arab Emirates, Uruguay, Venezuela, Yemen, Zambia, Zimbabwe (Information obtained through an email from Novartis Malaysia dated 13/7/2011)</p> <p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 December 2015, this active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on NPRA website for more information.</p>				
18.	Maprotiline	i) Ludiomil 25mg Tablets (MAL20001251A) ii) Ludiomil Tablet50mg (MAL19861465A)	Novartis Urunleri, Turkey Novartis Farmaceutica S.A., Spain	01/07/2011	01/07/2011	01/07/2011

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19.	Nortriptyline	i) Nortrilen Tablet 10mg (PBKD1986043197A)	H. Lundbeck A/S., Denmark	01/07/2011	01/07/2011	01/07/2011
		ii) Nortrilen Tablet 25mg (PBKD861452A)	H. Lundbeck A/S., Denmark			
		<p>Products are available in Belgium, Czee Republic, Iceland, Italy, Germany, Denmark, Estonia, Hong Kong, Finland, Latvia, Lithuania, Luxemburg, Malta, Netherland, Norway, Saudi Arabia, Sweden, Switzerland (Information obtained through a letter from IDS Services (M) Sdn Bhd dated 25/8/2011)</p> <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information.</p>				
20.	Pregabalin	i) Lyrica 75mg Capsules (MAL20081831AZ)	Pfizer manufacturing Deutschland GmbH., Germany	01/07/2011	01/07/2011	01/07/2011
		ii) Lyrica 50mg Capsules (MAL20081830AZ)	Pfizer manufacturing Deutschland GmbH., Germany			
		iii) Lyrica 150mg	Pfizer manufacturing			

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
		Capsules (MAL20081832AZ)	Deutschland GmbH., Germany			
21.	Diazepam	i) Valium Roche Tablet 2mg (PBKD861254A) ii) Valium Roche Tablet 5mg (PBKD861263A) iii) Valium Roche Tablet 10mg (PBKD861274A)	F. Hoffman-La Roche., Switzerland F. Hoffman-La Roche., Switzerland F. Hoffman-La Roche., Switzerland	01/07/2011	01/07/2011	01/07/2011
		As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2013 – 13 March 2013: Valium Tablet from France, USA & Spain can also be used as a comparator.				
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014, 23 April 2014, the following products are being added to the existing list of comparator:				
		i)Diazepam 10mg Tablet (MAL19860207AZ)	Idaman Pharma Manufacturing Sdn Bhd, Malaysia			

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		ii) Diazepam 5mg Tablet (MAL19860211AZ)	Idaman Pharma Manufacturing Sdn Bhd, Malaysia			
22.	Nitrazepam	i) Mogadon 5mg Tablets (MAL06091378ACR)	Labiana Pharmaceuticals SL, Spain	01/07/2011	01/07/2011	01/07/2011
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 December 2015: This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <u>biowaiver page</u> on NPRA website for more information.				
23.	Zolpidem	i) Stilnox 10mg Film Coated Tablet (MAL19940650AZ)	Sanofi Winthrop Industrie, France	01/07/2011	01/07/2011	01/07/2011
24.	Chlordiazepoxide	i) Librium Roche Dragee 5mg (PBKD861319A)	F. Hoffman-La Roche., Switzerland	01/07/2011	01/07/2011	01/07/2011
		ii) Librium Roche Dragee 10mg (PBKD861317A)	F. Hoffman-La Roche., Switzerland			

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		Trade Mark/Registration No./ Reference No.	Manufacturer	New Application	Imported Products	Local Products
		<p>Products are available in United States of America (Information obtained through an email from Inova Pharma dated 27/12/2012)</p> <p>This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on NPRA website for more information.</p>				
25.	Alprazolam	i) Xanax Tablet 0.25mg (MAL05121165ACRSZ)	Sanico N.V., Belgium	01/07/2011	01/07/2011	01/07/2011
		ii) Xanax Tablet 0.5mg (MAL05121161ACRSZ)	Sanico N.V., Belgium			
		iii) Xanax Tablet 1mg (MAL05121166ACRSZ)	Sanico N.V., Belgium			
		iv) Xanax 0.5mg Tablets (MAL20021408A)	Pfizer Manufacturing Belgium NV			
		v) Xanax Tablet 0.25mg (MAL19861297A)	Pfizer Manufacturing Belgium NV			
		vi) Xanax 1.0mg Tablets (MAL20021409A)	Pfizer Manufacturing Belgium NV			

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		vii) Xanax Tablet 0.25MG (MAL19861296A)	Pfizer Pharmaceuticals LLC, Puerto Rico			
		viii) Xanax Tablet 1mg (MAL19861299A)	Pfizer Pharmaceuticals LLC, Puerto Rico			
		ix) Xanax Tablet 0.5mg (MAL19861301A)	Pfizer Pharmaceuticals LLC, Puerto Rico			
26.	Lorazepam	i) Ativan Tablet 0.5mg (MAL19871462A)	Wyeth Pharma GmbH, West Germany	01/07/2011	01/07/2011	01/07/2011
		ii) Ativan 0.5mg Tablet (MAL19991388A)	Wyeth Medica Ireland, Ireland			
		iii) Ativan 1mg Tablet (MAL19991389A)	Wyeth Medica Ireland, Ireland			
		Products are available in Europe . (Information obtained through an email from Pfizer Malaysia dated 12/7/2011)				
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2013, 2 nd December 2013, the following product is being added to the existing list of comparator:-				

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		Apo-Lorazepam Tablet 1mg (MAL19984741ARZ)	Apotex Inc, Canada			
27.	Bromazepam	i) Lexotan Roche Tablet 1.5mg (MAL19861302ARZ)	Roche S.P.A., Italy	01/07/2011	01/07/2011	01/07/2011
28.	Clobazam	i) Frisium Tablet 10mg (MAL19861330AZ)	Sanofi Winthrop Industrie, France	01/07/2011	01/07/2011	01/07/2011
29.	Zopiclone	i) Imovane Tablet 7.5mg (MAL19900140AZ)	Sanofi Winthrop Industrie, France	01/07/2011	01/07/2011	01/07/2011

*Note:

1) Bioequivalence study requirement is also applied for Fixed Dose Combination product which contains the listed active substance as above.

Updated on 08/08/2017