

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
**(MARCH 2017)**

Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
1.	<b>Abiraterone acetate</b>	ZYTIGA 250MG TABLET MAL12085056ACRZ	PATHEON INC, CANADA
2.	<b>Acarbose</b>	GLUCOBAY TABLET 50MG MAL19940745AZ  GLUCOBAY TABLET 100MG MAL19940746AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
3.	<b>Acebutolol hydrochloride</b>	SECTRAL CAPSULE 100MG (MAL19870251A)  SECTRAL CAPSULE 200MG (MAL19870052A)  SECTRAL TABLET 400MG (MAL19870053A)	MAY & BAKER LTD, MAY & BAKER LTD, DAGENHAM, ESSEX, RM107XS, ENGLAND
		SECTRAL 200MG CAPSULE MAL19920620A	RHONE-POULENC RORER, JL LAWANG GINTUNG, BOGUR, WEST JAVA, INDONESIA
4.	<b>Acemetacin</b>	RANTUDIL CAPSULE 60MG (MAL19986936A)	BAYER AG, WEST GERMANY
		RANTUDIL RETARD 90MG CAPSULE (MAL19992054AZ)	BAYER SCHERING PHARMA AG, GERMANY
5.	<b>Acipimox</b>	OLBETAM CAPSULE 250 MG (MAL19900589A)	PHARMACIA S.P.A, ITALY
6.	<b>Acitretin</b>	NEOTIGASON CAPSULE 10 MG (MAL06091392ACZ)  NEOTIGASON CAPSULE 25 MG (MAL06091393ACZ)	PATHEON INC, CANADA
		NEOTIGASON HARD GELATIN CAPSULE 10MG (MAL19921411A)  NEOTIGASON HARD GELATIN CAPSULE 25* (MAL19921412A)	ROCHE PRODUCTS LTD, UNITED KINGDOM
7.	<b>Acrivastine</b>	SEMPREX CAPSULE 8MG (MAL19900013A)	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM

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		Trade Mark/Registration No./ Reference No.	Manufacturer
8.	<b>Adefovir</b>	HEPSERA TABLET 10MG MAL20040907ARZ	GLAXOSMITHKLINE (TIANJIN) CO. LTD., CHINA
9.	<b>Aliskiren Hemifumarate</b>	RASILEZ 150MG FILM-COATED TABLET MAL20081730ARZ  RASILEZ 300MG FILM-COATED TABLET MAL20081731ARZ	NOVARTIS PHARMA S.P.A, VIA PROVINCIALE SCHITO 131, 80058 TORRE ANNUNZIATA (NA), ITALY
10.	<b>Allopurinol</b>	ZYLORIC 100MG TABLETS MAL19973571AZ  ZYLORIC TABLET 300MG MAL19972499AZ	ASPEN PORT ELIZABETH (PTY) LTD CNRS FAIRCLOUGH ROAD AND GIBAUD ROAD, KORSTEN PORT ELIZABETH, 6020 REPUBLIC OF SOUTH AFRICA, SOUTH AFRICA.
This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.			
11.	<b>Alverin citrate</b>	SPASMAVERINE TABLET 0.04G MAL19871806A	LABORATOIR BELLON, FRANCE
This product can be obtained from <b>Vietnam &amp; Cambodia</b> (Information obtained from Sanofi Aventis (M) Sdn. Bhd dated 29 <sup>th</sup> November 2013 via an email)			
12.	<b>Amantadine hydrochloride</b>	SYMMETREL SOFT GELATIN CAPSULE 100* 1986040644A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
13.	<b>Amantadine sulphate</b>	PK-MERZ TABLET 100MG MAL19860850AZ	MERZ PHARMA GMBH & CO. KGAA,GERMANY
14.	<b>Ambrisentan</b>	VOLIBRIS 5 MG FILM COATED TABLET MAL20102008ACRZ  VOLIBRIS 10 MG FILM COATED TABLET MAL20102009ACRZ	PATHEON INC. CANADA
15.	<b>Amiodarone hydrochloride</b>	CORDARONE 200MG MAL19987968ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE
16.	<b>Amisulpride</b>	SOLIAN 100MG SCORED TABLET MAL20032239AZ	SANOFI WINTHROP INDUSTRIE, FRANCE

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		SOLIAN 400MG SCORED FILM-COATED TABLET MAL20032240AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
17.	<b>Amodiaquine</b>	CAMOQUIN	PFIZER, UNITED KINGDOM
18.	<b>Anastrozole</b>	ARIMIDEX TABLET 1MG MAL19987960ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
19.	<b>Aprepitant</b>	EMEND 80MG CAPSULE MAL20040905AR  EMEND 125MG CAPSULE MAL20040906AR	MERCK SHARP & DOHME CORP.*, UNITED STATES
20.	<b>Atomoxetine</b>	STRATTERA 60MG CAPSULE MAL20051406AZ  STRATTERA 40MG CAPSULES MAL20051405AZ  STRATTERA 25MG CAPSULES MAL20051404AZ  STRATTERA 18MG CAPSULES MAL20051403AZ  STRATTERA 10MG CAPSULES MAL20051402AZ	LILLY S.A, MADRID, SPAIN
21.	<b>Baclofen</b>	LIORESAL 10MG TABLET MAL20000748ACRZ	NOVARTIS FARMA S.P.A., ITALY
22.	<b>Benfluorex</b>	MEDIAXAL TABLET 150MG MAL19870176A	LES LABS SERVIER INDUSTRIE, FRANCE
23.	<b>Benzhexol</b>	ARTANE TABLET 2MG PBKD861498A  ARTANE TABLET 2MG PBKD861497A	AMERICAN CYANAMID CO, UNITED STATES CYANAMID OF GREAT BRITAIN, UNITED KINGDOM
		This product can be obtained from <b>Nagoya, Japan</b> (Information updated from Pfizer on 25 <sup>th</sup> January 2013 via a letter)	
24.	<b>Benztropine mesylate</b>	COGENTIN TABLET 2MG MAL19870343AR	MERCK SHARP & DOHME INT, UNITED STATES

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25.	<b>Betahistine dihydrochloride</b>	BETASERC 24MG TABLET MAL07061394AZ  BETASERC 16MG TABLETS MAL19972468AZ	ABBOTT HEALTHCARE SAS, FRANCE
		Betaserc 16mg tablets (MAL19972468AZ) can be obtained from the following countries:- Argentina, Armenia, Australia, Azerbaijan, Bahrain, Belarus, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, Germany, Guatemala, Honduras, Hong Kong, India, Israel, Jordan, Kazakhstan, Kuwait, Lebanon, Mexico, Moldova, Nicaragua, Oman, Pakistan, Panama, Philippines, Qatar, Russian Federation, Saudi Arabia, Singapore, South Africa, Sri Lanka, Thailand, Turkey, Turkmenistan, Ukraine, United Arab Emirates, Uruguay, Uzbekistan, Venezuela, Vietnam, Yemen, Kyrgyzstan, Macau (Email dated 8 July 2015 from Abbott (M) Sdn Bhd)	
26.	<b>Betahistine mesylate</b>	MERISLON TABLET 6MG MAL19861236AZ	EISAI CO LTD, JAPAN
27.	<b>Betaxolol</b>	KERLONE TABLET 20MG MAL19872264AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
28.	<b>Bicalutamide</b>	CASODEX TABLET 50MG MAL19990958ACRZ  CASODEX 150MG TABLET MAL20040082AR	CORDEN PHARMA GMBH, GERMANY.  ASTRAZENECA GMBH , GERMANY
29.	<b>Bisoprolol fumarate</b>	CONCOR 2.5MG FILM COATED TABLET MAL20020792AZ  CONCOR 5 FILM COATED TABLET MAL19890389AZ  CONCOR 10 FILM-COATED TABLET MAL19890390AZ	MERCK KGAA, GERMANY
30.	<b>Bosentan monohydrate</b>	TRACLEER TABLET 62.5 MG MAL20041084ACRZ  TRACLEER TABLET 125 MG MAL20041085ACRZ	PATHEON INC., CANADA

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31.	<b>Brompheniramine maleate</b>	DIMETANE TABLET 4MG 1986041234A	A.H.ROBINS PTY LTD, AUSTRALIA
32.	<b>Bumetanide</b>	BURINEX TABLET 1MG MAL19913216AZ	LEO PHARM PRODUCTS, DENMARK
33.	<b>Busulphan</b>	MYLERAN TABLETS 2MG MAL05051050ACZ	EXCELLA GMBH, GERMANY
34.	<b>Butropium bromide</b>	COLIOPAN TABLET 5MG MAL19910111ACZ	BORA PHARMACEUTICALS CO., LTD, TAIWAN  EISAI TAIWAN INC, TAIWAN
35.	<b>Cabergoline</b>	DOSTINEX TABLET 0.5MG MAL19971775AZ	PFIZER ITALIA S.R.L., ITALY
36.	<b>Candesartan Cilexetil Tablet</b>	ATACAND TABLET 8MG MAL20001218ARZ  ATACAND TABLET 16MG MAL20001219ARZ  ATACAND TABLET 4MG MAL20001217A  ATACAND TABLET 32MG MAL09042471A  BLOPRESS TABLET 8MG MAL20002652ARZ  BLOPRESS TABLET 16MG MAL20002653AZ	ASTRAZENECA AB, SWEDEN  ASTRAZENECA AB, SWEDEN  ASTRAZENECA AB, SWEDEN  ASTRAZENECA AB, SWEDEN  TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN  TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
37.	<b>Capecitabine</b>	XELODA TABLET 150MG MAL20000001ARZ  XELODA TABLET 500MG MAL20000002ARZ	PRODUCTOS ROCHE S.A DE C.V, MEXICO

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38.	<b>Carbimazole</b>	NEOMERCAZOLE TABLET 5 MG MAL05092230AC	APTUIT (EDINBURGH) LIMITED, UNITED KINGDOM
		NEOMERCAZOLE® TABLET 5 MG MAL12020025ACZ	CENEXI SAS, FRANCE
<p><b>Neomercazole (MAL12020025ACZ) can be obtained from Denmark, Bahrain, Cyprus, Kenya, Malaysia, Mauritius, Morocco, Norway, Oman, Philippines, Qatar, Senegal, South Africa, Sudan, UAE, UK, New Zealand, Australia, Yemen, Jamaica, Trinidad &amp; Tobago, Kuwait, Hong Kong, Saudi Arabia, Ireland. (Information obtained from Manarini Singapore Pte Ltd via an email dated 16th March 2015)</b></p>			
39.	<b>Cefaclor</b>	DISTACLOR CAPSULE 250MG MAL19962114A	ELI LILLY & CO (TAIWAN) INC, TAIWAN
		DISTACLOR CAPSULE 500MG MAL19962115A	
<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 December 2015:</p> <p>i) DISTACLOR 250MG from <b>Lilly Suzhou Pharmaceutical Co, Ltd</b> No. 6 Baiyu Road, Suzhou Industrial Park, Jiangsu Province, <b>China</b></p> <p>ii) DISTACLOR 500MG from <b>Vianex S.A, (Factory D)</b> VI.PE Patras 250 18 Ag. Stefanos, <b>Greece</b></p> <p>can also be used as a comparator. It can be obtained from Greece and China. Distaclor is sold in China and Greece under the brand name of Ceclor Capsule (Information obtained from Eli Lilly via an email dated 23 Jun 2016).</p>			
40.	<b>Cefadroxil monohydrate</b>	DURICEF CAPSULE 500MG MAL19860523A	BRISTOL-M BARCELONETA INC, PUERTO RISO, UNITED STATES
		DURICEF TABLET 1GM MAL19940665A	
<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: DURICEF CAPSULE AND</p>			

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		TABLET from <b>Corden Pharmaceuticals Italy</b> can also be used as a comparator. It can be obtained from Belgium, Luxembourg, Bulgaria, Czech Rep, Estonia, Lithuania, Latvia, and Poland and is sold under the brand name of Duracef (Information obtained from Valeant Pharmaceuticals via an email dated 5 Jan 2017).	
41.	<b>Cefdinir</b>	OMNICEF CAPSULE 100MG MAL19991688AC	UPHA PHARMACEUTICAL MFG. (M) SDN BHD, MALAYSIA
42.	<b>Cefixime</b>	SUPRAX TABLET	LEDERLE
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 <sup>th</sup> December 2015: SUPRAX TABLET from <b>Famar Lyon, France</b> and <b>Merck Pharma, Spain</b> can be used as a comparator. It can be obtained from United Kingdom and Canada. (Information obtained from Sanofi via an email dated 26 November 2015)	
43.	<b>Cefprozil</b>	PROCEF TABLET 250MG MAL19940487A  PROCEF TABLET 500MG MAL19940483A	BRISTOL-M BARCELONETA INC, UNITED STATES
44.	<b>Ceftibuten</b>	CEDAX CAPSULE 200MG MAL19950228A  CEDAX CAPSULE 400MG MAL19950227AZ	SIFI S.P.A., ITALY & MERCK SHARP & DOHME CORP, UNITED STATES (As approved by DCA 273, February 2014)
45.	<b>Celecoxib</b>	CELEBREX CAPSULE 100MG MAL20000004ARZ  CELEBREX CAPSULE 200MG MAL20000005ARZ  CELEBREX 400MG CAPSULES MAL08051748ARZ	PFIZER PHARMACEUTICAL LLC, KM1.9 ROAD 689, VEGA BAJA, PUERTO RICO 00693, USA
		Celebrex Capsule 100mg can be obtained from Greece, Spain, Italy, Sweden, France, Norway, Finland, Brazil, Hong Kong, New Zealand, Philippines, Indonesia, Japan, Canada and United States. (Information obtained from Pfizer via an email dated 21 September 2015)	
46.	<b>Cephradine</b>	VELOSEF CAPSULE 500MG MAL19920468A	BRISTOL-MYERS SQUIBB AEBE, GREECE
47.	<b>Ciprofibrate</b>	MODALIM TABLET 100MG MAL19950391AZ	PT AVENTIS PHARMA, INDONESIA

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48.	<b>Chloroquine sulphate</b>	NIVAQUINE TABLET 200MG MAL19912313A	MAY & BAKER LTD, UNITED KINGDOM
49.	<b>Chloroquine phosphate</b>	SERVIQUIN TABLET 250MG MAL19910558X	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		This active ingredient has been granted biowaiver List B based on unavailability/ inaccessibility of comparator/ innovator product. Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.	
50.	<b>Chlorothiazide</b>	CHLOTRIDE TABLET 500MG 1986040263A	MERCK SHARP & DOHME INT, UNITED STATES
51.	<b>Chlorpropamide</b>	DIABENESE TABLET 250MG MAL19986461A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		DIABINESE TABLET 250MG MAL19870382A	PFIZER PHARM DIV., PHILIPINES
52.	<b>Chlortetracycline</b>	AUREOMYCIN CAPSULE 250MG MAL19871950A	INTERTHAI PHARMACEUTICAL MANUFACTURING LTD, THAILAND
53.	<b>Cilostazol</b>	PLETAAL 50MG TABLETS MAL20061476AZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, KOREA
		PLETAAL 100MG TABLETS MAL20061475AZ	
54.	<b>Cinnarizine</b>	STUGERON 25MG TABLET MAL19871481AZ	JANSSEN CILAG SPA, ITALY
55.	<b>Clemastine fumarate</b>	TAVEGYL TABLET 1MG PBKD861195A	NOVARTIS PHARMA AG, SWITZERLAND
56.	<b>Clodronate</b>	OSTAC CAPSULE 1989120003A	ROCHE DIAGNOSTICS GMBH, GERMANY
57.	<b>Clomiphene Citrate</b>	CLOMID TABLET 50MG MAL19950686AZ	PATHEON FRANCE S.A., FRANCE
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2016 – 16 Jun 2016: Both isomers (enclomiphene and zuclophene) need to be measured and analysed in BE study. However, BE study conducted earlier and analysis was only done on clomiphene, the report can still be considered for evaluation.	
58.	<b>Clonazepam</b>	RIVOTRIL ROCHE TABLET 0.5MG MAL19860961ARZ	ROCHE FARMA S.A., SPAIN
		RIVOTRIL ROCHE TABLET 2MG MAL19860962ARZ	
59.	<b>Clonidine</b>	DIXARIT TABLET 25MCG MAL19870080A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY.
		DIXARIT SUGAR-COATED	BOEHRINGER INGELHEIM



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		Trade Mark/Registration No./ Reference No.	Manufacturer
		TABLET 0.025MG MAL19986979A	FRANCE, FRANCE.
		CATAPRES TABLET 0.15MG MAL19861621A	BOEHRINGER INGELHEIM LTD, SOUTH KOREA
60.	<b>Clorazepate dipotassium</b>	TRANXENE CAPSULE 5MG PBKD861331AR	SANOFI WINTHROP INDUSTRIE, FRANCE
		TRANXENE CAPSULE 10MG PBKD861332AR	
61.	<b>Conjugated Oestrogen</b>	PREMARIN TABLET 0.625MG MAL19870652AZ	PFIZER IRELAND PHARMACEUTICALS IRELAND
		PREMARIN 0.3 TABLET MAL19991386ASZ	
62.	<b>Crizotinib</b>	XALKORI 200MG HARD CAPSULES MAL12095102AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
63.	<b>Cycloserine</b>	CYCLOSERINE CAPSULE BP 250MG MAL19900001A	ELI LILLY AND COMPANY LIMITED, UNITED KINGDOM
64.	<b>Cyproterone acetate</b>	ANDROCUR 50MG TABLET MAL19993023ARZ	DELPHARM LILLE S.A.S., FRANCE BAYER WEIMAR GMBH, GERMANY
65.	<b>Dabigatran Etextilate Mesilate</b>	PRADAXA 150MG, HARD CAPSULES MAL20112114AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		PRADAXA 110MG, HARD CAPSULE MAL20091869AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		PRADAXA 75MG, HARD CAPSULE MAL20091868AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
66.	<b>Daclatasvir dihydrochloride</b>	DAKLINZA 30MG FILM-COATED TABLETS MAL16045046ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES

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		DAKLINZA 60MG FILM-COATED TABLETS MAL16045037ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
67.	<b>Danazol</b>	LADOGAL CAPSULE 50MG PBKD870433A  LADOGAL CAPSULE 100MG PBKD870434A  LADOGAL CAPSULE 200MG PBKD870435A  LADOGAL CAPSULE 200MG MAL19987969A  LADOGAL CAPSULE 100MG MAL19987970A	NYCOMED PUERTO RICO INC, SPAIN    SANOFI-SYNTHELABO LTD, UNITED KINGDOM  SANOFI-SYNTHELABO LTD, UNITED KINGDOM
Product is available in <b>Taiwan &amp; Philliphines</b> (Information obtained via an email from Sanofi Aventis (M) Sdn. Bhd dated 22 May 2013)			
As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2015, 21 April 2015: Anagril Capsule 100mg (MAL19890682A) and Anagril Capsule 200mg (MAL19871961A) are being added to the existing list of comparator.			
		ANARGIL CAPSULE 100MG (MAL19890682AZ)  ANARGIL CAPSULE 200MG (MAL19871961AZ)	MEDOCHEMIE LTD CYPRUS  MEDOCHEMIE LTD CYPRUS
68.	<b>Dapoxetine Hydrochloride</b>	PRILIGY 30MG FILM COATED TABLETS MAL20102027AZ  PRILIGY 60MG FILM COATED TABLETS MAL20102028AZ	MENARINI- VON HEYDEN GMBH, LEIPZIGER STRASSE 7-13, 01097 DRESDEN, FEDERAL REPUBLIC OF GERMANY
69.	<b>Dasatinib</b>	SPRYCEL 20MG TABLET MAL20071695AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

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		SPRYCEL 50MG TABLET MAL20071696AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		SPRYCEL 70MG TABLET MAL20071697AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
70.	<b>Deferiprone</b>	FERRIPROX 500MG TABLET MAL20033480ACZ	APOTEX INC CANADA
71.	<b>Desogestrel</b>	CERAZETTE TABLET MAL20031939AZ	N.V ORGANON, NETHERLAND
72.	<b>Desloratadine</b>	AERIUS TABLET MAL20020876ARZ	SCHERING PLOUGH SPA, ITALY
		AERIUS TABLET 5MG MAL10053655A\$Z	SCHERING-PLOUGH LABO N.V., BELGIUM
73.	<b>Desmopressin</b>	MINIRIN TABLET 0.1MG MAL19950096ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND
		MINIRIN TABLET 0.2MG MAL19950097ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND
74.	<b>Dexketoprofen trometamol</b>	KETESSE 25MG FILM COATED TABLET MAL20061602AZ	A. MENARINI MANUFACTURING LOGISTIES AND SERVICES S.R.L, ITALY
75.	<b>Diacerein</b>	ARTRODAR MAL20041211AZ	TRB PHARMA S.A, ARGENTINA
76.	<b>Diclofenac potassium</b>	VOLTAREN DOLO 12.5 MG FILM- COATED TABLETS MAL06071043AZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		CATAFLAM 25MG TABLETS MAL19960970A	NOVARTIS FARMA S.P.A., ITALY
		CATAFLAM TABLET 50MG MAL19960971ARZ	NOVARTIS SAGLIK, TURKEY
77.	<b>Diclofenac sodium</b>	VOLTAREN TABLET 25MG MAL19861069AZ	NOVARTIS SAGLIK, TURKEY
			NOVARTIS FARMA S.P.A., ITALY

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		VOLTAREN TABLET 50MG MAL19861068ARZ	NOVARTIS SAGLIK, TURKEY  NOVARTIS FARMA S.P.A., ITALY
78.	<b>Didanosine</b>	VIDEX TABLET 25MG MAL19973593A  VIDEX TABLET 50MG MAL19973594A  VIDEX TABLET 100MG MAL19973595A  VIDEX TABLET 200MG MAL20020813A  VIDEX EC DELAYED-RELEASE CAPSULE 125MG MAL20021388A  VIDEX EC DELAYED-RELEASE CAPSULE 200MG MAL20021389A  VIDEX EC DELAYED-RELEASE CAPSULE 250MG MAL20021390A  VIDEX EC DELAYED-RELEASE CAPSULE 400MG MAL20021391A	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES         BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
79.	<b>Dihydrocodeine Tartrate</b>	DF 118 TABLET MAL19962828ARSZ	GLAXOSMITHKLINE S.A. (PTY) LTD 39, HAWKINS AVENUE, EPPING, CAPE TOWN 7460 SOUTH AFRICA
Product is available in Hong Kong & Kenya (Information obtained via an email from GSK Malaysia dated 5 June 2015)			

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80.	<b>Disodium Clodronate Tetrahydrate</b>	BONEFOS 400MG TABLETS MAL19988453A	BAYER OY, FINLAND
		BONEFOS 800MG TABLETS MAL19988452AZ	BAYER OY, FINLAND
81.	<b>Diflunisal</b>	DOLOBID TABLET 250MG MAL19861106AR	MERCK SHARP & DOHME INT, UNITED STATES
		DOLOBID TABLET 500MG MAL19890178AR	
82.	<b>Dihydroergotamine mesylate</b>	SEGLOR CAPSULE 5MG MAL19870274AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
83.	<b>Diphenidol hydrochloride</b>	CEPHADOL TABLET 25MG MAL19861237AZ	NIPPON SHINYAKU CO LTD, JAPAN
84.	<b>Domperidone</b>	MOTILIUM TABLET 10MG MAL19872254ARZ	JANSSEN CILAG, FRANCE
85.	<b>Donepezil</b>	ARICEPT F.C. 5MG MAL20013565ACZ	BORA PHARMACEUTICALS CO., LTD., TAIWAN  EISAI TAIWAN INC, TAIWAN
		ARICEPT TABLET 10MG MAL05020190ACZ	BORA PHARMACEUTICALS CO., LTD., TAIWAN  EISAI TAIWAN INC, TAIWAN
86.	<b>Dothiepin</b>	PROTHIADEN CAPSULE 25MG MAL19861459A	THE BOOTS COMPANY PLC, UNITED KINGDOM
		PROTHIADEN TABLET 75MG MAL19861460A	
		DOTHEP 75MG TABLET MAL19970063AZ	ALPHAPHARM PTY LTD, AUSTRALIA
As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016, 13 <sup>th</sup> January 2017: DOTHEP 75MG TABLET (MAL19970063AZ) is being added to the existing list of comparator.			

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
**(MARCH 2017)**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
87.	<b>Doxazosin</b>	CARDURA TABLET 2MG MAL19990562ASZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
88.	<b>Dronedaron Hydrochloride</b>	MULTAQ 400MG FILM-COATED TABLETS MAL20102016AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
89.	<b>Drotaverine</b>	NO-SPA TABLETS 40MG MAL19900596A  NO-SPA FORTE TABLET MAL20001801A	CHINOIN PHARMACEUTICAL & CHEMICAL WORKS PRIVATE CO LTD, HUNGARY
<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: NO-SPA 40mg Tablet from <b>Sanofi-Aventis, Vietnam</b> can also be used as a comparator.</p> <p><b>Sanofi-Aventis Vietnam</b> <b>123 Nguyen khoai, District 4, Ho Chi Minh, Vietnam</b></p>			
90.	<b>Dutasteride</b>	AVODART SOFT GELATIN CAPSULES MAL20040194ARZ	RP SCHERER SA, FRANCE GLAXO SMITH KLINE PHARMACEUTICALS, POLAND
91.	<b>Dydrogesterone</b>	DUPHASTON TABLET 10MG MAL19920643AZ	ABBOTT BIOLOGICALS B. V., NETHERLANDS
92.	<b>Eletriptan hydrobromide</b>	RELPAK 20MG TABLET MAL20021359A  RELPAK 40MG TABLET MAL20021360A  RELPAK 80MG TABLET MAL20021361A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA  PFIZER AUSTRALIA PTY. LTD., AUSTRALIA  PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
93.	<b>Eltrombopag Olamine</b>	REVOLADE FILM COATED TABLET 25MG MAL20102010ACRZ  REVOLADE FILM COATED TABLET 50 MG MAL20102011ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
94.	<b>Entacapone</b>	COMTAN TABLET 200MG MAL19992996ARZ	ORION CORP, FINLAND
95.	<b>Entecavir</b>	BARACLUDE TABLET 0.5 MG MAL20061502ARZ	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
**(MARCH 2017)**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		BARACLUDE TABLET 1MG, MAL20061503AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
96.	<b>Eperisone hydrochloride</b>	MYONAL TABLET 50MG MAL19940448ACZ	MISATO PLANT OF EISAI CO, JAPAN  BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN
97.	<b>Eplerenone</b>	INSPIRA 25MG FILM-COATED TABLETS MAL20081801ARZ  INSPIRA 50MG FILM-COATED TABLETS MAL20081802ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
98.	<b>Erlotinib</b>	TARCEVA FILM-COATED TABLET 25 MG MAL10100027ARSZ  TARCEVA FILM COATED TABLET 100MG MAL10100029ARSZ  TARCEVA FILM COATED TABLET 150MG MAL10100028ARSZ  TARCEVA FILM-COATED TABLET 25 MG MAL20071623ACRZ  TARCEVA FILM-COATED TABLET 100 MG MAL20071624ACRZ  TARCEVA FILM-COATED TABLET 150 MG MAL20071625ACRZ	ROCHE S.P.A ITALY  ROCHE S.P.A ITALY  ROCHE S.P.A ITALY  F.HOFFMANN-LA ROCHE LTD, SWITZERLAND  F.HOFFMANN-LA ROCHE LTD, SWITZERLAND  F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
99.	<b>Esomeprazole magnesium</b>	NEXIUM MUPS TABLET 20MG MAL20020238ARZ	ASTRAZENECA AB, SWEDEN

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		NEXIUM MUPS TABLET 40MG MAL20020239ARZ	ASTRAZENECA AB, SWEDEN
100.	<b>Estradiol</b>	PROGYNOVA 1MG TABLET MAL09020971ACZ  PROGYNOVA TABLET 2MG MAL09020972ACRZ	DELPHARM LILLE S.A.S., FRANCE
101.	<b>Estramustine sodium phosphate</b>	ESTRACYT CAPSULE 140MG MAL19990993A	PFIZER ITALIA S.R.L., ITALY
102.	<b>Etoricoxib</b>	ARCOXIA 60MG TABLET MAL20034170AR  ARCOXIA 90MG TABLET MAL20034179AR  ARCOXIA 120MG TABLET MAL20034182AR  ARCOXIA 120MG TABLET MAL12065084ACRZ  ARCOXIA 30MG TABLET MAL12065063ACRZ  ARCOXIA 60MG TABLET MAL12065082ACRZ  ARCOXIA 90MG TABLET MAL12065065ACRZ	MERCK & CO INC, UNITED STATES  MERCK & CO INC, UNITED STATES  MERCK & CO INC, UNITED STATES  FROSST IBERICA S.A, SPAIN  FROSST IBERICA S.A, SPAIN  FROSST IBERICA S.A, SPAIN  FROSST IBERICA S.A, SPAIN
103.	<b>Everolimus</b>	AFINITOR 10MG TABLET MAL20091943ARZ  AFINITOR 5MG TABLET MAL20091942ARZ  AFINITOR 2.5MG TABLET MAL12085055ARZ  CERTICAN 1.0MG TABLETS MAL20071692ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND  NOVARTIS PHARMA STEIN AG, SWITZERLAND  NOVARTIS PHARMA STEIN AG, SWITZERLAND  NOVARTIS PHARMA STEIN AG, SWITZERLAND



**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		CERTICAN 0.75MG TABLETS MAL20071691ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CERTICAN 0.50MG TABLETS MAL20071690ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CERTICAN 0.25MG TABLETS MAL20071689ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
104.	<b>Exemestane</b>	AROMASIN TABLET 25MG MAL08111847AZ	PFIZER ITALIA S.R.L., ITALY
		AROMASIN 25MG TABLETS MAL20013341A	
105.	<b>Ezetimibe</b>	EZETROL 10MG MAL20034627ARZ	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, UNITED STATES
			SCHERING PLOUGH PRODUCTS, UNITED STATES
106.	<b>Famciclovir</b>	FAMVIR TILTAB TABLET 250MG MAL19950237A	NOVARTIS FARMACEUTICA S.A., SPAIN
		This product can be obtained from Armenia, Australia, Azerbaijan, Bahrain, Bangladesh, Botswana, Canada, Georgia, Germany, Greece, Guatemala, Hong Kong, Hungary, Indonesia, Ireland, Italy, Jordon, Kazakhstan, Kenya, Korea, Kuwait, Malta, Moldova, Oman, Pakistan, Qatar, Russia, Saudi Arabia, South Africa, Spain, Switzerland, Taiwan, Thailand, Turkey, Ukraine, United Arab, Emirates, United Kingdom and United States. (Information obtained via an email from Novartis Malaysia dated 23 November 2015)	
107.	<b>Famotidine</b>	PEPCIDINE 20MG TABLET MAL19900506A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		FAMOPSIN 20 F.C TABLET MAL19920504AZ	REMEDICA LTD., CYPRUS
		FAMOPSIN 40 F. C TABLET MAL19920503AZ	REMEDICA LTD, CYPRUS
		ULCERAN TABLET 40MG MAL19900021AZ	MEDOCHEMIE LTD., CYPRUS
		ULCERAN TABLET 20MG MAL19900020AZ	MEDOCHEMIE LTD., CYPRUS
As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013			
108.	<b>Febuxostat</b>	FEBURIC 80MG FILM-COATED TABLETS MAL16075031ACRZ	PANTHEON FRANCE, FRANCE
109.	<b>Fenofibrate</b>	LIPANTHYL SUPRA 160MG FILM- COATED TABLET MAL20020488AZ	RECIPHARM FONTAINE, FRANCE
		LIPANTHYL PENTA 145 FILM COATED TABLET MAL10053648AZ	
		LIPANTHYL MICRO CAPSULE MAL19983968AZ	LABS FOURNIER SA, FRANCE
		LIPANTHYL MICRO 267 CAPSULE MAL20014486A	
Product is available in <b>Indonesia, Philippines, Singapore, Switzerland, Thailand &amp; Vietnam</b> (Information obtained via an email from Abbott Malaysia dated 12 April 2013)			
		GEN-FENOFIBRATE MICRO 200MG CAPSULE MAL20040063ACRZ	ALPHAPHARM PTY LTD, AUSTRALIA
As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014, 18 <sup>th</sup> August 2014: GEN-FENOFIBRATE MICRO			

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		200MG CAPSULE (MAL20040063ACR) is being added to the existing list of comparator	
110.	<b>Fexofenadine hydrochloride</b>	TELFAST 30MG TABLET MAL20031923AZ	AVENTIS PHARMA INC, UNITED STATES
		TELFAST 60MG TABLET MAL20051395ARZ	
		TELFAST 120MG MAL20000714AZ	HOECHST MARION ROUSSEL INC, UNITED STATES
		TELFAST 180MG TABLET MAL20000715AZ	SANOFI-AVENTIS U.S. LLC, UNITED STATES
		PT AVENTIS PHARMA, INDONESIA	
		PT AVENTIS PHARMA INDONESIA	
111.	<b>Finasteride</b>	PROPECIA TABLET MAL19992040ACRZ	AIAC INTERNATIONAL PHARMA, LLC, UNITED STATES
		PROSCAR 5MG TABLET MAL19985910ACRZ	
		PROSCAR 5MG TABLET MAL19930510AR	MSD INTERNATIONAL GMBH (Puerto Rico Branch) LLC, PEURTO RICE
		MERCK SHARP & DOHME LTD, UNITED KINGDOM	
112.	<b>Fingolimod hydrochloride</b>	GILENYA 0.5MG HARD CAPSULE MAL12015017ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
113.	<b>Flavoxate</b>	URISPAS 200 TABLET MAL20033669AZ	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A., ITALY
114.	<b>Flecainide</b>	TAMBOCOR TABLET 100MG MAL19871528ARZ	3M HEALTHCARE LTD, UNITED KINGDOM
115.	<b>Fludarabine</b>	FLUDARA 10MG FILM COATED TABLETS MAL05051075ACZ	BAYER SCHERING PHARMA AG, GERMANY
116.	<b>Flunarizine hydrochloride</b>	SIBELIUM CAPSULE 5MG MAL19880179ARZ	JANSSEN-CILAG S.P.A., ITALY

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		SIBELIUM TABLET 5 MG MAL09100238AZ	JANSSEN-CILAG S.P.A., ITALY
		Products are available in <b>Turkey, Oman, Taiwan &amp; Korea</b> (Information obtained from Johnson & Johnson Malaysia dated 7 <sup>th</sup> March 2014 through an email	
117.	<b>Fluvastatin</b>	LESCOL 40MG CAPSULE MAL19962845A	NOVARTIS PHARMA AG, SWITZERLAND
		LESCOL 20MG CAPSULE MAL19962844A	NOVARTIS PHARMA AG, SWITZERLAND
		LESCOL CAPSULE 20MG MAL19992682ACRZ	NOVARTIS FARMACEUTICA SA, SPAIN
		LESCOL CAPSULE 40MG MAL19992683ACRZ	
		LESCOL XL 80MG TABLETS MAL20032266ARZ	
118.	<b>Fluoxymesterone</b>	HALOTESTIN TABLETS 5MG (BELGIUM) MAL19920022A	PHARMACIA & UPJOHN S.A., BELGIUM
119.	<b>Flupentixol dihydrochloride</b>	FLUANXOL TABLET 0.5MG MAL19890543AZ	H.LUNDBECK A/S, DENMARK
		FLUANXOL TABLETS 3MG MAL19890544A	
		FLUANXOL TABLETS 1MG MAL19900451A	
120.	<b>Flurazepam Monohydrochloride</b>	DALMADORM 15MG CAPSULES MAL07050892AC	LABIANA PHARMACEUTICALS SL, SPAIN
121.	<b>Flurbiprofen</b>	FROBEN TABLET 50MG MAL19861117A	THE BOOTS COMPANY PLC, UNITED KINGDOM
122.	<b>Fosinopril sodium</b>	MONOPRIL TABLET 10MG MAL19992695AS	PT BRISTOL-MYERS SQUIBB INDONESIA TBK
		MONOPRIL TABLET 10MG MAL19950242A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		MONOPRIL TABLET 20MG MAL19950243A	

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
123.	<b>Gabapentin</b>	NEURONTIN 100MG CAPSULE MAL06071076AZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		NEURONTIN 300MG CAPSULE MAL19984786AZ	
		NEURONTIN 400MG CAPSULE MAL19984785AZ	
		NEURONTIN 300MG CAPSULE MAL19962169A	PFIZER PHARMACEUTICALS LLC, UNITED STATES
NEURONTIN 400MG CAPSULE MAL19962170A			
NEURONTIN TABLET 600MG MAL20031747AZ			
NEURONTIN TABLET 800MG MAL20031748A			
124.	<b>Galantamine hydrobromide</b>	REMINYL TABLET 4MG MAL20020123A	JANSSEN CILAG SPA, ITALY
		REMINYL TABLET 8MG MAL20020124A	
		REMINYL TABLET 12MG MAL20020125A	
125.	<b>Ganciclovir</b>	CYMEVENE CAPSULE 250MG MAL19993019AR	ROCHE PRODUCTS LTD, UNITED KINGDOM
		CYMEVENE HARD-GELATIN CAPSULE 250MG MAL19970079A	SYNTEX PUERTO RICO INC, UNITED STATES
126.	<b>Gemfibrozil</b>	LOPID CAPSULE 300MG MAL19990998A	PARKE DAVIS PTY LTD, AUSTRALIA
		LOPID 600MG TABLET MAL19984784AS	PARKE DAVIS PTY LTD, AUSTRALIA
		LOPID 600MG TABLET MAL19900442AR	PARKE DAVIS PHARMA PTY LTD, UNITED STATES

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		LOPID 450MG TABLET MAL19921617ARS	GOEDECKE A.G, WEST GERMANY
		<b>Products are available in Argentina, Australia, Austria, Brazil, Switzerland, Chile, Germany, Denmark, Spain, France, United Kingdom, Greece, Hong Kong, Indonesia, India, Ireland, Italy, Mexico, Netherlands, Norway, Peru, Portugal, Philippines, Sweden, Thailand, Turkey, Taiwan, United States</b>	
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014, 23 April 2014, the following product is being added to the existing list of comparator:	
		PHARMANIAGA GEMFIBROZIL CAPSULE 300MG CAPSULE MAL19972153AZ	PHARMANIAGA MANUFACTURING BERHAD
127.	<b>Gestrinone</b>	DIMETRIOSE CAPSULE MAL19940494A	ROUSSEL LABS LTD, UNITED KINGDOM
128.	<b>Glipizide</b>	MINIDIAB 5MG TABLET MAL19913361AZ	PFIZER ITALIA S.R.L., ITALY
129.	<b>Granisetron hydrochloride</b>	KYTRIL TABLET 1MG MAL19940574ARZ	ROCHE S.P.A., ITALY  F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
130.	<b>Hydroxychloroquine</b>	PLAQUENIL TABLET MAL19991702AZ  PLAQUENIL TABLETS MAL04103442AZ	SANOFI-SYNTHELABO LTD, UNITED KINGDOM  SANOFI-AVENTIS, S.A., SPAIN
131.	<b>Hyoscine butylbromide</b>	BUSCOPAN TABLET 10MG MAL09051577AZ	DELPHARM REIMS, FRANCE
132.	<b>Hydroxyurea/ Hydroxycarbamide</b>	HYDREA CAPSULE 500MG, MAL19962497A  HYDREA CAPSULE 500MG, MAL19993027A	BRISTOL MYERS SQUIBB US  BRISTOL MYERS SQUIBB S.R.L, ITALY
		<b>Product is available in Australia, United Kingdom, United States , Ireland and France</b> (Information obtained from Bristol Myers Asia Pacific through an email dated 18 <sup>th</sup> September 2013). As agreed upon in “Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2015 – 21 April 2015, Hyrea Capsule (MAL19993027A) from <b>Coden Pharma Latina Italy</b> can also be used as comparator.	
133.	<b>Hydrochlorothiazide</b>	DICHLOTRIDE TABLET 25MG, MAL19870271AR	MERCK SHARP & DOHME UNITED KINGDOM

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		DICHLOTRIDE TABLET 50MG, MAL19870201AR	MERCK SHARP & DOHME UNITED KINGDOM
		DICHLOTRIDE 25MG TABLET, MAL19940018AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		DICHLOTRIDE 50MG TABLET, MAL19940019AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		APO-HYDRO 50MG TABLET MAL19984688ARZ	APOTEX INC, CANADA
		APO-HYDRO 25MG TABLET MAL19984694ARZ	
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013	
134.	<b>Hydrocortisone</b>	CORTEF TABLET 10MG	CATALENT PHILADELPHIA
		Product is available in <b>Bosnia, Canada, Georgia, Croatia, Hungary, Poland, Russia, Saudi Arabia, Thailand, Tunisia and United States. (Information obtained from Pfizer via a letter dated 25/1/2013)</b>	
		As agreed upon in “Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2015” – 7 September 2015, the following product is being added to the existing list of comparator:-	
		HYDROCORTISON ORION 10MG TABLET MAL15085015ACZ	MERCK KGAA & CO, AUSTRIA
135.	<b>Ibandronic acid</b>	BONDRONAT FILM-COATED TABLET 50 MG MAL20071698ARZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		BONVIVA FILM-COATED TABLETS 150 MG MAL20071629AZ	
136.	<b>Imatinib mesylate</b>	GLIVEC 50MG CAPSULES MAL20020355A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GLIVEC 100MG CAPSULES MAL20020356A	NOVARTIS PHARMA STEIN AG, SWITZERLAND

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		GLIVEC TABLET 100MG MAL06011679ARZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY  NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GLIVEC TABLET 400MG MAL06011681ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
137.	<b>Imidapril hydrochloride</b>	TANATRIL 2.5MG TABLET MAL20034616A	PT TANABE INDONESIA, INDONESIA
		TANATRIL 5MG TABLET MAL20034617AZ	PT TANABE INDONESIA, INDONESIA
		TANATRIL 10MG TABLET MAL20034618AZ	PT TANABE INDONESIA, INDONESIA
138.	<b>Indapamide</b>	NATRILIX TABLET MAL19972491AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		NATRILIX TABLET 0.0025G MAL19870270ARZ	
		Product is available in <b>Australia, Bangladesh, China, India, Pakistan, France and United Kingdom</b> (Information obtained from Servier (M) Sdn. Bhd on 4 <sup>th</sup> April 2013)	
		As agreed upon in “Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2015” – 7 September 2015, the following product is being added to the existing list of comparator:-	
		APO-INDAPAMIDE 2.5MG TABLET MAL19986967AZ	APOTEX INC, CANADA
139.	<b>Indomethacin</b>	INDOCID CAPSULE 25MG MAL19930412AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD
		INDOCID CAPSULE 25MG MAL19861080A	MERCK SHARP & DOHME INT, UNITED STATES
		As agreed upon in “Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2013” – 13 March 2013, the above products can be obtained from Aspen Pharmacare Australia and manufactured by Aspen Pharmacare South Africa.	
140.	<b>Isosorbide Dinitrate</b>	ISORDIL ORAL TABLET 10MG MAL19871489A	WYETH CANADA



**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		As agreed upon 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016' – 16 Jun 2016, Isordil Oral Tablet manufactured by <b>Interphil, Philippines</b> can be used as comparator.	
141.	<b>Isosorbide-5-mononitrate</b>	ELANTAN 20MG TABLET MAL19900069AZ  ELANTAN 40MG TABLET MAL19900070AZ	SCHWARZ GMBH MITTELSTRASSE 11-13 D-4019 MONHEIM, GERMANY
142.	<b>Isotretinoin</b>	ROACCUTANE ROCHE CAPSULE 20MG PBKD861795A	F. HOFFMAN-LA ROCHE, SWITZERLAND
		ROACCUTANE ROCHE CAPSULE 10MG PBKD861794A	F. HOFFMAN-LA ROCHE, SWITZERLAND
		ROACCUTANE CAPSULE 20MG MAL19991721ACRZ  ROACCUTANE CAPSULE 10MG MAL19991720ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY  R. P. SCHERER GMBH, GERMANY  CATALENT GERMANY EBERBACH GMBH, GERMANY  R. P. SCHERER GMBH, GERMANY
143.	<b>Itopride Hydrochloride</b>	GANATON TABLET 50MG MAL20051433ACZ	MYLAN EPD G.K., JAPAN
144.	<b>Ketorolac Tromethamine</b>	TORADOL 10 MG FILM-COATED TABLET MAL19973601A	ROCHE FARMA S.A, SPAIN
		Product is available in <b>Australia, Indonesia, Georgia, Canada, Italy, and Portugal</b> (Information obtained from Roche (M) Sdn Bhd on 9 <sup>th</sup> March 2015)	
145.	<b>Ketotifen fumarate</b>	ZADITEN 1MG TABLET MAL20000272ARZ	NOVARTIS PHARM UK LTD, UNITED KINGDOM
146.	<b>Labetalol</b>	TRANDATE TABLET 100MG, MAL19870059A	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		TRANDATE TABLET 200MG MAL19870060A	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
		TRANDATE TABLETS 200MG MAL06011678AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		TRANDATE TABLETS 100MG MAL06011677AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
147.	<b>Lacidipine</b>	LACIPIL TABLET 2MG MAL19950005A	GLAXO WELLCOME S.A.SPAIN
		LACIPIL TABLET 4MG MAL19950006ARZ	
148.	<b>Lacosamide</b>	VIMPAT 50MG FILM-COATED TABLETS MAL12055002AZ	AESICA PHARMACEUTICALS GMBH, GERMANY
		VIMPAT 100MG FILM-COATED TABLETS MAL12055008AZ	
		VIMPAT 150MG FILM-COATED TABLETS MAL12055009AZ	
		VIMPAT 200MG FILM-COATED TABLETS MAL12055010AZ	
149.	<b>Lansoprazole</b>	PREVACID 30MG CAPSULE MAL19961284AR	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		This product is available in <b>Anguilla, Aruba, Austria, Bahamas, Bahrain, Barbados, Belgium, Benin, Bermuda Botswana, Burkina Faso, Cambodia, Cameroon, Canada ,Cayman Islands, Chad,China, Colombia, Congo, Costa Rica, Cote D'ivoire, Curacao, Dominican Republic Ecuador, Egypt, El Salvador, France, Gabon, Germany, Greece, Grenada, Guatemala, Guinea, Haiti, Honduras, Hungary, Iraq, Italy, Ivory Coast, Jamaica Japan, Jordan, Jordan, Korea, Republic Of [Kr] [South Korea], Kuwait, Lebanon Libyan Arab Jamahiriya, Luxembour, Madagascar, Mali, Mauritania, Mexico, Morocco, Myanmar, Namibia, Netherland, Nicaragua, Niger, Oman,</b>	

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		Pakistan , Panama, Peru, Philippines, Portugal, Qatar, Saint Lucia, Saudi Arabia, Senegal Singapore, South Africa, Spain, Switzerland, Syrian Arab Republic, Taiwan, Province Of China, Thailand, Togo, Trinidad And Tobago, Tunisia, Turkey, United Arab Emirates, United Kingdom, United States, Venezuela, Yemen (Information obtained from Invida dated 25 <sup>th</sup> February 2013)	
150.	<b>Lapatinib ditosylate</b>	TYKERB FILM-COATED TABLETS 250MG MAL20071677ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
151.	<b>Leflunomide</b>	ARAVA 10MG TABLET MAL20001528ARZ  ARAVA 20MG TABLET MAL20001527AZ  ARAVA TABLET 100MG MAL20001529AZ	SANOFI WINTHROP INDUSTRIE, FRANCE  SANOFI WINTHROP INDUSTRIE, FRANCE  SANOFI WINTHROP INDUSTRIE, FRANCE
152.	<b>Lenalidomide</b>	REVLIMID (LENALIDOMIDE) CAPSULES 5MG MAL20091851ACRZ  REVLIMID (LENALIDOMIDE) CAPSULE 10MG MAL20091852ACRZ  REVLIMID (LENALIDOMIDE) CAPSULE 15MG MAL20091853ACRZ  REVLIMID (LENALIDOMIDE) CAPSULE 25MG MAL20091854ACRZ  REVLIMID (LENALIDOMIDE) CAPSULES 5MG MAL12040005ARSZ  REVLIMID (LENALIDOMIDE) CAPSULES 10MG MAL12040006ARSZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM  PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM  PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM  CELGENE INTERNATIONAL SARL, SWITZERLAND  CELGENE INTERNATIONAL SARL, SWITZERLAND

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		REVLIMID (LENALIDOMIDE) CAPSULES 15MG MAL12040004ARSZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		REVLIMID (LENALIDOMIDE) CAPSULES 25MG MAL12040007ARSZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
153.	<b>Lercanidipine HCl</b>	ZANIDIP 10MG FILM COATED TABLETS MAL20041041AZ	RECORDATI CHIMICA E FARMACEUTICA S.P.A., ITALY
		ZANIDIP 20MG, FILM-COATED TABLET MAL07050024AZ	RECORDATI S.p.A - INDUSTRIA CHIMICA e FARMACEUTICA, ITALY
154.	<b>Levamisole hydrochloride</b>	ERGAMISOL TABLET 50MG MAL19990537A	JANSSEN PHARMACEUTICA N.V., BELGIUM
155.	<b>Levetiracetam</b>	KEPPRA 250MG FILM COATED TABLET MAL20031725ARZ	UCB S.A. SECTOR PHARMA, BELGIUM
		KEPPRA 500MG FILM COATED TABLET MAL20031726ARZ	UCB S.A. SECTOR PHARMA, BELGIUM
		KEPPRA 1000MG FILM COATED TABLET MAL20031727ARZ	UCB S.A. SECTOR PHARMA, BELGIUM
156.	<b>Levocetirizine dihydrochloride</b>	XYZAL 5MG FILM COATED TABLET MAL20051323ARZ	UCB FARCHIM S.A., SWITZERLAND
157.	<b>Levonorgestrel</b>	POSTINOR-2 TABLET 0.75MG MAL19872263ARZ	GEDEON RICHTER PLC, HUNGARY
		ESCAPELLE TABLET 1.5MG MAL06030792AZ	GEDEON RICHTER PLC, HUNGARY
		This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.	
158.	<b>Levothyroxine sodium</b>	OROXINE 100MCG TABLET MAL06071058AZ	ASPEN BAD OLDESLOE GMBH, GERMANY

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		OROXINE 50MCG TABLET MAL06071059AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
159.	<b>Linagliptin</b>	TRAJENTA 5MG FILM-COATED TABLETS MAL12045094ACZ	BOEHRINGER INGELHEIM ROXANE, INC, UNITED STATES
160.	<b>Linezolid</b>	ZYVOX 400MG TABLETS MAL20020873AR  ZYVOX 600MG TABLETS MAL20020874AZ	PFIZER PHARMACEUTICALS LLC, PUERTO RICO  PFIZER PHARMACEUTICALS LLC, UNITED STATES
161.	<b>Lomefloxacin hydrochloride</b>	MAXAQUIN 400MG TABLET MAL19940539A MAXAQUIN 400MG TABLET MAL19940540AS	SEARLE DE MEXICO, MEXICO MONSANTO FRANCE SA, FRANCE
162.	<b>Lomustine</b>	CEENU CAPSULE 40MG MAL19991719A	BRISTOL-MYERS SQUIBB S.R.L., ITALY
163.	<b>Loperamide</b>	IMODIUM CAPSULE 2MG MAL19871473ARZ	JANSSEN CILAG, FRANCE
164.	<b>Mebeverine</b>	DUSPATALIN TABLET 100MG MAL19920644A DUSPATALIN TABLET 135MG MAL19940428ACZ	ABBOTT BIOLOGICALS B.V., NETHERLAND ABBOTT HEALTHCARE SAS, FRANCE
165.	<b>Medroxyprogesterone acetate</b>	FARLUTAL TABLET 100MG MAL19991379A  FARLUTAL TABLET 500MG MAL19991380A PROVERA TABLET 5MG MAL19872113A PROVERA 10MG TABLET MAL20000997AZ PROVERA 5MG TABLET MAL06051306AZ	PFIZER ITALIA S.R.L., ITALY  PFIZER ITALIA S.R.L., ITALY PHARMACIA & UPJOHN CO, UNITED STATES PFIZER ITALIA S.R.L., ITALY PFIZER PHARMACEUTICAL LLC, PUERTO RICO
166.	<b>Mefloquine hydrochloride</b>	LARIAM TABLET 250MG MAL19921123ARZ	F.HOFFMAN-LA ROCHE, SWITZERLAND
167.	<b>Megestrol acetate</b>	MEGACE TABLET 160MG MAL19962089A	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, AUSTRALIA

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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MEGACE TABLET 40MG MAL19962090A	HAUPT PHARMA REGENSBURG GMBH, GERMANY
168.	<b>Melphalan</b>	ALKERAN TABLETS 2MG MAL07101257ACZ	EXCELLA GMBH, GERMANY
169.	<b>Memantine hydrochloride</b>	EBIXA FILM-COATED TABLET 10MG MAL20061488ACRZ EBIXA FILM-COATED TABLET 20 MG MAL10120014ACRZ	ROTTENDORF PHARMA GMBH, GERMANY  ROTTENDORF PHARMA GMBH, GERMANY
170.	<b>Mequitazine</b>	PRIMALAN TABLET 5MG MAL19871736A	MAY & BAKER LTD, UNITED KINGDOM
171.	<b>Mercaptopurine</b>	PURI-NETHOL TABLET 50MG MAL19861668A	THE WELLCOME FOUNDATION LTD, UNITED KINGDOM
		<p>Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2015 – 9 September 2015 agreed that products manufactured by <b>Excella GmbH, Germany</b> and <b>DSM Pharmaceuticals, Inc, United State</b> can be used as comparator.</p> <p>This product can be obtained from Hong Kong, Thailand, Egypt, Iran, Sri Lanka, Bangladesh, Qatar, Lebanon, Yemen, Saudi Arabia, Turkey, UAE, Kuwait, Iraq, Bahrain, Oman, Jordan, Denmark, Germany, Belgium, Italy, Norway, Netherlands, Portugal, Serbia &amp; Montenegro, Sweden, Spain, Estonia, Czech Republic, Romania, Iceland, Slovakia, Ukraine, Slovenia, Lithuania, Belarus, Georgia, Armenia, South Africa, Morocco, Tunisia, Sudan, United States, South America (Colombia, Argentina, Brazil, Uruguay, Paraguay, Chile), North America (Caribbean, Mexico) and Central America. (Information obtained via email dated 3 December 2014 from GSK, Malaysia)</p>	
172.	<b>Mesna</b>	UROMITEXAN TABLET 400MG MAL20014208AZ  UROMITEXAN TABLET 600MG MAL20014209AZ	TEMMLER PHARMA GMBH & CO KG, GERMANY  TEMMLER PHARMA GMBH & CO KG, GERMANY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
173.	<b>Mesalazine</b>	SALOFALK 500 ENTERIC-COATED TABLET MAL19987336ACSZ  SALOFALK 250 ENTERIC-COATED TABLET MAL19987335ACSZ	LOSAN PHARMA GMBH, GERMANY
174.	<b>Mesterolone</b>	PROVIRONUM TABLET 25MG MAL09122025ACZ	SCHERING DA BRASIL QUIMICAE FARMACEUTICA LTDA., BRAZIL
175.	<b>Methoxsalen</b>	OXSORALEN-ULTRA CAPSULES 10MG MAL19920052A	ICN PHARM INC, UNITED STATES
		MELADININE TABLET 10MG MAL05090015ACZ	LABOBORATOIRES MACORS, FRANCE
176.	<b>Methylphenidate hydrochloride</b>	RITALIN TABLET 10MG MAL19910002ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
177.	<b>Methylprednisolone</b>	MEDROL TABLET 4MG MAL19990558A MEDROL TABLET 16MG MAL19990559A	PHARMACIA & UPJOHN CO, UNITED STATES
		This product can be obtained from <b>Algeria, Armenia, Bangladesh, Canada, Chile, China, Colombia, Denmark, Finland, France, Greece, Hungary, India, Indonesia, Israel, Italy, Thailand, Sweden, Sri Lanka, Saudi Arabia, Vietnam</b> (Information obtained via email dated 15 <sup>th</sup> January 2014 from Pfizer, Malaysia)	
178.	<b>Metoclopramide hydrochloride</b>	MAXOLON TABLET 10MG MAL19921400A	BEECHAM PHARM, UNITED KINGDOM
		This product can be obtained from <b>South Africa, Australia and Pakistan</b> . (Information obtained via email dated 26 <sup>th</sup> Sept 2012 from GSK, Malaysia and agreed upon 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013)  Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014 – 23 April 2014 agreed that products manufactured by <b>GSK Karachi</b> and <b>GSK Cape Town</b> can be used as comparator.	

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
179.	<b>Mexiletine Hydrochloride</b>	MEXITIL CAPSULE 50MG PBKD861806A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY
		MEXITIL CAPSULE 200MG PBKD861808A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY
		MEXITIL CAPSULE 100MG PBKD861807A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY
		MEXITIL CAPSULE 100MG MAL19989013A	BOEHRINGER INGELHEIM TAIWAN LTD., TAIWAN
180.	<b>Mianserin hydrochloride</b>	TOLVON TABLET 10MG MAL19900637A	N.V. ORGANON, NETHERLANDS
		TOLVON TABLET 30MG MAL19900638A	N.V. ORGANON, NETHERLANDS
		TOLVON TABLET 60MG MAL19900639A	N.V. ORGANON, NETHERLANDS
181.	<b>Midazolam</b>	DORMICUM ROCHE TABLET 7.5 MG MAL19890299ARZ	PRODUCTOS ROCHE MEXICO
		DORMICUM FILM-COATED TABLET 15MG MAL19920037A	F.HOFFMAN-LA ROCHE, SWITZERLAND
182.	<b>Miglitol</b>	DIASTABOL 50MG MAL19990973A	BAYER AG, GERMANY
		DIASTABOL 100MG MAL19990974A	
183.	<b>Milnacipran hydrochloride</b>	IXEL 25MG HARD CAPSULES MAL20061611A	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
		IXEL 50MG HARD CAPSULES MAL20061612A	
184.	<b>Minoxidil</b>	LONITEN 5MG TABLETS MAL20014500AR	GLOBAL PHARM LTD, CANADA



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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		LONITEN 10MG TABLETS MAL20014501AR	
		LONITEN TABLET 5MG MAL19861624A	UPJOHN LTD, UNITED KINGDOM
		LONITEN TABLET 10MG MAL19861623A	
		This product can be obtained from <b>Australia, Brazil, Canada, France, Germany, Ireland, Italy, Netherlands, New Zealand, South Africa, Spain, Switzerland, Taiwan &amp; United Kingdom</b> (Information obtained via email dated 3 <sup>rd</sup> May 2013 from Zeullig Pharma Sdn. Bhd., Malaysia)	
185.	<b>Misoprostol</b>	CYTOTEC TABLET 200MCG MAL19890225ARZ	PIRAMAL HEALTHCARE UK LIMITED, UNITED KINGDOM
186.	<b>Mizolastin</b>	MIZOLLEN TABLET 10MG MAL20001215A	SANOFI WINTHROP INDUSTRIE, FRANCE
187.	<b>Moclobemide</b>	AURORIX FILM-COATED TABLET 150MG MAL19910811A	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		AURORIX FILM-COATED TABLET 300MG MAL19987972A	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		AURORIX FILM COATED TABLET 150MG MAL13035054ACZ	CENEXI, FRANCE
		AURORIX FILM COATED TABLET 300MG MAL13035055ACZ	CENEXI, FRANCE
188.	<b>Montelukast sodium</b>	SINGULAIR TABLET 10MG MAL19990957ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
189.	<b>Morphine sulphate</b>	KAPANOL CAPSULES 20MG MAL19984000AR	F.H. FAULDING & CO LTD, AUSTRALIA
		KAPANOL CAPSULES 50MG MAL19984001AR	

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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		KAPANOL CAPSULES 100MG MAL19984002AR	
190.	<b>Moxifloxacin hydrochloride</b>	AVELOX TABLET MAL20012664AZ	BAYER PHARMA AG, GERMANY  BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
191.	<b>Moxonidine</b>	PHYSIOTENS 0.2MG TABLET MAL20033335ACZ  PHYSIOTENS 0.3MG TABLET MAL20033336ACZ  PHYSIOTENS 0.4MG TABLET MAL20033337ACZ	MYLAN LABORATORIES SAS, FRANCE  ABBOTT HEALTHCARE SAS, FRANCE
192.	<b>Naltrexone hydrochloride</b>	REVIA TABLET 50MG MAL20013367A  TREXAN TABLET 50MG MAL19930054A	DUPONT PHARM COMPANY, UNITED STATES  DU PONT PHARM INC,N.YORK, UNITED STATES
193.	<b>Nateglinide</b>	STARLIX 60MG TABLET MAL20014476A  STARLIX 120MG TABLET MAL20014477AR	NOVARTIS FARMA S.P.A., ITALY  NOVARTIS FARMA S.P.A., ITALY
194.	<b>Nebivolol</b>	NEBILET TABLET MAL20041163AZ	BERLIN-CHEMIE AG, GERMANY
195.	<b>Neostigmine bromide</b>	PROSTIGMIN ROCHE TABLET 15MG MAL19871818A	ROCHE PRODUCTS LTD, UNITED KINGDOM
196.	<b>Nilotinib hydrochloride monohydrate</b>	TASIGNA 150MG CAPSULE MAL11105040ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
197.	<b>Nimodipine</b>	NIMOTOP TABLET 30MG MAL19940001AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
198.	<b>Nisoldipine</b>	SYSCOR CC 10MG TABLET MAL20000264AC	BAYER AG, WEST GERMANY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		SYSCOR CC TABLET 20MG MAL20000265AC	
		SYSCOR CC TABLET 30MG MAL20000266AC	
		SYSCOR CC TABLET 40MG MAL20000267AC	
199.	<b>Nizatidine</b>	PU 3144 AXID CAPSULE 150MG MAL19950508AC	LILLY S.A., SPAIN
200.	<b>Norethisterone 5mg</b>	PRIMOLUT-N TABLET 5MG MAL19900564A	SCHERING AG BERLIN, GERMANY
		PRIMOLUT-N TABLET 5MG MAL08120874A	SCHERING GMBH & CO. PRODUKTIONS KG GERMANY
		PRIMOLUT-N 5MG TABLET MAL20002234AS	BAYER WEIMAR GMBH UND CO.KG  PT SCHERING INDONESIA
<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18<sup>th</sup> August 2014:</p> <p>PRIMOLUT-N 5MG TABLET (MAL08120874A) can be obtained from <b>Vietnam</b> while PRIMOLUT-N 5mg (MAL20002234AS) manufactured by PT Schering Indonesia is no longer available in Vietnam. (Information obtained via email dated 8<sup>th</sup> May 2015 from Bayer Co (M) Sdn Bhd)</p> <p>Primolut N tablet can be obtained from Singapore, Thailand, Australia and New Zealand (Information obtained via email dated 21 June 2016 from Bayer Co (M) Sdn Bhd).</p> <p>This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.</p>			

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016 – 13<sup>th</sup> January 2017:</p> <p>Should generic product containing norethisterone unable to fulfill the requirements in Malaysian Guidance on Biopharmaceutics Classification System (BCS) - Based Biowaiver, bioequivalence study would be required to prove the interchangeability between the generic product and comparator product.</p>	
201.	<b>Norethisterone 0.35mg</b>	NORIDAY TABLET MAL19992549AZ	PIRAMAL HEALTHCARE UK LIMITED
		<p>This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer <a href="#">biowaiver page</a> on NPRA website for more information.</p>	
202.	<b>Nystatin</b>	MYCOSTATIN ORAL TABLET 500000 IU MAL19921327A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		<p>This product can be obtained from <b>Mexico</b>. (Information obtained via email dated 13th December 2012 from Bristol Myers Squibb, Asia Pacific)</p> <p>As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan” 1/2013 – 13 March, bioequivalence study can be waived due to local effect and no significant systemic absorption. However, in-vitro comparative dissolution profile study between the test and reference product need to be conducted to prove similarity.</p> <p>As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan” 1/2016 – 13 Jun 2016, Mycostatin Oral Tablet from Bristol Myers Squibb, Mexico can also be used as a comparator.</p>	
203.	<b>Olmesartan Medoxomil</b>	OLMETEC 40MG FILM-COATED TABLET MAL20051373ACRZ	DAICHII SANKYO EUROPE GMBH, GERMANY
		OLMETEC 20MG FILM-COATED TABLET MAL20051374ACRZ	DAICHII SANKYO EUROPE GMBH, GERMANY
		OLMETEC 10MG FILM-COATED TABLET MAL20051375ACRZ	DAICHII SANKYO EUROPE GMBH, GERMANY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
204.	<b>Ondansetron hydrochloride dihydrate</b>	ZOFRAN TABLET 4MG MAL19950007ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		ZOFRAN TABLET 8MG MAL19950013ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
205.	<b>Orlistat</b>	XENICAL CAPSULE 120MG MAL19992994ARZ	F.HOFFMANN,LA ROCHE LTD, SWITZERLAND
		XENICAL CAPSULE 120 MG MAL05032548ARZ	ROCHE S.P.A., ITALY
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 <sup>th</sup> August 2014:  Bioequivalence study for generic immediate release, oral solid dosage form Orlistat need to be done using pharmacodynamic (PD) endpoint which is as percent of fecal fat excretion expressed as a ratio of the amount of fat excretion over a 24 hour period at steady state relative to the amount of daily ingested fat.	
206.	<b>Orphenadrine citrate</b>	NORFLEX TABLET 100MG MAL19861502A	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		NORFLEX TABLET 100MG MAL13055067ACRZ	ADCOCK INGRAM, INDIA
207.	<b>Oxcarbazepine</b>	TRILEPTAL 600 MG FILM-COATED TABLET MAL07050038ARSZ	NOVARTIS FARMA S.P.A., ITALY
		TRILEPTAL 600MG TABLETS MAL20021156A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		TRILEPTAL 300MG MAL20021155ARZ	NOVARTIS FARMA S.P.A., ITALY
		TRILEPTAL 600 MG FILM-COATED TABLET MAL07050038ARSZ	
208.	<b>Oxybutynin hydrochloride</b>	DRIPTANE TABLET 5MG MAL19991351ARZ	LABS FOURNIER SA, FRANCE

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
209.	<b>Oxycodone hydrochloride</b>	OXYNORM 5MG CAPSULES MAL10070560ACZ  OXYNORM 10MG CAPSULES MAL10070561ACZ  OXYNORM 20MG CAPSULES MAL10070562ACZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
210.	<b>Oxymetholone</b>	ANAPOLON 50 TABLET MAL19870679A	SYNTEX INCORPORATED, CANADA
		ANAPOLON 50 TABLET MAL19870678A	SYNTEX PHARM LTD, UNITED KINGDOM
211.	<b>Pantoprazole</b>	CONTROLOC 20MG TABLET MAL20032151AZ	NYCOMED GMBH, GERMANY
		CONTROLOC 40MG TABLET MAL19972093ARZ	
212.	<b>Paricalcitol</b>	ZEMPLAR CAPSULES 1 MCG MAL20071708ACZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
		ZEMPLAR CAPSULES 2 MCG MAL20071709ACZ	
		ZEMPLAR CAPSULES 4 MCG MAL20071710ACZ	
213.	<b>Pazopanib Hydrochloride</b>	VOTRIENT FILM-COATED TABLET 200MG MAL20102071ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
		VOTRIENT FILM-COATED TABLET 400MG MAL20102072ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
214.	<b>Penicillamine</b>	ARTAMIN CAPSULE 250MG MAL20021153ACZ	HAUPT PHARMA BERLIN GMBH, GERMANY
215.	<b>Pentoxifylline</b>	TRENTAL 400 TABLET MAL19990996AZ	SANOFI-AVENTIS DE MEXICO SA DE CV
216.	<b>Phentermine Hydrochloride</b>	DUROMINE CAPSULE 15MG MAL19871769AR	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		DUROMINE CAPSULE 30MG MAL19871774AR	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		<p>Generic products may contain Phentermine Hydrochloride as specified in the United States Pharmacopeia (USP), in which, do not possess similar drug release specification as Duromine Capsule containing Phentermine resin/ion resin complex.</p> <p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2013- 13 March 2013', bioequivalence study is not required for all generic products containing Phentermine Hydrochloride. However, the label on the generic product must include the following statement:-</p> <p><b>'Not Interchangeable with Duromine and other brand of product Containing Phentermine Resin'.</b></p>	
217.	<b>Phthalylsulphathiazole</b>	THALAZOLE TABLET 500MG 1986040494A	MAY & BAKER LTD, UNITED KINGDOM
218.	<b>Pinaverium bromide</b>	DICETEL 50MG FILM-COATED TABLET MAL12045092AZ	ABBOTT HEALTHCARE SAS, FRANCE
		DICETEL 100MG FILM-COATED TABLET MAL20122215AZ	MYLAN LABORATORIES SAS, FRANCE
219.	<b>Pindolol</b>	VISKEN TABLET 5MG PBKD870587A	NOVARTIS PHARMA AG, SWITZERLAND
		VISKEN TABLET 10MG PBKD870074A	NOVARTIS PHARMA AG, SWITZERLAND
220.	<b>Pioglitazone</b>	ACTOS 15MG TABLET MAL20051432AR	TAKEDA PHARMACEUTICAL LTD., JAPAN
		ACTOS 30MG TABLET MAL20051431ARZ	TAKEDA PHARMACEUTICAL LTD., JAPAN
		ACTOS 15MG TABLETS MAL11100026ACRZ	DAITO PHARMACEUTICAL TOYOMA, JAPAN

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
221.	<b>Pipemidic acid</b>	URIXIN FILMTAB TABLET MAL19910050A	ABBOTT LABS, PHILIPPINES
		URIXIN FILMTAB 400MG MAL19871869A	ABBOTT LABS, PAKISTAN
		This product can be obtained from <b>Pakistan</b> (Information obtained from Abbott Laboratories (M) Sdn Bhd via an email dated 27 June 2016)	
222.	<b>Piracetam</b>	NOOTROPIL TABLET 800 MG MAL07021408ARZ	UCB S.A. - SECTEUR PHARMA, BELGIUM
		NOOTROPIL TABLET 1200 MG MAL07021409ARZ	
223.	<b>Pizotifen malate</b>	SANDOMIGRAN TABLET 0.5MG MAL19860378A	NOVARTIS FARMA S.P.A., ITALY
		This products can be obtained from <b>Australia, Hong Kong, New Zealand and Sri Lanka</b> (Information obtained from Novartis Corporation (M) Sdn Bhd via an email dated 11 <sup>th</sup> May 2015). Sandomigran Tablet made in Italy and distributed by AFT Pharmaceuticals Pty Ltd can be used as comparator (Information obtained from Novartis Corporation (M) Sdn Bhd via an email 9 December 2016).	
224.	<b>Pramipexole Dihydrochloride Monohydrate</b>	SIFROL TABLET 0.125MG MAL20000717AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		SIFROL TABLET 0.25MG MAL20000718AZ	
		SIFROL TABLET 1MG MAL20000719AZ	
225.	<b>Prasugrel Hydrochloride</b>	EFFIENT FILM-COATED TABLETS 10 MG MAL20102003AZ	ELI LILLY AND COMPANY, USA
		EFFIENT FILM-COATED TABLETS 5 MG MAL20102002AZ	
226.	<b>Pravastatin sodium</b>	PRAVACHOL TABLET 10MG MAL20032161A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		PRAVACHOL TABLET 10MG PBKD 921380A	E.R. SQUIBB & SONS LTD



**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		PRAVACHOL TABLET 10MG MAL19940249A PRAVACHOL TABLET 20MG MAL20013463AC  PRAVACHOL TABLET 20MG MAL20021397AS  PRAVACHOL TABLET 20MG PBKD921379A PRAVACHOL TABLET 20MG MAL19940250A  PRAVACHOL TABLET 40MG MAL19991374A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA PHARMANIAGA MANUFACTURING BERHAD  BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA  E.R. SQUIBB & SONS LTD  BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA  BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		This products can be obtained from <b>Canada, France, Germany, Ireland and United Kingdom</b> (Information obtained from Bristol Myers Squibb Asia Pacific via an email dated 27 <sup>th</sup> March 2013)	
227.	<b>Prazosin</b>	MINIPRESS TABLET 1MG MAL19870096AZ  MINIPRESS TABLET 2MG MAL19870098AZ  MINIPRESS TABLET 5MG MAL19870100AZ	PFIZER AUSTRALIA PTY. LTD.
		MINIPRESS TABLET 1MG MAL19930148ACZ  MINIPRESS TABLET 2MG MAL19930149ACZ  MINIPRESS TABLET 5MG MAL19930150ACZ	PHARMANIAGA MANUFACTURING BERHAD
228.	<b>Primidone</b>	MYSOLINE 250MG TABLETS	UNITED KINGDOM
229.	<b>Procatamol hydrochloride</b>	MEPTIN TABLET 0.05MG MAL19890453ACZ	OTSUKA PHARMACEUTICAL CO., LTD, JAPAN

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
230.	<b>Progesterone</b>	UTROGESTAN CAPSULE 100MG MAL19971796AZ	BESINS MANUFACTURING BELGIUM, BELGIUM
231.	<b>Proguanil hydrochloride</b>	PALUDRINE TABLETS 100MG PBKD911193A	ASTRAZENECA UK LIMITED, UNITED KINGDOM
		This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer <a href="#">biowaiver page</a> on BPFK website for more information.	
232.	<b>Propafenone</b>	RYTMONORM TABLET 150MG MAL19880156AZ	ABBOT GMBH & CO. KG, GERMANY
233.	<b>Propantheline</b>	PRO-BANTHINE TABLET 15MG PBKD861516A	SEARLE LABS, AUSTRALIA. G.D. SEARLE & CO, UNITED KINGDOM
		PRO-BANTHINE TABLET 15MG PBKD861515A	
234.	<b>Propiverine</b>	MICTONORM TABLET MAL20061584AZ	APOGEPHA ARZNEIMITTEL GMBH, GERMANY
235.	<b>Prucalopride succinate</b>	RESOLOR 1MG FILM COATED TABLETS MAL12025075AZ	JANSSEN CILAG SPA, ITALY
		RESOLOR 2MG FILM COATED TABLETS MAL12025076AZ	JANSSEN CILAG SPA, ITALY
236.	<b>Pseudoephedrine</b>	SUDAFED TABLET 60MG, MAL19870799A	WELLCOME AUSTRALIA LTD, AUSTRALIA
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2013 – 13 March 2013: Sudafed Tablet 60mg from <b>GlaxoSmithKline Chittagong, Bangladesh</b> can also be used as a comparator.	
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: Sudafed Tablet 60mg from <b>GlaxoSmithKline Pulogadong, Indonesia</b> can also be used as a comparator.	
237.	<b>Pyridostigmine bromide</b>	MESTINON TABLET 10MG MAL05090001ACRZ	LABIANA PHARMACEUTICALS, SL, SPAIN
		MESTINON DRAGEES 60MG MAL04112698ACRZ	
		MESTINON 60MG TABLET MAL19861730A	F.HOFFMAN-LA ROCHE, SWITZERLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MESTINON ROCHE TABLET 10MG MAL19861729A	F.HOFFMAN-LA ROCHE, SWITZERLAND
		MESTINON 60MG TABLET MAL20041049A	ICN CANADA LTD, CANADA
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014 – 23 APRIL 2014: Since Mestinon 10mg Tablet (MAL05090001ACR) is not commercialised actively in Malaysia, it can be obtained by contacting the manufacturer's contact person as below for further enquiries:</p> <p align="center">                     Qualified Person                      Maria Merce Roca Solsona  <a href="mailto:Mariamerce.roca@labiana.com">Mariamerce.roca@labiana.com</a>                      Tel: 003493 622 29 00                 </p>	
238.	<b>Repaglinide</b>	NOVONORM TABLET 0.5MG MAL20001007ACRZ	BOEHRINGER INGELHEIM PHARMA KG, WEST GERMANY
		NOVONORM TABLET 1.0MG MAL20001008ACRZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		NOVONORM TABLET 2.0MG MAL20001009ACRZ	
239.	<b>Reserpine</b>	SERPASIL TABLET 0.10MG 1986044940A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		SERPASIL TABLET 0.25MG 1986044921A	
240.	<b>Ribavirin</b>	REBETOL CAPSULES 200MG MAL20001524ARZ	MSD International GmbH (PUERTO RICO BRANCH) UNITED STATES
		COPEGUS FILM-COATED TABLET 200MG MAL05012334AZ	SCHERING-PLOUGH LABO N.V., BELGIUM
		COPEGUS FILM COATED TABLET 200MG MAL08051760ACRSZ	HOFFMANN-LA ROCHE INC, UNITED STATES
241.	<b>Rifabutin</b>	MYCOBUTIN 150MG CAPSULES MAL19960957A	PFIZER ITALIA S.R.L.

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
242.	<b>Riluzole</b>	RILUTEK TABLETS 50MG MAL20051294AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
243.	<b>Risedronate sodium</b>	ACTONEL FILM-COATED TABLET 5MG MAL20012657ARZ	OSG NORWICH PHARM INC, UNITED STATES
		ACTONEL 30MG TABLET MAL20012656AR	
		ACTONEL 35MG TABLET MAL20034605ACRZ	NORWICH PHARMACEUTICALS INC., UNITED STATES
244.	<b>Rivaroxaban</b>	XARELTO 20MG FILM-COATED TABLET MAL11115001AZ	BAYER PHARMA AG, GERMANY
		XARELTO 15MG FILM-COATED TABLET MAL11115002AZ	BAYER PHARMA AG, GERMANY
245.	<b>Rivastigmine hydrogen tartrate</b>	EXELON 1.5MG CAPSULES MAL19990976ARZ  EXELON 3MG CAPSULES MAL19990977ARZ  EXELON 4.5MG CAPSULES MAL19990978ARZ  EXELON 6MG CAPSULES MAL19990979ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
246.	<b>Rizatriptan benzoate</b>	MAXALT TABLET 5MG MAL20000249ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		MAXALT TABLET 10MG MAL20000250ARZ	
247.	<b>Roflumilast</b>	DAXAS 500 MCG FILM-COATED TABLETS MAL20112164AZ	TAKEDA GMBH, GERMANY
248.	<b>Ropinirole hydrochloride</b>	REQUIP TABLET 0.25MG MAL19990966ARZ	GLAXO WELLCOME SA, SPAIN

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		REQUIP TABLET 1MG MAL19990967ARZ	GLAXO WELLCOME SA, SPAIN
		REQUIP TABLET 2MG MAL19990968AZ	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
		REQUIP TABLET 5MG MAL19990969AZ	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
249.	<b>Rosiglitazone</b>	AVANDIA TABLET 2MG MAL20000007A	GLAXO WELLCOME S.A., SPAIN
		AVANDIA TABLET 4MG MAL20000008ARZ	
		AVANDIA TABLET 8MG MAL20000009ARZ	
250.	<b>Rosuvastatin calcium</b>	CRESTOR 5 MG TABLET MAL20051356ARZ	IPR PHARMACEUTICALS INC, PUERTO RICO
		CRESTOR 10MG TABLET MAL20041089ARZ	
		CRESTOR 20MG TABLET MAL20051357ARZ	
251.	<b>Salbutamol Sulphate (Sustained release)</b>	VOLMAX 4MG CR TABLET MAL19890618AR	GLAXOSMITHKLINE SPA, STRADA ASOLANA 68, SAN POLO DI TORRILE PARMA, 43056 ITALY
		VOLMAX 4MG CR TABLET MAL19890619AR	
		Product is available in <b>Saudi Arabia</b> and several African countries e.g. <b>Rwanda and Burundi</b> (Information obtained from GSK, Malaysia dated via an email dated 2 <sup>nd</sup> October 2013)	
252.	<b>Saxagliptin</b>	ONGLYZA TABLET 2.5MG MAL20102019ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
			BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		ONGLYZA TABLET 5MG MAL20102020ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES  BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
253.	<b>Selegiline</b>	JUMEX TABLET 5MG MAL19950723AZ	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PVT. CO. LTD., HUNGARY
254.	<b>Sevelamer Carbonate</b>	REVELA (SEVELAMER CARBONATE) TABLETS MAL20102007AZ	GENZYME IRELAND LIMITED, IRELAND
		As agreed upon in Mesyuarat Dasar Regulatori 1/2013 dated 20 <sup>th</sup> Mac 2013, bioequivalence study is not required due to local effect. However, the following studies are required to support the interchangeability between the test and comparator product:- 1. In-Vitro Equilibrium Binding Study 2. In-Vitro Kinetic Binding Study	
255.	<b>Sildenafil citrate</b>	VIAGRA 25MG TABLET MAL19990542A  VIAGRA 50MG TABLET MAL19990543A  VIAGRA 100MG TABLET MAL19990544A	PFIZER INC, UNITED STATES
		VIAGRA 25MG TABLET MAL20012709ASZ  VIAGRA 50MG TABLET MAL20012710ACSZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA  FAREVA AMBOISE, FRANCE
		VIAGRA 100MG TABLET MAL20012711ACSZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA  FAREVA AMBOISE, FRANCE  PFIZER AUSTRALIA PTY. LTD., AUSTRALIA

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		REVATIO 20 MG FILM-COATED TABLET MAL20071716ACZ	FAREVA AMBOISE, FRANCE
256.	<b>Sitagliptin</b>	JANUVIA 25 MG TABLET MAL20071662ARZ  JANUVIA 50 MG TABLET MAL20071663ARZ  JANUVIA 100 MG TABLET MAL20071664ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
257.	<b>Sodium Iodide</b>	SODIUM IODIDE (1311) THERAPY CAPSU* MAL19930360AZ	GE HEALTHCARE LIMITED, UNITED KINGDOM
258.	<b>Sodium fusidate</b>	FUCIDIN TABLET 250MG (FILM COATED) MAL19910821AZ	LEO PHARM PRODUCTS, DENMARK
259.	<b>Sodium rabeprazole</b>	PARIET TABLET 10MG MAL19992540ACRZ  PARIET TABLET 20MG MAL19992541ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN  EISAI CO LTD, JAPAN
260.	<b>Solifenacin Succinate</b>	VESICARE 5 MG (FILM COATED TABLET) MAL20091963AZ  VESICARE 10MG (FILM COATED TABLET) MAL20091964AZ	ASTELLAS PHARMA EUROPE B.V, NETHERLAND
261.	<b>Sofosbuvir</b>	SOVALDI 400MG FILM-COATED TABLETS MAL15095034AZ	GILEAD SCIENCES IRELAND UC, IRELAND
262.	<b>Sorafenib tosylate</b>	NEXAVAR FILM-COATED TABLETS 200 MG MAL20071668AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
263.	<b>Sotalol hydrochloride</b>	SOTACOR TABLET 80MG MAL19930231A	BRISTOL-MYERS CO LTD, UNITED KINGDOM
		SOTACOR TABLET 160MG MAL19930232A	
		SOTACOR TABLET 80MG MAL19940601AS	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		SOTACOR TABLET 160MG MAL19940602AS	
264.	<b>Spiramycin</b>	ROVAMYCINE TABLET 1.5 MILLION IU MAL19890558A	FAMAR LYON, FRANCE
		ROVAMYCINE 3 M.I.U. TABLETS MAL19962132AZ	FAMAR LYON, FRANCE
265.	<b>Spirolactone</b>	ALDACTONE TABLET 100MG MAL19870236A	SEARLE LABS, AUSTRALIA
		ALDACTONE TABLET 25MG	
<p>This product is available in <b>Argentina, Aruba, Australia, Bahamas, Bahrain, Barbados, Belgium, Belize, Bermuda, Brazil, Cambodia, Canada, Colombia, France, Ghana, Greece, Hong Kong, Iceland, Ireland, Israel, Jamaica, Japan, Kenya, Kuwait, Lebanon, , Korea, Mexico, Myanmar, Nigeria, Norway, Oman, Phillipines, Qatar, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Thailand, UK, UAE, Vietnam.</b> (Information obtained from Pfizer Malaysia dated 10<sup>th</sup> June 2013 via an email)</p>			
266.	<b>Sulindac</b>	CLINORIL 200MG TABLET MAL19950546A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
267.	<b>Sulodexide</b>	VESSEL DUE F 250 LSU CAPSULE MAL19992679AZ	ALFA WASSERMANN S.P.A., ITALY
268.	<b>Sulphasalazine</b>	SALAZOPYRIN EN TABLET 500MG MAL19950470AZ	KEMWELL AB, SWEDEN
269.	<b>Sultamicillin tosylate</b>	UNASYN TABLET MAL19910104AZ	PFIZER JAPAN INC



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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		UNASYN ORAL TABLET 375MG MAL20020026ACSZ	PHARMANIAGA MANUFACTURING BERHAD
270.	<b>Sumatriptan succinate</b>	IMIGRAN TABLET 50MG MAL19973576ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND
		IMIGRAN TABLET 100MG MAL19950008AZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		This products are available in <b>Korea, Hong Kong, Singapore, Sri Lanka, Australia, Phillipines &amp; Thailand</b> (Information obtained from GlaxoSmithKline Pharmaceutical Sdn. Bhd. dated 23 <sup>rd</sup> June 2013 via an email)	
271.	<b>Sunitinib Malate</b>	SUTENT 12.5MG CAPSULE MAL20071632AZ	PFIZER ITALIA S.R.L., ITALY
		SUTENT 25MG CAPSULE MAL20071633AZ	PFIZER ITALIA S.R.L., ITALY
		SUTENT 50MG CAPSULE MAL20071634AZ	PFIZER ITALIA S.R.L., ITALY
272.	<b>Tadalafil</b>	CIALIS 2.5MG FILM-COATED TABLETS MAL14125151AZ	LILLY DEL CARIBE INC., PUERTO RICO
		CIALIS 5MG FILM-COATED TABLETS MAL14125149AZ	LILLY S.A., SPAIN
		CIALIS 10MG FILM COATED TABLET MAL20034164AZ	LILLY S.A., SPAIN
		CIALIS 20MG FILM COATED TABLET MAL20034166AZ	LILLY S.A., SPAIN
273.	<b>Tamsulosin</b>	HARNAL OCAS 400MCG FILM- COATED TABLET MAL20091914AZ	ASTELLAS PHARMA EUROPE B.V., NETHERLANDS
274.	<b>Tegafur</b>	FUTRAFUL CAPSULE 200MG MAL19861648A	TAIHO PHARM CO LTD, JAPAN

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
275.	<b>Telbivudine</b>	SEBIVO 600 MG TABLETS MAL20071671ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
276.	<b>Telithromycin</b>	KETEK 400MG TABLET MAL20033479AZ	AVENTIS PHARMA S.P.A, ITALY
277.	<b>Telmisartan</b>	MICARDIS TABLET 20MG MAL20014487A MICARDIS TABLET 40MG MAL19992673AZ MICARDIS TABLET 80MG MAL19992674AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
278.	<b>Temozolomide</b>	TEMODAL CAPSULES 5MG MAL07082878ACR  TEMODAL CAPSULES 5 MG MAL06071048ACRS  TEMODAL CAPSULES 20MG MAL07082880ACRZ  TEMODAL CAPSULES 20 MG MAL06071049ACRSZ  TEMODAL CAPSULES 100MG MAL07082881ACRZ  TEMODAL CAPSULES 250 MG MAL06071051ACRS	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 20MG MAL20032408AR  TEMODAL CAPSULES 100MG MAL20032409AR  TEMODAL CAPSULES 250MG MAL20032410AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES
279.	<b>Tenoxicam</b>	TILCOTIL` ROCHE` LACQ-COATED TAB 20MG MAL19890224A	F.HOFFMAN-LA ROCHE, SWITZERLAND



**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
284.	<b>Thyroxine sodium</b>	ELTROXIN TABLET 0.05 MG MAL19890455A  ELTROXIN TABLET 0.1MG MAL19890456A	GLAXO WELLCOME OPERATIONS UK LTD
285.	<b>Tibolone</b>	LIVIAL TABLET 2.5MG MAL19913394AZ	N.V. ORGANON, NETHERLANDS
286.	<b>Ticagrelor</b>	BRILINTA 90MG FILM-COATED TABLET MAL20112115ARZ	ASTRAZENECA AB, SWEDEN
287.	<b>Tolterodine l-tartrate</b>	DETRUSITOL TABLET 2MG MAL19991686AZ	PFIZER ITALIA S.R.L., ITALY
288.	<b>Topotecan hydrochloride</b>	HYCAMTIN 0.25MG HARD CAPSULES MAL20091960ACZ  HYCAMTIN 1 MG HARD CAPSULES MAL20091961ACZ	GLAXOSMITHKLINE MANUFACTURING S.P.A, ITALY
289.	<b>Tranexamic Acid</b>	TRANSAMIN CAPSULE 250MG MAL19890202ACZ  TRANSAMIN CAPSULE 250MG	CMIC CMO CO. LTD, JAPAN  DAIICHI PHARMACEUTICAL LTS, JAPAN
290.	<b>Tramadol hydrochloride</b>	TRAMAL CAPSULE MAL19921516A	GRUNENTHAL GMBH, WEST GERMANY
<p><b>Product is available in Australia, Austria, Bahrain, Belgium, China, Croatia, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Jordan, Kenya, Kuwait, Lebanon, New Zealand, Netherlands, Nigeria, Norway, Oman, Portugal, Poland, Qatar, Saudia Arabia, Sweden, Taiwan, Thailand, Switzerland, UAE, UK, Yemen</b> (Information obtained via an email from Grunenthal GmbH, Germany dated 28<sup>th</sup> March 2013)</p> <p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2015 – 21 April 2015: Tramal Capsule (MAL19921516A) from <b>Farmaceutici Formenti S.P.A, Via di Vittorio 2, 21040 Oriddio, Italy</b> can also be used as a comparator.</p>			

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Bil.	TEST PRODUCTS ( <i>Pharmaceutical name</i> )	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2015, 21 April 2015: Tramadol 50 Capsule (MAL19985903AC) and Tramox Capsule 50mg (MAL08042453AC) are being added to the existing list of comparator.	
		TRAMADOLOR 50 CAPSULE MAL19985903ACZ	SALUTAS PHARMA GMBH, GERMANY
		TRAMOX CAPSULE 50MG MAL08042453ACZ	AEGIS LTD, CYPRUS  DELORBIS PHARMACEUTICALS, CYPRUS
291.	<b>Tretinoin</b>	VESANOID SOFT-GELATIN CAPSULE 10MG MAL19960996ACZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
292.	<b>Triazolam</b>	SOMESE TABLET 0.25 MG MAL07050020AZ	PFIZER ITALIA S.R.L., ITALY  SANICO N.V., BELGIUM
293.	<b>Triflusal</b>	GRENDIS 300MG CAPSULE MAL20051420AZ	J. URIACH & CIA,S.A., SPAIN
294.	<b>Trimebutine maleate</b>	DEBRIDAT TABLET 1990040029A	JOUEVINAL LABS, FRANCE
295.	<b>Trimetazidine hydrochloride/ Trimetazidine Dihydrochloride</b>	VASTAREL COATED TABLET 20MG MAL19870169AZ	LES LABS SERVIER INDUSTRIE, FRANCE
296.	<b>Ulipristal Acetate</b>	ELLA TABLET 30mg MAL12035079ACZ	CENEXI, FRANCE
297.	<b>Ursodeoxycholic acid</b>	URSOFALK CAPSULE 250MG MAL19990011ACSZ	LOSAN PHARMA GMBH, GERMANY
298.	<b>Valganciclovir</b>	VALCYTE TABLETS 450MG MAL20040021ARZ	PATHEON INC, CANADA
299.	<b>Vigabatrin</b>	SABRIL 500MG TABLET MAL19961357AZ	PATHEON FRANCE S.A., FRANCE
300.	<b>Vildagliptin</b>	GALVUS 50MG TABLETS MAL20081792ARZ	NOVARTIS FARMACEUTICA S.A, SPAIN
301.	<b>Vinorelbine tartrate</b>	NAVELBINE 20MG SOFT CAPSULE MAL20071635AZ	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE

**LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES**  
**(MARCH 2017)**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		NAVELBINE 30MG SOFT CAPSULE MAL20071636AZ	
302.	<b>Voriconazole</b>	VFEND 50MG TABLET MAL20040542ARZ  VFEND 200MG TABLET MAL20040543ARZ	PFIZER ITALIA S.R.L ITALY  PFIZER MANUFACTURING DEUTSHLAND GMBH, GERMANY
303.	<b>Vorinostat</b>	ZOLINZA 100MG CAPSULE MAL20102001ACRZ	PATHEON INC. CANADA
304.	<b>Ziprasidone hydrochloride</b>	ZELDOX CAPSULE 20MG MAL20032622A  ZELDOX CAPSULE 40MG MAL20032623AZ  ZELDOX CAPSULE 60MG MAL20032624AZ  ZELDOX CAPSULE 80MG MAL20032625AZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
305.	<b>Zofenopril calcium</b>	BIFRIL 30 MAL20061470AZ	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L., ITALY
306.	<b>Zuclopenthixol</b>	CLOPIXOL TABLET 10MG MAL19890537A	H.LUNDBECK A/S, DENMARK

**Note:**

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