

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(NOVEMBER 2017)

Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
1.	Abiraterone acetate	ZYTIGA 250MG TABLET MAL12085056ACRZ	PATHEON INC, CANADA
2.	Acarbose	GLUCOBAY TABLET 50MG MAL19940745AZ GLUCOBAY TABLET 100MG MAL19940746AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
3.	Acebutolol hydrochloride	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.	Acemetacin	RANTUDIL CAPSULE 60MG (MAL19986936A)	BAYER AG, WEST GERMANY
		RANTUDIL RETARD 90MG CAPSULE (MAL19992054AZ)	BAYER SCHERING PHARMA AG, GERMANY
5.	Acipimox	OLBETAM CAPSULE 250 MG (MAL19900589A)	PHARMACIA S.P.A, ITALY
6.	Acitretin	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.	Acrivastine	SEMPREX CAPSULE 8MG (MAL19900013A)	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM

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8.	Adefovir	HEPSERA TABLET 10MG MAL20040907ARZ	GLAXOSMITHKLINE (TIANJIN) CO. LTD., CHINA
9.	Aliskiren Hemifumarate	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.	Allopurinol	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 biowaiver page on NPRA website for more information.			
11.	Alverin citrate	SPASMAVERINE TABLET 0.04G MAL19871806A	LABORATOIR BELLON, FRANCE
This product can be obtained from Vietnam & Cambodia (Information obtained from Sanofi Aventis (M) Sdn. Bhd dated 29 th November 2013 via an email)			
12.	Amantadine hydrochloride	SYMMETREL SOFT GELATIN CAPSULE 100* 1986040644A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
13.	Amantadine sulphate	PK-MERZ TABLET 100MG MAL19860850AZ	MERZ PHARMA GMBH & CO. KGAA,GERMANY
14.	Ambrisentan	VOLIBRIS 5 MG FILM COATED TABLET MAL20102008ACRZ VOLIBRIS 10 MG FILM COATED TABLET MAL20102009ACRZ	PATHEON INC. CANADA
15.	Amiodarone hydrochloride	CORDARONE 200MG MAL19987968ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE

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16.	Amisulpride	SOLIAN 100MG SCORED TABLET MAL20032239AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		SOLIAN 400MG SCORED FILM- COATED TABLET MAL20032240AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
17.	Amodiaquine	CAMOQUIN	PFIZER, UNITED KINGDOM
18.	Anastrozole	ARIMIDEX TABLET 1MG MAL19987960ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
19.	Aprepitant	EMEND 80MG CAPSULE MAL20040905AR	MERCK SHARP & DOHME CORP.*, UNITED STATES
		EMEND 125MG CAPSULE MAL20040906AR	
20.	Atomoxetine	STRATTERA 60MG CAPSULE MAL20051406AZ	LILLY S.A, MADRID, SPAIN
		STRATTERA 40MG CAPSULES MAL20051405AZ	
		STRATTERA 25MG CAPSULES MAL20051404AZ	
		STRATTERA 18MG CAPSULES MAL20051403AZ	
		STRATTERA 10MG CAPSULES MAL20051402AZ	
21.	Baclofen	LIORESAL 10MG TABLET MAL20000748ACRZ	NOVARTIS FARMA S.P.A., ITALY
22.	Benfluorex	MEDIAXAL TABLET 150MG MAL19870176A	LES LABS SERVIER INDUSTRIE, FRANCE
23.	Benzhexol	ARTANE TABLET 2MG PBKD861498A	AMERICAN CYANAMID CO, UNITED STATES
		ARTANE TABLET 2MG PBKD861497A	CYANAMID OF GREAT BRITAIN, UNITED KINGDOM
		This product can be obtained from Nagoya, Japan (Information updated from Pfizer on 25 th January 2013 via a letter)	

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2017”, 27 September 2017, the following product is being added to the existing list of comparator:-	
		APO-TRIHES TABLET 2MG MAL19984756AZ	APOTEX INC, CANADA
24.	Benzotropine mesylate	COGENTIN TABLET 2MG MAL19870343AR	MERCK SHARP & DOHME INT, UNITED STATES
25.	Betahistine dihydrochloride	BETASERC 24MG TABLET MAL07061394AZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
		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.	Betahistine mesylate	MERISLON TABLET 6MG MAL19861236AZ	EISAI CO LTD, JAPAN
27.	Betaxolol	KERLONE TABLET 20MG MAL19872264AZ	SANOBI WINTHROP INDUSTRIE, FRANCE
28.	Bicalutamide	CASODEX TABLET 50MG MAL19990958ACRZ	CORDEN PHARMA GMBH, GERMANY.
		CASODEX 150MG TABLET MAL20040082AR	ASTRAZENECA GMBH , GERMANY
29.	Bisoprolol fumarate	CONCOR 2.5MG FILM COATED TABLET	MERCK KGAA, GERMANY

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL20020792AZ CONCOR 5 FILM COATED TABLET MAL19890389AZ CONCOR 10 FILM-COATED TABLET MAL19890390AZ	
30.	Bosentan monohydrate	TRACLEER TABLET 62.5 MG MAL20041084ACRZ TRACLEER TABLET 125 MG MAL20041085ACRZ	PATHEON INC., CANADA
31.	Brompheniramine maleate	DIMETANE TABLET 4MG 1986041234A	A.H.ROBINS PTY LTD, AUSTRALIA
32.	Bumetanide	BURINEX TABLET 1MG MAL19913216AZ	LEO PHARM PRODUCTS, DENMARK
33.	Busulphan	MYLERAN TABLETS 2MG MAL05051050ACZ	EXCELLA GMBH, GERMANY
34.	Butropium bromide	COLIOPAN TABLET 5MG MAL19910111ACZ	BORA PHARMACEUTICALS CO., LTD, TAIWAN EISAI TAIWAN INC, TAIWAN
35.	Cabergoline	DOSTINEX TABLET 0.5MG MAL19971775AZ	PFIZER ITALIA S.R.L., ITALY
36.	Candesartan Cilexetil Tablet	ATACAND TABLET 8MG MAL20001218ARZ ATACAND TABLET 16MG MAL20001219ARZ ATACAND TABLET 4MG MAL20001217A ATACAND TABLET 32MG MAL09042471A	ASTRAZENECA AB, SWEDEN ASTRAZENECA AB, SWEDEN ASTRAZENECA AB, SWEDEN ASTRAZENECA AB, SWEDEN

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		BLOPRESS TABLET 8MG MAL20002652ARZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		BLOPRESS TABLET 16MG MAL20002653AZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
37.	Capecitabine	XELODA TABLET 150MG MAL20000001ARZ	PRODUCTOS ROCHE S.A DE C.V, MEXICO
		XELODA TABLET 500MG MAL20000002ARZ	
38.	Carbimazole	NEOMERCAZOLE TABLET 5 MG MAL05092230AC	APTUIT (EDINBURGH) LIMITED, UNITED KINGDOM
		NEOMERCAZOLE® TABLET 5 MG MAL12020025ACZ	CENEXI SAS, FRANCE
		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 & Tobago, Kuwait, Hong Kong, Saudi Arabia, Ireland. (Information obtained from Manarini Singapore Pte Ltd via an email dated 16th March 2015)	
39.	Cefaclor	DISTACLOR CAPSULE 250MG MAL19962114A	ELI LILLY & CO (TAIWAN) INC, TAIWAN
		DISTACLOR CAPSULE 500MG MAL19962115A	
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 December 2015: i) DISTACLOR 250MG from Lilly Suzhou Pharmaceutical Co, Ltd No. 6 Baiyu Road, Suzhou Industrial Park, Jiangsu Province, China ii) DISTACLOR 500MG from Vianex S.A, (Factory D) VIPE Patras 250 18 Ag. Stefanos,	

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		<p style="text-align: center;">Greece</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.	Cefadroxil monohydrate	DURICEF CAPSULE 500MG MAL19860523A DURICEF TABLET 1GM MAL19940665A	BRISTOL-M BARCELONETA INC, PUERTO RISO, UNITED STATES
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: DURICEF CAPSULE AND TABLET from Corden Pharmaceuticals Italy 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).</p>	
41.	Cefdinir	OMNICEF CAPSULE 100MG MAL19991688AC	UPHA PHARMACEUTICAL MFG. (M) SDN BHD, MALAYSIA
42.	Cefixime	SUPRAX TABLET	LEDERLE
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9th December 2015: SUPRAX TABLET from Famar Lyon, France and Merck Pharma, Spain 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)</p>	
43.	Cefprozil	PROCEF TABLET 250MG MAL19940487A PROCEF TABLET 500MG MAL19940483A	BRISTOL-M BARCELONETA INC, UNITED STATES
44.	Ceftibuten	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.	Celecoxib	CELEBREX CAPSULE 100MG MAL20000004ARZ CELEBREX CAPSULE 200MG MAL20000005ARZ	PFIZER PHARMACEUTICAL LLC, KM1.9 ROAD 689, VEGA BAJA, PUERTO RICO 00693, USA

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		CELEBREX 400MG CAPSULES MAL08051748ARZ	
		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.	Cephradine	VELOSEF CAPSULE 500MG MAL19920468A	BRISTOL-MYERS SQUIBB AEBE, GREECE
47.	Ciprofibrate	MODALIM TABLET 100MG MAL19950391AZ	PT AVENTIS PHARMA, INDONESIA
48.	Chloroquine sulphate	NIVAQUINE TABLET 200MG MAL19912313A	MAY & BAKER LTD, UNITED KINGDOM
49.	Chloroquine phosphate	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 biowaiver page on NPRA website for more information.	
50.	Chlorothiazide	CHLOTRIDE TABLET 500MG 1986040263A	MERCK SHARP & DOHME INT, UNITED STATES
51.	Chlorpropamide	DIABENESE TABLET 250MG MAL19986461A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		DIABINESE TABLET 250MG MAL19870382A	PFIZER PHARM DIV., PHILIPINES
52.	Chlortetracycline	AUREOMYCIN CAPSULE 250MG MAL19871950A	INTERTHAI PHARMACEUTICAL MANUFACTURING LTD, THAILAND
53.	Cilostazol	PLETAAL 50MG TABLETS MAL20061476AZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, KOREA
		PLETAAL 100MG TABLETS MAL20061475AZ	
54.	Cinnarizine	STUGERON 25MG TABLET MAL19871481AZ	JANSSEN CILAG SPA, ITALY
55.	Clemastine fumarate	TAVEGYL TABLET 1MG PBKD861195A	NOVARTIS PHARMA AG, SWITZERLAND
56.	Clodronate	OSTAC CAPSULE 1989120003A	ROCHE DIAGNOSTICS GMBH, GERMANY

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57.	Clomiphene Citrate	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.	Clonazepam	RIVOTRIL ROCHE TABLET 0.5MG MAL19860961ARZ	ROCHE FARMA S.A., SPAIN
		RIVOTRIL ROCHE TABLET 2MG MAL19860962ARZ	
59.	Clonidine	DIXARIT TABLET 25MCG MAL19870080A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY.
		DIXARIT SUGAR-COATED TABLET 0.025MG MAL19986979A	BOEHRINGER INGELHEIM FRANCE, FRANCE.
		CATAPRES TABLET 0.15MG MAL19861621A	BOEHRINGER INGELHEIM LTD, SOUTH KOREA
60.	Clorazepate dipotassium	TRANXENE CAPSULE 5MG PBKD861331AR	SANOFI WINTHROP INDUSTRIE, FRANCE
		TRANXENE CAPSULE 10MG PBKD861332AR	
61.	Conjugated Oestrogen	PREMARIN TABLET 0.625MG MAL19870652AZ	PFIZER IRELAND PHARMACEUTICALS IRELAND
		PREMARIN 0.3 TABLET MAL19991386ASZ	
62.	Crizotinib	XALKORI 200MG HARD CAPSULES MAL12095102AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		XALKORI 200MG HARD CAPSULES MAL12095103AZ	
63.	Cycloserine	CYCLOSERINE CAPSULE BP 250MG MAL19900001A	ELI LILLY AND COMPANY LIMITED, UNITED KINGDOM
This active ingredient has been granted biowaiver List B based on			

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		unavailability/ inaccessibility of comparator/ innovator product. Kindly refer biowaiver page on NPRA website for more information.	
64.	Cyproterone acetate	ANDROCUR 50MG TABLET MAL19993023ARZ	DELPHARM LILLE S.A.S., FRANCE BAYER WEIMAR GMBH, GERMANY
65.	Dabigatran Etextilate Mesilate	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.	Daclatasvir dihydrochloride	DAKLINZA 30MG FILM-COATED TABLETS MAL16045046ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
		DAKLINZA 60MG FILM-COATED TABLETS MAL16045037ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
67.	Danazol	LADOGAL CAPSULE 50MG PBKD870433A	NYCOMED PUERTO RICO INC, SPAIN
		LADOGAL CAPSULE 100MG PBKD870434A	
		LADOGAL CAPSULE 200MG PBKD870435A	
		LADOGAL CAPSULE 200MG MAL19987969A	SANOFI-SYNTHELABO LTD, UNITED KINGDOM
		LADOGAL CAPSULE 100MG MAL19987970A	SANOFI-SYNTHELABO LTD, UNITED KINGDOM
Product is available in Taiwan & Philliphines (Information obtained via an email from Sanofi Aventis (M) Sdn. Bhd dated 22 May 2013)			

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		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)	MEDOCHEMIE LTD CYPRUS
		ANARGIL CAPSULE 200MG (MAL19871961AZ)	MEDOCHEMIE LTD CYPRUS
68.	Dapoxetine Hydrochloride	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.	Dasatinib	SPRYCEL 20MG TABLET MAL20071695AR SPRYCEL 50MG TABLET MAL20071696AR SPRYCEL 70MG TABLET MAL20071697AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
70.	Deferiprone	FERRIPROX 500MG TABLET MAL20033480ACZ	APOTEX INC CANADA
71.	Desogestrel	CERAZETTE TABLET MAL20031939AZ	N.V ORGANON, NETHERLAND
72.	Desloratadine	AERIUS TABLET MAL20020876ARZ AERIUS TABLET 5MG MAL10053655AZ	SCHERING PLOUGH SPA, ITALY SCHERING-PLOUGH LABO N.V., BELGIUM
73.	Desmopressin	MINIRIN TABLET 0.1MG MAL19950096ARZ MINIRIN TABLET 0.2MG MAL19950097ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND FERRING INTERNATIONAL CENTER SA, SWITZERLAND

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74.	Dexketoprofen trometamol	KETESSE 25MG FILM COATED TABLET MAL20061602AZ	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L, ITALY
75.	Diacerein	ARTRODAR MAL20041211AZ	TRB PHARMA S.A, ARGENTINA
76.	Diclofenac potassium	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.	Diclofenac sodium	VOLTAREN TABLET 25MG MAL19861069AZ	NOVARTIS SAGLIK, TURKEY
		VOLTAREN TABLET 50MG MAL19861068ARZ	NOVARTIS FARMA S.P.A., ITALY
		VOLTAREN TABLET 50MG MAL19861068ARZ	NOVARTIS SAGLIK, TURKEY
78.	Didanosine	VIDEX TABLET 25MG MAL19973593A	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES
		VIDEX TABLET 50MG MAL19973594A	
		VIDEX TABLET 100MG MAL19973595A	
		VIDEX TABLET 200MG MAL20020813A	
		VIDEX EC DELAYED-RELEASE CAPSULE 125MG MAL20021388A	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

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		VIDEX EC DELAYED-RELEASE CAPSULE 200MG MAL20021389A	
		VIDEX EC DELAYED-RELEASE CAPSULE 250MG MAL20021390A	
		VIDEX EC DELAYED-RELEASE CAPSULE 400MG MAL20021391A	
79.	Dienogest	VISANNE 2MG TABLET MAL12105068ARZ	BAYER WEIMAR GMBH CO. KG, GERMANY
80.	Dihydrocodeine Tartrate	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). DF 118 Tablet obtained from South Africa, manufactured by GSK S.A. (pty) Ltd., Epping and distributed by Aspen Pharmacare can be used as comparator (Information obtained from GSK Malaysia via an email 11 May 2017).	
81.	Disodium Clodronate Tetrahydrate	BONEFOS 400MG TABLETS MAL19988453A	BAYER OY, FINLAND
		BONEFOS 800MG TABLETS MAL19988452AZ	BAYER OY, FINLAND
82.	Diflunisal	DOLOBID TABLET 250MG MAL19861106AR	MERCK SHARP & DOHME INT, UNITED STATES
		DOLOBID TABLET 500MG MAL19890178AR	
83.	Dihydroergotamine mesylate	SEGLOR CAPSULE 5MG MAL19870274AZ	SANOFI WINTHROP INDUSTRIE, FRANCE

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84.	Diphenidol hydrochloride	CEPHADOL TABLET 25MG MAL19861237AZ	NIPPON SHINYAKU CO LTD, JAPAN
85.	Domperidone	MOTILIUM TABLET 10MG MAL19872254ARZ	JANSSEN CILAG, FRANCE
86.	Donepezil	ARICEPT F.C. 5MG MAL20013565ACZ ARICEPT TABLET 10MG MAL05020190ACZ	BORA PHARMACEUTICALS CO., LTD., TAIWAN EISAI TAIWAN INC, TAIWAN BORA PHARMACEUTICALS CO., LTD., TAIWAN EISAI TAIWAN INC, TAIWAN
Product is available in Indonesia, Taiwan, Sri Lanka, Hong Kong, Macao, Jordan and Dominican Republic (Information obtained from Eisai (M) Sdn Bhd on 19 th September 2017)			
87.	Dothiepin	PROTHIADEN CAPSULE 25MG MAL19861459A PROTHIADEN TABLET 75MG MAL19861460A DOTHEP 75MG TABLET MAL19970063AZ	THE BOOTS COMPANY PLC, UNITED KINGDOM ALPHAPHARM PTY LTD, AUSTRALIA
As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016, 13 th January 2017: DOTHEP 75MG TABLET (MAL19970063AZ) is being added to the existing list of comparator.			
88.	Doxazosin	CARDURA TABLET 2MG MAL19990562ASZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
89.	Dronedarone Hydrochloride	MULTAQ 400MG FILM-COATED TABLETS MAL20102016AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
90.	Drotaverine	NO-SPA TABLETS 40MG MAL19900596A	CHINOIN PHARMACEUTICAL &

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
		NO-SPA FORTE TABLET MAL20001801A	CHEMICAL WORKS PRIVATE CO LTD, HUNGARY
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18 August 2014: NO-SPA 40mg Tablet from Sanofi-Aventis, Vietnam can also be used as a comparator.	
		Sanofi-Aventis Vietnam 123 Nguyen khoai, District 4, Ho Chi Minh, Vietnam	
91.	Dutasteride	AVODART SOFT GELATIN CAPSULES MAL20040194ARZ	RP SCHERER SA, FRANCE GLAXO SMITH KLINE PHARMACEUTICALS, POLAND
92.	Dydrogesterone	DUPHASTON TABLET 10MG MAL19920643AZ	ABBOTT BIOLOGICALS B. V., NETHERLANDS
93.	Eletriptan hydrobromide	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
94.	Eltrombopag Olamine	REVOLADE FILM COATED TABLET 25MG MAL20102010ACRZ REVOLADE FILM COATED TABLET 50 MG MAL20102011ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
95.	Entacapone	COMTAN TABLET 200MG MAL19992996ARZ	ORION CORP, FINLAND
96.	Entecavir	BARACLUE TABLET 0.5 MG MAL20061502ARZ BARACLUE TABLET 1MG, MAL20061503AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(NOVEMBER 2017)

Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
97.	Eperisone hydrochloride	MYONAL TABLET 50MG MAL19940448ACZ	MISATO PLANT OF EISAI CO, JAPAN BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN
98.	Eplerenone	INSPIRA 25MG FILM-COATED TABLETS MAL20081801ARZ INSPIRA 50MG FILM-COATED TABLETS MAL20081802ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
99.	Erlotinib	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
100.	Esomeprazole magnesium	NEXIUM MUPS TABLET 20MG MAL20020238ARZ NEXIUM MUPS TABLET 40MG MAL20020239ARZ	ASTRAZENECA AB, SWEDEN ASTRAZENECA AB, SWEDEN

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
101.	Estradiol	PROGYNOVA 1MG TABLET MAL09020971ACZ PROGYNOVA TABLET 2MG MAL09020972ACRZ	DELPHARM LILLE S.A.S., FRANCE
102.	Estramustine sodium phosphate	ESTRACYT CAPSULE 140MG MAL19990993A	PFIZER ITALIA S.R.L., ITALY
103.	Etoricoxib	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
104.	Everolimus	AFINITOR 10MG TABLET MAL20091943ARZ AFINITOR 5MG TABLET MAL20091942ARZ AFINITOR 2.5MG TABLET MAL12085055ARZ CERTICAN 1.0MG TABLETS MAL20071692ARZ CERTICAN 0.75MG TABLETS MAL20071691ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND 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
(NOVEMBER 2017)

Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		CERTICAN 0.50MG TABLETS MAL20071690ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CERTICAN 0.25MG TABLETS MAL20071689ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
105.	Exemestane	AROMASIN TABLET 25MG MAL08111847AZ	PFIZER ITALIA S.R.L., ITALY
		AROMASIN 25MG TABLETS MAL20013341A	
106.	Ezetimibe	EZETROL 10MG MAL20034627ARZ	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, UNITED STATES
			SCHERING PLOUGH PRODUCTS, UNITED STATES
107.	Famciclovir	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)	
108.	Famotidine	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 (<i>Pharmaceutical name</i>)	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			
109.	Febuxostat	FEBURIC 80MG FILM-COATED TABLETS MAL16075031ACRZ	PANTHEON FRANCE, FRANCE
110.	Fenofibrate	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 Indonesia, Philippines, Singapore, Switzerland, Thailand & Vietnam (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 th August 2014: GEN-FENOFIBRATE MICRO 200MG CAPSULE (MAL20040063ACR) is being added to the existing list of comparator			

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
111.	Fexofenadine hydrochloride	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
112.	Finasteride	PROPECIA TABLET MAL19992040ACRZ	AIAC INTERNATIONAL PHARMA, LLC, UNITED STATES
		PROSCAR 5MG TABLET MAL19985910ACRZ	
		PROSCAR 5MG TABLET MAL19930510AR	
113.	Fingolimod hydrochloride	GILENYA 0.5MG HARD CAPSULE MAL12015017ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
114.	Flavoxate	URISPAS 200 TABLET MAL20033669AZ	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A., ITALY
115.	Flecainide	TAMBOCOR TABLET 100MG MAL19871528ARZ	3M HEALTHCARE LTD, UNITED KINGDOM
116.	Fludarabine	FLUDARA 10MG FILM COATED TABLETS MAL05051075ACZ	BAYER SCHERING PHARMA AG, GERMANY

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(NOVEMBER 2017)

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
117.	Flunarizine hydrochloride	SIBELIUM CAPSULE 5MG MAL19880179ARZ	JANSSEN-CILAG S.P.A., ITALY
		SIBELIUM TABLET 5 MG MAL09100238AZ	JANSSEN-CILAG S.P.A., ITALY
		Products are available in Turkey, Oman, Taiwan & Korea (Information obtained from Johnson & Johnson Malaysia dated 7 th March 2014 through an email	
118.	Fluvastatin	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	
119.	Fluoxymesterone	HALOTESTIN TABLETS 5MG (BELGIUM) MAL19920022A	PHARMACIA & UPJOHN S.A., BELGIUM
120.	Flupentixol dihydrochloride	FLUANXOL TABLET 0.5MG MAL19890543AZ	H.LUNDBECK A/S, DENMARK
		FLUANXOL TABLETS 3MG MAL19890544A	
		FLUANXOL TABLETS 1MG MAL19900451A	
121.	Flurazepam Monohydrochloride	DALMADORM 15MG CAPSULES MAL07050892AC	LABIANA PHARMACEUTICALS SL, SPAIN
122.	Flurbiprofen	FROBEN TABLET 50MG MAL19861117A	THE BOOTS COMPANY PLC, UNITED KINGDOM
123.	Fosinopril sodium	MONOPRIL TABLET 10MG MAL19992695AS	PT BRISTOL-MYERS SQUIBB INDONESIA TBK

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(NOVEMBER 2017)

Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MONOPRIL TABLET 10MG MAL19950242A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		MONOPRIL TABLET 20MG MAL19950243A	
124.	Gabapentin	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			
125.	Galantamine hydrobromide	REMINYL TABLET 4MG MAL20020123A	JANSSEN CILAG SPA, ITALY
		REMINYL TABLET 8MG MAL20020124A	
		REMINYL TABLET 12MG MAL20020125A	
126.	Ganciclovir	CYMEVENE CAPSULE 250MG MAL19993019AR	ROCHE PRODUCTS LTD, UNITED KINGDOM
		CYMEVENE HARD-GELATIN CAPSULE 250MG MAL19970079A	SYNTEX PUERTO RICO INC, UNITED STATES
127.	Gemfibrozil	LOPID CAPSULE 300MG MAL19990998A	PARKE DAVIS PTY LTD, AUSTRALIA

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		LOPID 600MG TABLET MAL19984784AS	PARKE DAVIS PTY LTD, AUSTRALIA
		LOPID 600MG TABLET MAL19900442AR	PARKE DAVIS PHARMA PTY LTD, UNITED STATES
		LOPID 450MG TABLET MAL19921617ARS	GOEDECKE A.G, WEST GERMANY
		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	
		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
128.	Gestrinone	DIMETRIOSE CAPSULE MAL19940494A	ROUSSEL LABS LTD, UNITED KINGDOM
129.	Glipizide	MINIDIAB 5MG TABLET MAL19913361AZ	PFIZER ITALIA S.R.L., ITALY
130.	Granisetron hydrochloride	KYTRIL TABLET 1MG MAL19940574ARZ	ROCHE S.P.A., ITALY F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
131.	Hydroxychloroquine	PLAQUENIL TABLET MAL19991702AZ PLAQUENIL TABLETS MAL04103442AZ	SANOFI-SYNTHELABO LTD, UNITED KINGDOM SANOFI-AVENTIS, S.A., SPAIN
132.	Hyoscine butylbromide	BUSCOPAN TABLET 10MG MAL09051577AZ	DELPHARM REIMS, FRANCE
133.	Hydroxyurea/ Hydroxycarbamide	HYDREA CAPSULE 500MG, MAL19962497A HYDREA CAPSULE 500MG, MAL19993027A	BRISTOL MYERS SQUIBB US BRISTOL MYERS SQUIBB S.R.L, 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
		Product is available in Australia, United Kingdom, United States , Ireland and France (Information obtained from Bristol Myers Asia Pacific through an email dated 18 th September 2013). As agreed upon in “Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2015 – 21 April 2015, Hyrea Capsule (MAL19993027A) from Coden Pharma Latina Italy can also be used as comparator.	
134.	Hydrochlorothiazide	DICHLOTRIDE TABLET 25MG, MAL19870271AR	MERCK SHARP & DOHME UNITED KINGDOM
		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	
135.	Hydrocortisone	CORTEF TABLET 10MG	CATALENT PHILADELPHIA
		Product is available in 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)	
		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
136.	Ibandronic acid	BONDRONAT FILM-COATED TABLET 50 MG MAL20071698ARZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		BONVIVA FILM-COATED TABLETS 150 MG MAL20071629AZ	
137.	Imatinib mesylate	GLIVEC 50MG CAPSULES MAL20020355A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GLIVEC 100MG CAPSULES MAL20020356A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GLIVEC TABLET 100MG MAL06011679ARZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY
		GLIVEC TABLET 400MG MAL06011681ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
138.	Imidapril hydrochloride	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
139.	Indapamide	NATRILIX TABLET MAL19972491AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		NATRILIX TABLET 0.0025G MAL19870270ARZ	
		Product is available in Australia, Bangladesh, China, India, Pakistan, France and United Kingdom (Information obtained from Servier (M) Sdn. Bhd on 4 th 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

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
140.	Indomethacin	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.	
141.	Isosorbide Dinitrate	ISORDIL ORAL TABLET 10MG MAL19871489A	WYETH CANADA
		As agreed upon ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016’ – 16 Jun 2016, Isordil Oral Tablet manufactured by Interphil, Philippines can be used as comparator.	
142.	Isosorbide-5-mononitrate	ELANTAN 20MG TABLET MAL19900069AZ	SCHWARZ GMBH MITTELSTRASSE 11-13 D- 4019 MONHEIM, GERMANY
		ELANTAN 40MG TABLET MAL19900070AZ	
143.	Isotretinoin	ROACCUTANE ROCHE CAPSULE 20MG PBKD861795A	F. HOFFMAN-LA ROCHE, SWITZERLAND
		ROACCUTANE ROCHE CAPSULE 10MG PBKD861794A	F. HOFFMAN-LA ROCHE, SWITZERLAND
		ROACCUTANE CAPSULE 20MG MAL19991721ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
		ROACCUTANE CAPSULE 10MG MAL19991720ACRZ	R. P. SCHERER GMBH, GERMANY
			CATALENT GERMANY EBERBACH GMBH, GERMANY
			R. P. SCHERER GMBH, GERMANY
144.	Itopride Hydrochloride	GANATON TABLET 50MG MAL20051433ACZ	MYLAN EPD G.K., JAPAN
145.	Ivabradine Hydrochloride	COROLAN 5MG FILM-COATED TABLETS	LES LABS SERVIER INDUSTRIE, FRANCE

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL20081755AZ COROLAN 7.5MG FILM-COATED TABLETS MAL20081756AZ	LES LABS SERVIER INDUSTRIE, FRANCE
146.	Ketorolac Tromethamine	TORADOL 10 MG FILM-COATED TABLET MAL19973601A	ROCHE FARMA S.A, SPAIN
		Product is available in Australia, Indonesia, Georgia, Canada, Italy, and Portugal (Information obtained from Roche (M) Sdn Bhd on 9 th March 2015)	
147.	Ketotifen fumarate	ZADITEN 1MG TABLET MAL20000272ARZ	NOVARTIS PHARM UK LTD, UNITED KINGDOM
148.	Labetalol	TRANDATE TABLET 100MG, MAL19870059A TRANDATE TABLET 200MG MAL19870060A TRANDATE TABLETS 200MG MAL06011678AZ TRANDATE TABLETS 100MG MAL06011677AZ	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA ASPEN BAD OLDESLOE GMBH, GERMANY ASPEN BAD OLDESLOE GMBH, GERMANY
149.	Lacidipine	LACIPIL TABLET 2MG MAL19950005A LACIPIL TABLET 4MG MAL19950006ARZ	GLAXO WELLCOME S.A.SPAIN
150.	Lacosamide	VIMPAT 50MG FILM-COATED TABLETS MAL12055002AZ VIMPAT 100MG FILM-COATED TABLETS MAL12055008AZ VIMPAT 150MG FILM-COATED TABLETS	AESICA PHARMACEUTICALS GMBH, GERMANY

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL12055009AZ VIMPAT 200MG FILM-COATED TABLETS MAL12055010AZ	
151.	Lansoprazole	PREVACID 30MG CAPSULE MAL19961284AR	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		This product is available in 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, 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 th February 2013)	
152.	Lapatinib ditosylate	TYKERB FILM-COATED TABLETS 250MG MAL20071677ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
153.	Leflunomide	ARAVA 10MG TABLET MAL20001528ARZ ARAVA 20MG TABLET MAL20001527AZ ARAVA TABLET 100MG MAL20001529AZ	SANOFI WINTHROP INDUSTRIE, FRANCE SANOFI WINTHROP INDUSTRIE, FRANCE SANOFI WINTHROP INDUSTRIE, FRANCE
154.	Lenalidomide	REVLIMID (LENALIDOMIDE) CAPSULES 5MG MAL20091851ACRZ REVLIMID (LENALIDOMIDE) CAPSULE 10MG	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL20091852ACRZ REVLIMID (LENALIDOMIDE) CAPSULE 15MG MAL20091853ACRZ REVLIMID (LENALIDOMIDE) CAPSULE 25MG MAL20091854ACRZ REVLIMID (LENALIDOMIDE) CAPSULES 5MG MAL12040005ARSZ REVLIMID (LENALIDOMIDE) CAPSULES 10MG MAL12040006ARSZ REVLIMID (LENALIDOMIDE) CAPSULES 15MG MAL12040004ARSZ REVLIMID (LENALIDOMIDE) CAPSULES 25MG MAL12040007ARSZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM CELGENE INTERNATIONAL SARL, SWITZERLAND CELGENE INTERNATIONAL SARL, SWITZERLAND CELGENE INTERNATIONAL SARL, SWITZERLAND CELGENE INTERNATIONAL SARL, SWITZERLAND
155.	Lercanidipine HCl	ZANIDIP 10MG FILM COATED TABLETS MAL20041041AZ ZANIDIP 20MG, FILM-COATED TABLET MAL07050024AZ	RECORDATI CHIMICA E FARMACEUTICA S.P.A., ITALY RECORDATI S.p.A - INDUSTRIA CHIMICA e FARMACEUTICA, ITALY
156.	Levamisole hydrochloride	ERGAMISOL TABLET 50MG MAL19990537A	JANSSEN PHARMACEUTICA N.V., BELGIUM
157.	Levetiracetam	KEPPRA 250MG FILM COATED TABLET MAL20031725ARZ KEPPRA 500MG FILM COATED TABLET MAL20031726ARZ	UCB S.A. SECTOR PHARMA, BELGIUM UCB S.A. SECTOR PHARMA, BELGIUM

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
		KEPPRA 1000MG FILM COATED TABLET MAL20031727ARZ	UCB S.A. SECTOR PHARMA, BELGIUM
158.	Levocetirizine dihydrochloride	XYZAL 5MG FILM COATED TABLET MAL20051323ARZ	UCB FARCHIM S.A., SWITZERLAND
159.	Levonorgestrel	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 biowaiver page on NPRA website for more information.	
160.	Levothyroxine sodium	OROXINE 100MCG TABLET MAL06071058AZ OROXINE 50MCG TABLET MAL06071059AZ	ASPEN BAD OLDESLOE GMBH, GERMANY ASPEN BAD OLDESLOE GMBH, GERMANY
161.	Linagliptin	TRAJENTA 5MG FILM-COATED TABLETS MAL12045094ACZ	BOEHRINGER INGELHEIM ROXANE, INC, UNITED STATES
162.	Linezolid	ZYVOX 400MG TABLETS MAL20020873AR	PFIZER PHARMACEUTICALS LLC, PUERTO RICO
		ZYVOX 600MG TABLETS MAL20020874AZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
163.	Lomefloxacin hydrochloride	MAXAQUIN 400MG TABLET MAL19940539A	SEARLE DE MEXICO, MEXICO
		MAXAQUIN 400MG TABLET MAL19940540AS	MONSANTO FRANCE SA, FRANCE
164.	Lomustine	CEENU CAPSULE 40MG MAL19991719A	BRISTOL-MYERS SQUIBB S.R.L., ITALY
165.	Loperamide	IMODIUM CAPSULE 2MG MAL19871473ARZ	JANSSEN CILAG, FRANCE
166.	Mebeverine	DUSPATALIN TABLET 100MG MAL19920644A	ABBOTT BIOLOGICALS B.V., NETHERLAND
		DUSPATALIN TABLET 135MG MAL19940428ACZ	ABBOTT HEALTHCARE SAS, FRANCE

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
167.	Medroxyprogesterone acetate	FARLUTAL TABLET 100MG MAL19991379A	PFIZER ITALIA S.R.L., ITALY
		FARLUTAL TABLET 500MG MAL19991380A	PFIZER ITALIA S.R.L., ITALY
		PROVERA TABLET 5MG MAL19872113A	PHARMACIA & UPJOHN CO, UNITED STATES
		PROVERA 10MG TABLET MAL20000997AZ PROVERA 5MG TABLET MAL06051306AZ	PFIZER ITALIA S.R.L., ITALY PFIZER PHARMACEUTICAL LLC, PUERTO RICO
168.	Mefloquine hydrochloride	LARIAM TABLET 250MG MAL19921123ARZ	F.HOFFMAN-LA ROCHE, SWITZERLAND
169.	Megestrol acetate	MEGACE TABLET 160MG MAL19962089A	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, AUSTRALIA
		MEGACE TABLET 40MG MAL19962090A	HAUPT PHARMA REGENSBURG GMBH, GERMANY
170.	Melphalan	ALKERAN TABLETS 2MG MAL07101257ACZ	EXCELLA GMBH, GERMANY
171.	Memantine hydrochloride	EBIXA FILM-COATED TABLET 10MG MAL20061488ACRZ	ROTTENDORF PHARMA GMBH, GERMANY
		EBIXA FILM-COATED TABLET 20 MG MAL10120014ACRZ	ROTTENDORF PHARMA GMBH, GERMANY
172.	Mequitazine	PRIMALAN TABLET 5MG MAL19871736A	MAY & BAKER LTD, UNITED KINGDOM
173.	Mercaptopurine	PURI-NETHOL TABLET 50MG MAL19861668A	THE WELLCOME FOUNDATION LTD, UNITED KINGDOM
		Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2015 – 9 September 2015 agreed that products manufactured by Excella GmbH, Germany and DSM Pharmaceuticals, Inc, United State can be used as comparator.	
This product can be obtained from Hong Kong, Thailand, Egypt, Iran,			

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
		Sri Lanka, Bangladesh, Qatar, Lebanon, Yemen, Saudi Arabia, Turkey, UAE, Kuwait, Iraq, Bahrain, Oman, Jordan, Denmark, Germany, Belgium, Italy, Norway, Netherlands, Portugal, Serbia & 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)	
174.	Mesna	UROMITEXAN TABLET 400MG MAL20014208AZ	TEMMLER PHARMA GMBH & CO KG, GERMANY
		UROMITEXAN TABLET 600MG MAL20014209AZ	TEMMLER PHARMA GMBH & CO KG, GERMANY
175.	Mesalazine	SALOFALK 500 ENTERIC-COATED TABLET MAL19987336ACSZ	LOSAN PHARMA GMBH, GERMANY
		SALOFALK 250 ENTERIC-COATED TABLET MAL19987335ACSZ	
176.	Mesterolone	PROVIRONUM TABLET 25MG MAL09122025ACZ	SCHERING DA BRASIL QUIMICAE FARMACEUTICA LTDA., BRAZIL
177.	Methoxsalen	OXSORALEN-ULTRA CAPSULES 10MG MAL19920052A	ICN PHARM INC, UNITED STATES
		MELADININE TABLET 10MG MAL05090015ACZ	LABOBORATOIRES MACORS, FRANCE
178.	Methylphenidate hydrochloride	RITALIN TABLET 10MG MAL19910002ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
179.	Methylprednisolone	MEDROL TABLET 4MG MAL19990558A	PHARMACIA & UPJOHN CO, 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
		MEDROL TABLET 16MG MAL19990559A	
		<p>This product can be obtained from Algeria, Armenia, Bangladesh, Canada, Chile, China, Colombia, Denmark, Finland, France, Greece, Hungary, India, Indonesia, Israel, Italy, Thailand, Sweden, Sri Lanka, Saudi Arabia, Vietnam (Information obtained via email dated 15th January 2014 from Pfizer, Malaysia)</p>	
180.	Metoclopramide hydrochloride	MAXOLON TABLET 10MG MAL19921400A	BEECHAM PHARM, UNITED KINGDOM
		<p>This product can be obtained from South Africa, Australia and Pakistan. (Information obtained via email dated 26th Sept 2012 from GSK, Malaysia and agreed upon 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013)</p> <p>Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014 – 23 April 2014 agreed that products manufactured by GSK Karachi and GSK Cape Town can be used as comparator.</p>	
181.	Mexiletine Hydrochloride	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
182.	Mianserin hydrochloride	TOLVON TABLET 10MG MAL19900637A	N.V. ORGANON, NETHERLANDS
		TOLVON TABLET 30MG MAL19900638A	N.V. ORGANON, NETHERLANDS
		TOLVON TABLET 60MG	N.V. ORGANON,

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
		MAL19900639A	NETHERLANDS
183.	Midazolam	DORMICUM ROCHE TABLET 7.5 MG MAL19890299ARZ DORMICUM FILM-COATED TABLET 15MG MAL19920037A	PRODUCTOS ROCHE MEXICO F.HOFFMAN-LA ROCHE, SWITZERLAND
184.	Miglitol	DIASTABOL 50MG MAL19990973A DIASTABOL 100MG MAL19990974A	BAYER AG, GERMANY
185.	Milnacipran hydrochloride	IXEL 25MG HARD CAPSULES MAL20061611A IXEL 50MG HARD CAPSULES MAL20061612A	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
186.	Minoxidil	LONITEN 5MG TABLETS MAL20014500AR	GLOBAL PHARM LTD, CANADA
		LONITEN 10MG TABLETS MAL20014501AR	
		LONITEN TABLET 5MG MAL19861624A	UPJOHN LTD, UNITED KINGDOM
		LONITEN TABLET 10MG MAL19861623A	
This product can be obtained from Australia, Brazil, Canada, France, Germany, Ireland, Italy, Netherlands, New Zealand, South Africa, Spain, Switzerland, Taiwan & United Kingdom (Information obtained via email dated 3 rd May 2013 from Zeullig Pharma Sdn. Bhd., Malaysia)			
187.	Misoprostol	CYTOTEC TABLET 200MCG MAL19890225ARZ	PIRAMAL HEALTHCARE UK LIMITED, UNITED KINGDOM
188.	Mizolastin	MIZOLLEN TABLET 10MG MAL20001215A	SANOFI WINTHROP INDUSTRIE, FRANCE
189.	Moclobemide	AURORIX FILM-COATED TABLET 150MG	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL19910811A AURORIX FILM-COATED TABLET 300MG MAL19987972A AURORIX FILM COATED TABLET 150MG MAL13035054ACZ AURORIX FILM COATED TABLET 300MG MAL13035055ACZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND CENEXI, FRANCE CENEXI, FRANCE
190.	Montelukast sodium	SINGULAIR TABLET 10MG MAL19990957ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
191.	Morphine sulphate	KAPANOL CAPSULES 20MG MAL19984000AR KAPANOL CAPSULES 50MG MAL19984001AR KAPANOL CAPSULES 100MG MAL19984002AR	F.H. FAULDING & CO LTD, AUSTRALIA
192.	Moxifloxacin hydrochloride	AVELOX TABLET MAL20012664AZ	BAYER PHARMA AG, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
193.	Moxonidine	PHYSIOTENS 0.2MG TABLET MAL20033335ACZ PHYSIOTENS 0.3MG TABLET MAL20033336ACZ PHYSIOTENS 0.4MG TABLET MAL20033337ACZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
194.	Naltrexone hydrochloride	REVIA TABLET 50MG MAL20013367A	DUPONT PHARM COMPANY, UNITED STATES
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2017' – 27 September 2017: Revia Tablet from Bristol-Myers Squibb Australia Pty Ltd, Australia dan Teva Canada Limited, Canada can also be used as a comparator.	
		TREXAN TABLET 50MG MAL19930054A	DU PONT PHARM INC,N.YORK, UNITED STATES
195.	Nateglinide	STARLIX 60MG TABLET MAL20014476A	NOVARTIS FARMA S.P.A., ITALY
		STARLIX 120MG TABLET MAL20014477AR	NOVARTIS FARMA S.P.A., ITALY
196.	Nebivolol	NEBILET TABLET MAL20041163AZ	BERLIN-CHEMIE AG, GERMANY
197.	Neostigmine bromide	PROSTIGMIN ROCHE TABLET 15MG MAL19871818A	ROCHE PRODUCTS LTD, UNITED KINGDOM
198.	Nilotinib hydrochloride monohydrate	TASIGNA 150MG CAPSULE MAL11105040ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
199.	Nimodipine	NIMOTOP TABLET 30MG MAL19940001AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
200.	Nisoldipine	SYSCOR CC 10MG TABLET MAL20000264AC	BAYER AG, WEST GERMANY
		SYSCOR CC TABLET 20MG MAL20000265AC	
		SYSCOR CC TABLET 30MG MAL20000266AC	
		SYSCOR CC TABLET 40MG MAL20000267AC	
201.	Nizatidine	PU 3144 AXID CAPSULE 150MG MAL19950508AC	LILLY S.A., SPAIN
202.	Norethisterone 5mg	PRIMOLUT-N TABLET 5MG MAL19900564A	SCHERING AG BERLIN, GERMANY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		PRIMOLUT-N TABLET 5MG MAL08120874A	SCHERING GMBH & CO. PRODUKTIONS KG GERMANY BAYER WEIMAR GMBH UND CO.KG
		PRIMOLUT-N 5MG TABLET MAL20002234AS	PT SCHERING INDONESIA
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18th August 2014:</p> <p>PRIMOLUT-N 5MG TABLET (MAL08120874A) can be obtained from Vietnam while PRIMOLUT-N 5mg (MAL20002234AS) manufactured by PT Schering Indonesia is no longer available in Vietnam. (Information obtained via email dated 8th 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 biowaiver page on NPRA website for more information.</p>	
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016 – 13th 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>	
203.	Norethisterone 0.35mg	NORIDAY TABLET MAL19992549AZ	PIRAMAL HEALTHCARE UK LIMITED
		<p>This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer biowaiver page on NPRA website for more information.</p>	
204.	Nystatin	MYCOSTATIN ORAL TABLET 500000 IU MAL19921327A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		<p>This product can be obtained from Mexico. (Information obtained via</p>	

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
		<p>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>	
205.	Olmesartan Medoxomil	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
206.	Ondansetron hydrochloride dihydrate	ZOFRAN TABLET 4MG MAL19950007ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		ZOFRAN TABLET 8MG MAL19950013ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
207.	Orlistat	XENICAL CAPSULE 120MG MAL19992994ARZ	F.HOFFMANN,LA ROCHE LTD, SWITZERLAND
		XENICAL CAPSULE 120 MG MAL05032548ARZ	ROCHE S.P.A., ITALY
		<p>As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18th August 2014:</p> <p>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</p>	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		the amount of daily ingested fat.	
208.	Orphenadrine citrate	NORFLEX TABLET 100MG MAL19861502A	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		NORFLEX TABLET 100MG MAL13055067ACRZ	ADCOCK INGRAM, INDIA
209.	Oxcarbazepine	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	
210.	Oxybutynin hydrochloride	DRIPTANE TABLET 5MG MAL19991351ARZ	LABS FOURNIER SA, FRANCE
211.	Oxycodone hydrochloride	OXYNORM 5MG CAPSULES MAL10070560ACZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
		OXYNORM 10MG CAPSULES MAL10070561ACZ	
		OXYNORM 20MG CAPSULES MAL10070562ACZ	
212.	Oxymetholone	ANAPOLON 50 TABLET MAL19870679A	SYNTEX INCORPORATED, CANADA
		ANAPOLON 50 TABLET MAL19870678A	SYNTEX PHARM LTD, UNITED KINGDOM
213.	Pantoprazole	CONTROLOC 20MG TABLET MAL20032151AZ	NYCOMED GMBH, GERMANY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		CONTROLOC 40MG TABLET MAL19972093ARZ	
214.	Paricalcitol	ZEMPLAR CAPSULES 1 MCG MAL20071708ACZ ZEMPLAR CAPSULES 2 MCG MAL20071709ACZ ZEMPLAR CAPSULES 4 MCG MAL20071710ACZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
215.	Pazopanib Hydrochloride	VOTRIENT FILM-COATED TABLET 200MG MAL20102071ACRZ VOTRIENT FILM-COATED TABLET 400MG MAL20102072ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM GLAXO OPERATIONS UK LTD, UNITED KINGDOM
216.	Penicillamine	ARTAMIN CAPSULE 250MG MAL20021153ACZ	HAUPT PHARMA BERLIN GMBH, GERMANY
217.	Pentoxifylline	TRENTAL 400 TABLET MAL19990996AZ	SANOFI-AVENTIS DE MEXICO SA DE CV
218.	Phentermine Hydrochloride	DUROMINE CAPSULE 15MG MAL19871769AR DUROMINE CAPSULE 30MG MAL19871774AR	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA 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>'Not Interchangeable with Duromine and other brand of product Containing Phentermine Resin'.</p>	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
219.	Phthalylsulphathiazole	THALAZOLE TABLET 500MG 1986040494A	MAY & BAKER LTD, UNITED KINGDOM
220.	Pinaverium bromide	DICETEL 50MG FILM-COATED TABLET MAL12045092AZ	ABBOTT HEALTHCARE SAS, FRANCE
		DICETEL 100MG FILM-COATED TABLET MAL20122215AZ	MYLAN LABORATORIES SAS, FRANCE
221.	Pindolol	VISKEN TABLET 5MG PBKD870587A	NOVARTIS PHARMA AG, SWITZERLAND
		VISKEN TABLET 10MG PBKD870074A	NOVARTIS PHARMA AG, SWITZERLAND
222.	Pioglitazone	ACTOS 15MG TABLET MAL20051432AR	TAKEDA PHARMACEUTICAL LTD., JAPAN
		ACTOS 30MG TABLET MAL20051431ARZ	TAKEDA PHARMACEUTICAL LTD., JAPAN
		ACTOS 15MG TABLETS MAL11100026ACRZ	DAITO PHARMACEUTICAL TOYOMA, JAPAN
223.	Pipemidic acid	URIXIN FILMTAB TABLET MAL19910050A	ABBOTT LABS, PHILIPPINES
		URIXIN FILMTAB 400MG MAL19871869A	ABBOTT LABS, PAKISTAN
This product can be obtained from Pakistan (Information obtained from Abbott Laboratories (M) Sdn Bhd via an email dated 27 June 2016)			
224.	Piracetam	NOOTROPIL TABLET 800 MG MAL07021408ARZ	UCB S.A. - SECTEUR PHARMA, BELGIUM
		NOOTROPIL TABLET 1200 MG MAL07021409ARZ	
225.	Pizotifen malate	SANDOMIGRAN TABLET 0.5MG MAL19860378A	NOVARTIS FARMA S.P.A., ITALY
		This products can be obtained from Australia, Hong Kong, New Zealand and Sri Lanka (Information obtained from Novartis Corporation (M) Sdn Bhd via an email dated 11 th May 2015).	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		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).	
226.	Pramipexole Dihydrochloride Monohydrate	SIFROL TABLET 0.125MG MAL20000717AZ SIFROL TABLET 0.25MG MAL20000718AZ SIFROL TABLET 1MG MAL20000719AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
227.	Prasugrel Hydrochloride	EFFIENT FILM-COATED TABLETS 10 MG MAL20102003AZ EFFIENT FILM-COATED TABLETS 5 MG MAL20102002AZ	ELI LILLY AND COMPANY, USA
228.	Pravastatin sodium	PRAVACHOL TABLET 10MG MAL20032161A PRAVACHOL TABLET 10MG PBKD 921380A 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 E.R. SQUIBB & SONS LTD 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 Canada, France, Germany, Ireland and United Kingdom (Information obtained from Bristol Myers Squibb Asia Pacific via an email dated 27 th March 2013)	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
229.	Prazosin	MINIPRESS TABLET 1MG MAL19870096AZ	PFIZER AUSTRALIA PTY. LTD.
		MINIPRESS TABLET 2MG MAL19870098AZ	
		MINIPRESS TABLET 5MG MAL19870100AZ	
		MINIPRESS TABLET 1MG MAL19930148ACZ	
MINIPRESS TABLET 2MG MAL19930149ACZ			
MINIPRESS TABLET 5MG MAL19930150ACZ			
230.	Primidone	MYSOLINE 250MG TABLETS	UNITED KINGDOM
231.	Procatenol hydrochloride	MEPTIN TABLET 0.05MG MAL19890453ACZ	OTSUKA PHARMACEUTICAL CO., LTD, JAPAN
232.	Progesterone	UTROGESTAN CAPSULE 100MG MAL19971796AZ	BESINS MANUFACTURING BELGIUM, BELGIUM
233.	Proguanil hydrochloride	PALUDRINE TABLETS 100MG PBKD911193A	ASTRAZENECA UK LIMITED, UNITED KINGDOM
		This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer biowaiver page on NPRA website for more information.	
234.	Propafenone	RYTMONORM TABLET 150MG MAL19880156AZ	ABBOT GMBH & CO. KG, GERMANY
235.	Propantheline	PRO-BANTHINE TABLET 15MG PBKD861516A	SEARLE LABS, AUSTRALIA.
		PRO-BANTHINE TABLET 15MG PBKD861515A	G.D. SEARLE & CO, UNITED KINGDOM
236.	Propiverine	MICTONORM TABLET MAL20061584AZ	APOGEPHA ARZNEIMITTEL 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
237.	Prucalopride succinate	RESOLOR 1MG FILM COATED TABLETS MAL12025075AZ	JANSSEN CILAG SPA, ITALY
		RESOLOR 2MG FILM COATED TABLETS MAL12025076AZ	JANSSEN CILAG SPA, ITALY
238.	Pseudoephedrine	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 GlaxoSmithKline Chittagong, Bangladesh 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 GlaxoSmithKline Pulogadong, Indonesia can also be used as a comparator.	
239.	Pyridostigmine bromide	MESTINON TABLET 10MG MAL05090001ACRZ	LABIANA PHARMACEUTICALS, SL, SPAIN
		MESTINON DRAGEES 60MG MAL04112698ACRZ	
		MESTINON 60MG TABLET MAL19861730A	F.HOFFMAN-LA ROCHE, SWITZERLAND
		MESTINON ROCHE TABLET 10MG MAL19861729A	F.HOFFMAN-LA ROCHE, SWITZERLAND
		MESTINON 60MG TABLET MAL20041049A	ICN CANADA LTD, CANADA
		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: Qualified Person Maria Merce Roca Solsona Mariamerce.roca@labiana.com Tel: 003493 622 29 00	
		240.	Rebamipide
241.	Repaglinide	NOVONORM TABLET 0.5MG MAL20001007ACRZ	BOEHRINGER INGELHEIM PHARMA KG, WEST GERMANY

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(NOVEMBER 2017)

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		NOVONORM TABLET 1.0MG MAL20001008ACRZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		NOVONORM TABLET 2.0MG MAL20001009ACRZ	
242.	Reserpine	SERPASIL TABLET 0.10MG 1986044940A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		SERPASIL TABLET 0.25MG 1986044921A	
243.	Ribavirin	REBETOL CAPSULES 200MG MAL20001524ARZ	MSD International GmbH (PUERTO RICO BRANCH) UNITED STATES
			SCHERING-PLOUGH LABO N.V., BELGIUM
		COPEGUS FILM-COATED TABLET 200MG MAL05012334AZ	HOFFMANN-LA ROCHE INC, UNITED STATES
		COPEGUS FILM COATED TABLET 200MG MAL08051760ACRSZ	PATHEON INC, CANADA
244.	Rifabutin	MYCOBUTIN 150MG CAPSULES MAL19960957A	PFIZER ITALIA S.R.L.
245.	Riluzole	RILUTEK TABLETS 50MG MAL20051294AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
246.	Risedronate sodium	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
247.	Rivaroxaban	XARELTO 20MG FILM-COATED TABLET MAL11115001AZ	BAYER PHARMA AG, GERMANY
		XARELTO 15MG FILM-COATED TABLET MAL11115002AZ	BAYER PHARMA AG, GERMANY

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
248.	Rivastigmine hydrogen tartrate	EXELON 1.5MG CAPSULES MAL19990976ARZ EXELON 3MG CAPSULES MAL19990977ARZ EXELON 4.5MG CAPSULES MAL19990978ARZ EXELON 6MG CAPSULES MAL19990979ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
249.	Rizatriptan benzoate	MAXALT TABLET 5MG MAL20000249ARZ MAXALT TABLET 10MG MAL20000250ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
250.	Roflumilast	DAXAS 500 MCG FILM-COATED TABLETS MAL20112164AZ	TAKEDA GMBH, GERMANY
251.	Ropinirole hydrochloride	REQUIP TABLET 0.25MG MAL19990966ARZ REQUIP TABLET 1MG MAL19990967ARZ REQUIP TABLET 2MG MAL19990968AZ REQUIP TABLET 5MG MAL19990969AZ	GLAXO WELLCOME SA, SPAIN GLAXO WELLCOME SA, SPAIN SMITHKLINE BEECHAM PHARM, UNITED KINGDOM SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
252.	Rosiglitazone	AVANDIA TABLET 2MG MAL20000007A AVANDIA TABLET 4MG MAL20000008ARZ AVANDIA TABLET 8MG MAL20000009ARZ	GLAXO WELLCOME S.A., SPAIN
253.	Rosuvastatin calcium	CRESTOR 5 MG TABLET MAL20051356ARZ	IPR PHARMACEUTICALS INC, PUERTO RICO

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
		CRESTOR 10MG TABLET MAL20041089ARZ CRESTOR 20MG TABLET MAL20051357ARZ	
254.	Salbutamol Sulphate (Sustained release)	VOLMAX 4MG CR TABLET MAL19890618AR VOLMAX 4MG CR TABLET MAL19890619AR	GLAXOSMITHKLINE SPA, STRADA ASOLANA 68, SAN POLO DI TORRILE PARMA, 43056 ITALY
		Product is available in Saudi Arabia and several African countries e.g. Rwanda and Burundi (Information obtained from GSK, Malaysia dated via an email dated 2 nd October 2013)	
255.	Saxagliptin	ONGLYZA TABLET 2.5MG MAL20102019ARZ ONGLYZA TABLET 5MG MAL20102020ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
256.	Selegiline	JUMEX TABLET 5MG MAL19950723AZ	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PVT. CO. LTD., HUNGARY
257.	Sevelamer Carbonate	RENVELA (SEVELAMER CARBONATE) TABLETS MAL20102007AZ	GENZYME IRELAND LIMITED, IRELAND
		As agreed upon in Mesyuarat Dasar Regulatori 1/2013 dated 20 th 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	

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(NOVEMBER 2017)

Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
258.	Sildenafil citrate	VIAGRA 25MG TABLET MAL19990542A	PFIZER INC, UNITED STATES
		VIAGRA 50MG TABLET MAL19990543A	
VIAGRA 100MG TABLET MAL19990544A			
258.	Sildenafil citrate	VIAGRA 25MG TABLET MAL20012709ASZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		VIAGRA 50MG TABLET MAL20012710ACSZ	FAREVA AMBOISE, FRANCE
		VIAGRA 100MG TABLET MAL20012711ACSZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		VIAGRA 100MG TABLET MAL20012711ACSZ	FAREVA AMBOISE, FRANCE
		REVATIO 20 MG FILM-COATED TABLET MAL20071716ACZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA FAREVA AMBOISE, FRANCE
259.	Sitagliptin	JANUVIA 25 MG TABLET MAL20071662ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		JANUVIA 50 MG TABLET MAL20071663ARZ	
		JANUVIA 100 MG TABLET MAL20071664ARZ	
260.	Sodium Iodide	SODIUM IODIDE (1311) THERAPY CAPSU* MAL19930360AZ	GE HEALTHCARE LIMITED, UNITED KINGDOM
261.	Sodium fusidate	FUCIDIN TABLET 250MG (FILM COATED) MAL19910821AZ	LEO PHARM PRODUCTS, DENMARK

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
262.	Sodium rabeprazole	PARIET TABLET 10MG MAL19992540ACRZ PARIET TABLET 20MG MAL19992541ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN EISAI CO LTD, JAPAN
263.	Solifenacin Succinate	VESICARE 5 MG (FILM COATED TABLET) MAL20091963AZ VESICARE 10MG (FILM COATED TABLET) MAL20091964AZ	ASTELLAS PHARMA EUROPE B.V, NETHERLAND
264.	Sofosbuvir	SOVALDI 400MG FILM-COATED TABLETS MAL15095034AZ	GILEAD SCIENCES IRELAND UC, IRELAND
265.	Sorafenib tosylate	NEXAVAR FILM-COATED TABLETS 200 MG MAL20071668AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
266.	Sotalol hydrochloride	SOTACOR TABLET 80MG MAL19930231A SOTACOR TABLET 160MG MAL19930232A SOTACOR TABLET 80MG MAL19940601AS SOTACOR TABLET 160MG MAL19940602AS	BRISTOL-MYERS CO LTD, UNITED KINGDOM BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
267.	Spiramycin	ROVAMYCINE TABLET 1.5 MILLION IU MAL19890558A ROVAMYCINE 3 M.I.U. TABLETS MAL19962132AZ	FAMAR LYON, FRANCE FAMAR LYON, FRANCE
268.	Spirolactone	ALDACTONE TABLET 100MG MAL19870236A	SEARLE LABS, 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
		ALDACTONE TABLET 25MG 1986030413A	SEARLE LABS, AUSTRALIA
		<p>This product is available in 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.</p> <p>(Information obtained from Pfizer Malaysia dated 10th June 2013 via an email)</p> <p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2017' – 24 May 2017: Aldactone Tablet 25mg manufactured by Piramal Healthcare UK Ltd, United Kingdom and distributed by Pfizer Australia Pty. Ltd can also be used as a comparator.</p>	
269.	Sulindac	CLINORIL 200MG TABLET MAL19950546A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
270.	Sulodexide	VESSEL DUE F 250 LSU CAPSULE MAL19992679AZ	ALFA WASSERMANN S.P.A., ITALY
271.	Sulphasalazine	SALAZOPYRIN EN TABLET 500MG MAL19950470AZ	KEMWELL AB, SWEDEN
272.	Sultamicillin tosylate	UNASYN TABLET MAL19910104AZ	PFIZER JAPAN INC
		UNASYN ORAL TABLET 375MG MAL20020026ACSZ	PHARMANIAGA MANUFACTURING BERHAD
273.	Sumatriptan succinate	IMIGRAN TABLET 50MG MAL19973576ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND
		IMIGRAN TABLET 100MG MAL19950008AZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		<p>This products are available in Korea, Hong Kong, Singapore, Sri Lanka, Australia, Phillipines & Thailand</p> <p>(Information obtained from GlaxoSmithKline Pharmaceutical Sdn. Bhd. dated 23rd June 2013 via an email)</p>	

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
274.	Sunitinib Malate	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
275.	Tadalafil	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 DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN
		CIALIS 20MG FILM COATED TABLET MAL20034166AZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN
276.	Tamsulosin	HARNAL OCAS 400MCG FILM- COATED TABLET MAL20091914AZ	ASTELLAS PHARMA EUROPE B.V., NETHERLANDS
277.	Tegafur	FUTRAFUL CAPSULE 200MG MAL19861648A	TAIHO PHARM CO LTD, JAPAN
278.	Telbivudine	SEBIVO 600 MG TABLETS MAL20071671ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
279.	Telithromycin	KETEK 400MG TABLET MAL20033479AZ	AVENTIS PHARMA S.P.A, ITALY
280.	Telmisartan	MICARDIS TABLET 20MG MAL20014487A	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		MICARDIS TABLET 40MG MAL19992673AZ	

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
		MICARDIS TABLET 80MG MAL19992674AZ	
281.	Temozolomide	TEMODAL CAPSULES 5MG MAL07082878ACR	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 5 MG MAL06071048ACRS	
TEMODAL CAPSULES 20MG MAL07082880ACRZ			
TEMODAL CAPSULES 20 MG MAL06071049ACRSZ			
TEMODAL CAPSULES 100MG MAL07082881ACRZ			
TEMODAL CAPSULES 250 MG MAL06071051ACRS			
		TEMODAL CAPSULES 20MG MAL20032408AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES
		TEMODAL CAPSULES 100MG MAL20032409AR	
		TEMODAL CAPSULES 250MG MAL20032410AR	
282.	Tenoxicam	TILCOTIL`ROCHE`LACQ-COATED TAB 20MG MAL19890224A	F.HOFFMAN-LA ROCHE, SWITZERLAND
		As agreed upon 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016' – 16 Jun 2016, Tilcotil Tablet manufactured by Cenexi SAS, France can be used as comparator.	
283.	Terazosin hydrochloride	HYTRIN 1MG TABLET MAL20014488ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM

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
		HYTRIN 2MG TABLET MAL20014489ACZ HYTRIN 5MG TABLET MAL20014490ACZ HYTRIN TABLET 1MG MAL19970934A HYTRIN TABLET 2MG MAL19970935A HYTRIN TABLET 5MG MAL19970936A HYTRIN 1MG TABLET MAL19920456A HYTRIN 2MG TABLET MAL19920457A HYTRIN 5MG MAL19920458A	ABBOTT AUSTRALIA P/L, AUSTRALIA ABBOTT LABORATORIES, UNITED STATES
284.	Testosterone Undecanoate	ANDRIOL TESTOCAPS CAPSULES 40MG MAL05032535ACZ ANDRIOL CAPSULE 40MG MAL19870663A	CATALENT FRANCE BEINHEIM SA, FRANCE R.P SCHERER GMBH & CO KG, GERMANY
285.	Thalidomide	DOMIDE 50MG CAPSULE, MAL20102065AZ	TTY BIOPHARM COMPANY LIMITED, TAIWAN
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013'	
286.	Thioguanine	LANVIS TABLETS 40MG MAL05032537ACR	DSM PHARMACEUTICALS INC, UNITED STATES
287.	Thyroxine sodium	ELTROXIN TABLET 0.05 MG MAL19890455A ELTROXIN TABLET 0.1MG MAL19890456A	GLAXO WELLCOME OPERATIONS UK 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
288.	Tibolone	LIVIAL TABLET 2.5MG MAL19913394AZ	N.V. ORGANON, NETHERLANDS
289.	Ticagrelor	BRILINTA 90MG FILM-COATED TABLET MAL20112115ARZ	ASTRAZENECA AB, SWEDEN
290.	Tolterodine l-tartrate	DETRUSITOL TABLET 2MG MAL19991686AZ	PFIZER ITALIA S.R.L., ITALY
291.	Topotecan hydrochloride	HYCAMTIN 0.25MG HARD CAPSULES MAL20091960ACZ HYCAMTIN 1 MG HARD CAPSULES MAL20091961ACZ	GLAXOSMITHKLINE MANUFACTURING S.P.A, ITALY
292.	Tranexamic Acid	TRANSAMIN CAPSULE 250MG MAL19890202ACZ TRANSAMIN CAPSULE 250MG	CMIC CMO CO. LTD, JAPAN DAIICHI PHARMACEUTICAL LTS, JAPAN
293.	Tramadol hydrochloride	TRAMAL CAPSULE MAL19921516A	GRUNENTHAL GMBH, WEST GERMANY
		<p>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 (Information obtained via an email from Grunenthal GmbH, Germany dated 28th March 2013)</p>	
		<p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2015 – 21 April 2015: Tramal Capsule (MAL19921516A) from Farmaceutici Formenti S.P.A, Via di Vittorio 2, 21040 Oriddio, Italy can also be used as a comparator.</p>	
		<p>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.</p>	

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Bil.	TEST PRODUCTS (<i>Pharmaceutical name</i>)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		TRAMADOLOR 50 CAPSULE MAL19985903ACZ	SALUTAS PHARMA GMBH, GERMANY
		TRAMOX CAPSULE 50MG MAL08042453ACZ	AEGIS LTD, CYPRUS DELORBIS PHARMACEUTICALS, CYPRUS
294.	Tretinoin	VESANOID SOFT-GELATIN CAPSULE 10MG MAL19960996ACZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
295.	Triazolam	SOMESE TABLET 0.25 MG MAL07050020AZ	PFIZER ITALIA S.R.L., ITALY SANICO N.V., BELGIUM
296.	Triflusal	GRENDIS 300MG CAPSULE MAL20051420AZ	J. URIACH & CIA,S.A., SPAIN
297.	Trimebutine maleate	DEBRIDAT TABLET 1990040029A	JOUEVINAL LABS, FRANCE
298.	Trimetazidine hydrochloride/ Trimetazidine Dihydrochloride	VASTAREL COATED TABLET 20MG MAL19870169AZ	LES LABS SERVIER INDUSTRIE, FRANCE
299.	Ulipristal Acetate	ELLA TABLET 30mg MAL12035079ACZ	CENEXI, FRANCE
300.	Ursodeoxycholic acid	URSOFALK CAPSULE 250MG MAL19990011ACZ	LOSAN PHARMA GMBH, GERMANY
301.	Valganciclovir	VALCYTE TABLETS 450MG MAL20040021ARZ	PATHEON INC, CANADA
302.	Vigabatrin	SABRIL 500MG TABLET MAL19961357AZ	PATHEON FRANCE S.A., FRANCE
303.	Vildagliptin	GALVUS 50MG TABLETS MAL20081792ARZ	NOVARTIS FARMACEUTICA S.A, SPAIN
304.	Vinorelbine tartrate	NAVELBINE 20MG SOFT CAPSULE MAL20071635AZ NAVELBINE 30MG SOFT CAPSULE MAL20071636AZ	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
305.	Voriconazole	VFEND 50MG TABLET MAL20040542ARZ	PFIZER ITALIA S.R.L ITALY

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

Note:

If you need further clarification, kindly email to somivaton@npra.gov.my,
muikiat@npra.gov.my, ngpeiling@npra.gov.my & amalina@npra.gov.my

Updated on 20/11/2017