

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(DECEMBER 2019)

Bil.	TEST PRODUCTS (Pharmaceutical name)	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	ROCHE PRODUCTS LTD, UNITED KINGDOM

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		(MAL19921411A) NEOTIGASON HARD GELATIN CAPSULE 25* (MAL19921412A)	
7.	Acrivastine	SEMPREX CAPSULE 8MG (MAL19900013A)	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
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)	

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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
16.	Amisulpride	SOLIAN 100MG SCORED TABLET MAL20032239AZ SOLIAN 400MG SCORED FILM- COATED TABLET MAL20032240AZ	SANOFI WINTHROP INDUSTRIE, FRANCE 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 EMEND 125MG CAPSULE MAL20040906AR	MERCK SHARP & DOHME CORP.*, UNITED STATES
20.	Atomoxetine	STRATTERA 60MG CAPSULE MAL20051406AZ STRATTERA 40MG CAPSULES	LILLY S.A, MADRID, SPAIN

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		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 ARTANE TABLET 2MG PBKD861497A	AMERICAN CYANAMID CO, UNITED STATES 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)	
		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.	Benztropine 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

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		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	SANOFI 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 MAL20020792AZ	MERCK KGAA, GERMANY
		CONCOR 5 FILM COATED TABLET MAL19890389AZ	
		CONCOR 10 FILM-COATED TABLET MAL19890390AZ	
30.	Bosentan monohydrate	TRACLEER TABLET 62.5 MG MAL20041084ACRZ	PATHEON INC., CANADA
		TRACLEER TABLET 125 MG	

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL20041085ACRZ	
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 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

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37.	Capecitabine	XELODA TABLET 150MG MAL20000001ARZ	PRODUCTOS ROCHE S.A DE C.V, MEXICO
		XELODA TABLET 500MG MAL20000002ARZ	
		XELODA TABLET 150MG MAL19096016ACRZ	EXCELLA GMBH & CO. KG, GERMANY
		XELODA TABLETS 500MG MAL19096011ACRZ	
		XELODA TABLETS 500MG MAL19091001ACRSZ	SHANGHAI ROCHE PHARMACEUTICALS LTD, CHINA
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	

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		ii) DISTACLOR 500MG from Vianex S.A. , (Factory D) VI.PE Patras 250 18 Ag. Stefanos, Greece 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).	
40.	Cefadroxil monohydrate	DURICEF CAPSULE 500MG MAL19860523A DURICEF TABLET 1GM MAL19940665A	BRISTOL-M BARCELONETA INC, PUERTO RISO, UNITED STATES
		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).	
41.	Cefdinir	OMNICEF CAPSULE 100MG MAL19991688AC	UPHA PHARMACEUTICAL MFG. (M) SDN BHD, MALAYSIA
42.	Cefixime	SUPRAX TABLET	LEDERLE
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015 – 9 th 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)	
43.	Cefprozil	PROCEF TABLET 250MG MAL19940487A PROCEF TABLET 500MG MAL19940483A	BRISTOL-M BARCELONETA INC, UNITED STATES

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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 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.	Cephadrine	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

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		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 PLETAAL 100MG TABLETS MAL20061475AZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, KOREA
54.	Cinacalcet hydrochloride	REGPARA TABLETS 25MG MAL13025055ACZ	OHARA PHARMACEUTICAL CO., LTD (KAMI FACTORY), JAPAN
55.	Cinnarizine	STUGERON 25MG TABLET MAL19871481AZ	JANSSEN CILAG SPA, ITALY
56.	Clemastine fumarate	TAVEGYL TABLET 1MG PBKD861195A	NOVARTIS PHARMA AG, SWITZERLAND
57.	Clodronate	OSTAC CAPSULE 1989120003A	ROCHE DIAGNOSTICS GMBH, GERMANY
58.	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.	
59.	Clonazepam	RIVOTRIL ROCHE TABLET 0.5MG MAL19860961ARZ	ROCHE FARMA S.A., SPAIN

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		Trade Mark/Registration No./ Reference No.	Manufacturer
		RIVOTRIL ROCHE TABLET 2MG MAL19860962ARZ	
60.	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
61.	Clorazepate dipotassium	TRANXENE CAPSULE 5MG PBKD861331AR	SANOFI WINTHROP INDUSTRIE, FRANCE
		TRANXENE CAPSULE 10MG PBKD861332AR	
62.	Co-Dergocrine Mesylate	HYDERGINE TABLET 1MG MAL19870102A	NOVARTIS FARMA S.P.A., ITALY
		HYDERGINE TABLET 1.5MG MAL19870106A	NOVARTIS PHARMA AG, SWITZERLAND
		HYDERGINE TABLET 4.5MG MAL19870111A	NOVARTIS PHARMA AG, SWITZERLAND
63.	Conjugated Oestrogen	PREMARIN TABLET 0.625MG MAL19870652AZ	PFIZER IRELAND PHARMACEUTICALS IRELAND
		PREMARIN 0.3 TABLET MAL19991386ASZ	
64.	Crizotinib	XALKORI 200MG HARD CAPSULES MAL12095102AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		XALKORI 200MG HARD CAPSULES MAL12095103AZ	

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		Trade Mark/Registration No./ Reference No.	Manufacturer
65.	Cycloserine	CYCLOSERINE CAPSULE BP 250MG MAL19900001A	ELI LILLY AND COMPANY LIMITED, UNITED KINGDOM
		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.	
66.	Cyproterone acetate	ANDROCUR 50MG TABLET MAL19993023ARZ	DELPHARM LILLE S.A.S., FRANCE BAYER WEIMAR GMBH, GERMANY
67.	Dabigatran Etextilate Mesilate	PRADAXA 150MG, HARD CAPSULES MAL20112114AZ PRADAXA 110MG, HARD CAPSULE MAL20091869AZ PRADAXA 75MG, HARD CAPSULE MAL20091868AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
68.	Daclatasvir dihydrochloride	DAKLINZA 30MG FILM-COATED TABLETS MAL16045046ACRZ DAKLINZA 60MG FILM-COATED TABLETS MAL16045037ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
69.	Danazol	LADOGAL CAPSULE 50MG PBKD870433A LADOGAL CAPSULE 100MG PBKD870434A LADOGAL CAPSULE 200MG PBKD870435A	NYCOMED PUERTO RICO INC, SPAIN

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		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)	
		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
70.	Dapagliflozin Propanediol	FORXIGA 5MG FILM-COATED TABLET (MAL14015013ARZ) FORXIGA 10MG FILM-COATED TABLET (MAL14015014ARZ)	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
71.	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
72.	Dasatinib	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
73.	Deferiprone	FERRIPROX 500MG TABLET MAL20033480ACZ	APOTEX INC CANADA
74.	Desogestrel	CERAZETTE TABLET MAL20031939AZ	N.V ORGANON, NETHERLAND
75.	Desloratadine	AERIUS TABLET MAL20020876ARZ	SCHERING PLOUGH SPA, ITALY
		AERIUS TABLET 5MG MAL10053655AZ	SCHERING-PLOUGH LABO N.V., BELGIUM
76.	Desmopressin	MINIRIN TABLET 0.1MG MAL19950096ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND
		MINIRIN TABLET 0.2MG MAL19950097ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND
77.	Dexketoprofen trometamol	KETESSE 25MG FILM COATED TABLET MAL20061602AZ	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L, ITALY
78.	Diacerein	ARTRODAR MAL20041211AZ	TRB PHARMA S.A, ARGENTINA
79.	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

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		CATAFLAM TABLET 50MG MAL19960971ARZ	NOVARTIS SAGLIK, TURKEY
80.	Diclofenac sodium	VOLTAREN TABLET 25MG MAL19861069AZ VOLTAREN TABLET 50MG MAL19861068ARZ	NOVARTIS SAGLIK GIDA VE TARIM, URUNLERI SANAYI VE TICARET A.S, TURKEY NOVARTIS FARMA S.P.A., ITALY NOVARTIS SAGLIK GIDA VE TARIM, URUNLERI SANAYI VE TICARET A.S, TURKEY NOVARTIS FARMA S.P.A., ITALY
81.	Didanosine	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	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

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		VIDEX EC DELAYED-RELEASE CAPSULE 400MG MAL20021391A	
82.	Dienogest	VISANNE 2MG TABLET MAL12105068ARZ	BAYER WEIMAR GMBH CO. KG, GERMANY
83.	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).	
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2019”, 19 November 2019, the following products are being added to the existing list of comparator: -	
		SUNCODIN TABLET MAL05090018AZ	SUNWARD PHARMACEUTICAL SDN BHD, MALAYSIA
84.	Disodium Clodronate Tetrahydrate	BONEFOS 400MG TABLETS MAL19988453A	BAYER OY, FINLAND
		BONEFOS 800MG TABLETS MAL19988452AZ	BAYER OY, FINLAND
85.	Diflunisal	DOLOBID TABLET 250MG MAL19861106AR	MERCK SHARP & DOHME INT, UNITED STATES
		DOLOBID TABLET 500MG MAL19890178AR	

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
86.	Dihydroergotamine mesylate	SEGLOR CAPSULE 5MG MAL19870274AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
87.	Diphenidol hydrochloride	CEPHADOL TABLET 25MG MAL19861237AZ	NIPPON SHINYAKU CO LTD, JAPAN
88.	Domperidone	MOTILIUM TABLET 10MG MAL19872254ARZ	JANSSEN CILAG, FRANCE
89.	Donepezil	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
		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)	
90.	Dothiepin	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 th January 2017: DOTHEP 75MG TABLET (MAL19970063AZ) is being added to the existing list of comparator.	
91.	Doxazosin	CARDURA TABLET 2MG MAL19990562AZ	PFIZER MANUFACTURING

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		CARDURA TABLET 4MG MAL19988455A	DEUTSCHLAND GMBH, GERMANY PFIZER AUSTRALIA PTY. LTD., AUSTRALIA PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
92.	Dronedaron Hydrochloride	MULTAQ 400MG FILM-COATED TABLETS MAL20102016AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
93.	Drotaverine	NO-SPA TABLETS 40MG MAL19900596A NO-SPA FORTE TABLET MAL20001801A	CHINOIN PHARMACEUTICAL & 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	
94.	Dutasteride	AVODART SOFT GELATIN CAPSULES MAL20040194ARZ	RP SCHERER SA, FRANCE GLAXO SMITH KLINE PHARMACEUTICALS, POLAND
95.	Dydrogesterone	DUPHASTON TABLET 10MG MAL19920643AZ	ABBOTT BIOLOGICALS B. V., NETHERLANDS
96.	Eletriptan hydrobromide	RELPAX 20MG TABLET MAL20021359A RELPAX 40MG TABLET MAL20021360A RELPAX 80MG TABLET MAL20021361A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA PFIZER AUSTRALIA PTY. LTD., AUSTRALIA PFIZER AUSTRALIA PTY. LTD., AUSTRALIA

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(DECEMBER 2019)

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
97.	Eltrombopag Olamine	REVOLADE FILM COATED TABLET 25MG MAL20102010ACRZ REVOLADE FILM COATED TABLET 50 MG MAL20102011ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
98.	Entacapone	COMTAN TABLET 200MG MAL19992996ARZ	ORION CORP, FINLAND
99.	Entecavir	BARACLUDE TABLET 0.5 MG MAL20061502ARZ BARACLUDE TABLET 1MG, MAL20061503AR	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
100.	Eperisone hydrochloride	MYONAL TABLET 50MG MAL19940448ACZ	MISATO PLANT OF EISAI CO, JAPAN BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN
101.	Eplerenone	INSPIRA 25MG FILM-COATED TABLETS MAL20081801ARZ INSPIRA 50MG FILM-COATED TABLETS MAL20081802ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
102.	Erlotinib	TARCEVA FILM-COATED TABLET 25 MG MAL10100027ARSZ	ROCHE S.P.A ITALY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		TARCEVA FILM COATED TABLET 100MG MAL10100029ARSZ	ROCHE S.P.A ITALY
		TARCEVA FILM COATED TABLET 150MG MAL10100028ARSZ	ROCHE S.P.A ITALY
		TARCEVA FILM-COATED TABLET 25 MG MAL20071623ACRZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		TARCEVA FILM-COATED TABLET 100 MG MAL20071624ACRZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		TARCEVA FILM-COATED TABLET 150 MG MAL20071625ACRZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
103.	Esomeprazole magnesium	NEXIUM MUPS TABLET 20MG MAL20020238ARZ	ASTRAZENECA AB, SWEDEN
		NEXIUM MUPS TABLET 40MG MAL20020239ARZ	ASTRAZENECA AB, SWEDEN
104.	Estradiol	PROGYNOVA 1MG TABLET MAL09020971ACZ	DELPHARM LILLE S.A.S., FRANCE
		PROGYNOVA TABLET 2MG MAL09020972ACRZ	
105.	Estramustine sodium phosphate	ESTRACYT CAPSULE 140MG MAL19990993A	PFIZER ITALIA S.R.L., ITALY
106.	Ethionamide	As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2019”, 3rd May 2019, the following product is being added to the existing list of comparator:-	
		ETHOMID TABLETS 250MG MAL06091362AZ	MACLEODS PHARMACEUTICALS LTD, INDIA

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
107.	Etoricoxib	ARCOXIA 60MG TABLET MAL20034170AR	MERCK & CO INC, UNITED STATES
		ARCOXIA 90MG TABLET MAL20034179AR	MERCK & CO INC, UNITED STATES
		ARCOXIA 120MG TABLET MAL20034182AR	MERCK & CO INC, UNITED STATES
		ARCOXIA 120MG TABLET MAL12065084ACRZ	FROSST IBERICA S.A, SPAIN
		ARCOXIA 30MG TABLET MAL12065063ACRZ	FROSST IBERICA S.A, SPAIN
		ARCOXIA 60MG TABLET MAL12065082ACRZ	FROSST IBERICA S.A, SPAIN
		ARCOXIA 90MG TABLET MAL12065065ACRZ	FROSST IBERICA S.A, SPAIN
108.	Everolimus	AFINITOR 10MG TABLET MAL20091943ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		AFINITOR 5MG TABLET MAL20091942ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		AFINITOR 2.5MG TABLET MAL12085055ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CERTICAN 1.0MG TABLETS MAL20071692ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		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

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
109.	Exemestane	AROMASIN TABLET 25MG MAL08111847AZ AROMASIN 25MG TABLETS MAL20013341A	PFIZER ITALIA S.R.L., ITALY
110.	Ezetimibe	EZETROL 10MG MAL20034627ARZ	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, UNITED STATES SCHERING PLOUGH PRODUCTS, UNITED STATES
111.	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, Jordan, 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)	
112.	Famotidine	PEPCIDINE 20MG TABLET MAL19900506A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		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	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL19900020AZ	MEDOCHEMIE LTD., CYPRUS
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013	
113.	Febuxostat	FEBURIC 80MG FILM-COATED TABLETS MAL16075031ACRZ	PANTHEON FRANCE, FRANCE
114.	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	
		As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2018 – 14 January 2019: LIPANTHYL MICRO CAPSULE from Rue Des Pres Potets, France can also be used as a comparator. (Information obtained from Abbott Malaysia via an email dated 23 March 2018).	
		Product is available in Indonesia, Philippines, Singapore, Switzerland, Thailand & Vietnam (Information obtained via an email from Abbott Malaysia dated 12 April 2013)	
		LIPANTHYL CAPSULE 300MG MAL19930138A	LABS FOURNIER, FRANCE
		Product is available in Vietnam, Qatar & Egypt	
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014, 18 th August 2014: GEN-FENO-FIBRATE MICRO	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		200MG CAPSULE (MAL20040063ACR) is being added to the existing list of comparator	
		GEN-FENOFIBRATE MICRO 200MG CAPSULE MAL20040063ACRZ	ALPHAPHARM PTY LTD, AUSTRALIA
115.	Fexofenadine hydrochloride	TELFAST 30MG TABLET MAL20031923AZ	AVENTIS PHARMA INC, UNITED STATES
		TELFAST 60MG TABLET MAL20051395ARZ	
		TELFAST 120MG MAL20000714AZ	HOECHST MARION ROUSSEL INC, UNITED STATES PT AVENTIS PHARMA, INDONESIA
		TELFAST 180MG TABLET MAL20000715AZ	SANOFI-AVENTIS U.S. LLC, UNITED STATES PT AVENTIS PHARMA INDONESIA
116.	Fimasartan Potassium Trihydrate	KANARB FILM-COATED TABLET 60MG MAL18026063ARZ	BORYUNG PHARMACEUTICAL CO LTD, SOUTH KOREA
		KANARB FILM-COATED TABLET 120MG MAL18026065ARZ	
117.	Finasteride	PROPECIA TABLET MAL19992040ACRZ	AIAC INTERNATIONAL PHARMA, LLC, UNITED STATES MSD INTERNATIONAL GMBH (Puerto Rico Branch) LLC, PEURTO RICE
		PROSCAR 5MG TABLET MAL19985910ACRZ	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		PROSCAR 5MG TABLET MAL19930510AR	MERCK SHARP & DOHME LTD, UNITED KINGDOM
118.	Fingolimod hydrochloride	GILENYA 0.5MG HARD CAPSULE MAL12015017ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
119.	Flavoxate	URISPAS 200 TABLET MAL20033669AZ	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A., ITALY
120.	Flecainide	TAMBOCOR TABLET 100MG MAL19871528ARZ	3M HEALTHCARE LTD, UNITED KINGDOM
121.	Fludarabine	FLUDARA 10MG FILM COATED TABLETS MAL05051075ACZ	BAYER SCHERING PHARMA AG, GERMANY
122.	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	
123.	Fluvastatin	LESCOL 40MG CAPSULE MAL19962845A LESCOL 20MG CAPSULE MAL19962844A LESCOL CAPSULE 20MG MAL19992682ACRZ LESCOL CAPSULE 40MG MAL19992683ACRZ LESCOL XL 80MG TABLETS MAL20032266ARZ	NOVARTIS PHARMA AG, SWITZERLAND NOVARTIS PHARMA AG, SWITZERLAND NOVARTIS FARMACEUTICA 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
124.	Fluoxymesterone	HALOTESTIN TABLETS 5MG (BELGIUM) MAL19920022A	PHARMACIA & UPJOHN S.A., BELGIUM
125.	Flupentixol dihydrochloride	FLUANXOL TABLET 0.5MG MAL19890543AZ FLUANXOL TABLETS 3MG MAL19890544A FLUANXOL TABLETS 1MG MAL19900451A	H.LUNDBECK A/S, DENMARK
126.	Flurazepam Monohydrochloride	DALMADORM 15MG CAPSULES MAL07050892AC	LABIANA PHARMACEUTICALS SL, SPAIN
127.	Flurbiprofen	FROBEN TABLET 50MG MAL19861117A	THE BOOTS COMPANY PLC, UNITED KINGDOM
128.	Fosinopril sodium	MONOPRIL TABLET 10MG MAL19992695AS	PT BRISTOL-MYERS SQUIBB INDONESIA TBK
		MONOPRIL TABLET 10MG MAL19950242A MONOPRIL TABLET 20MG MAL19950243A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
129.	Gabapentin	NEURONTIN 100MG CAPSULE MAL06071076AZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		NEURONTIN 300MG CAPSULE MAL19984786AZ	
		NEURONTIN 400MG CAPSULE MAL19984785AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		NEURONTIN 300MG CAPSULE MAL19962169A NEURONTIN 400MG CAPSULE	PFIZER PHARMACEUTICALS LLC, UNITED STATES

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL19962170A NEURONTIN TABLET 600MG MAL20031747AZ NEURONTIN TABLET 800MG MAL20031748A	
130.	Galantamine hydrobromide	REMINYL TABLET 4MG MAL20020123A REMINYL TABLET 8MG MAL20020124A REMINYL TABLET 12MG MAL20020125A	JANSSEN CILAG SPA, ITALY
131.	Ganciclovir	CYMEVENE CAPSULE 250MG MAL19993019AR	ROCHE PRODUCTS LTD, UNITED KINGDOM
		CYMEVENE HARD-GELATIN CAPSULE 250MG MAL19970079A	SYNTEX PUERTO RICO INC, UNITED STATES
132.	Gemfibrozil	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
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2018 – 14 January 2019: LOPID CAPSULE 300MG and LOPID 600MG TABLET from Pfizer Manufacturing Deutschland, GmbH, Freiburg, Germany can also be used as a comparator. It can be obtained from Argentina, Bahrain, Brazil, Cambodia, Chile, Colombia, Costa Rica, Curacao, Dominican Republic, Ecuador, Egypt, El Salvador, Guatemala, Hong Kong, India, Jordan, Kuwait, Lebanon, Macao, Mauritius, Mexico, Myanmar, Namibia, Netherland, New Zealand, Oman, Panama, Peru, Philippines, Qatar, Saudi Arabia, South Africa, Switzerland,	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		Taiwan, Trinidad and Tobago, Turkey, United Arab Emirates, Venezuela, Vietnam, United States, Thailand (Information obtained from Abbott Malaysia via an email dated 4 September 2018).	
		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:	
		As agreed upon in ‘Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2018 – 14 January 2018: Since Pharmaniaga Gemfibrozil Capsule 300mg (MAL19972153AZ) is under APPL contract in Malaysia, it can be obtained by contacting the manufacturer’s contact person as below for further enquiries:	
		Qualified Person En Mohd Izwan Ishak izwan@pharmaniaga.com	
		PHARMANIAGA GEMFIBROZIL CAPSULE 300MG CAPSULE MAL19972153AZ	PHARMANIAGA MANUFACTURING BERHAD
133.	Gestrinone	DIMETRIOSE CAPSULE MAL19940494A	ROUSSEL LABS LTD, UNITED KINGDOM
134.	Glipizide	MINIDIAB 5MG TABLET MAL19913361AZ	PFIZER ITALIA S.R.L., ITALY
135.	Granisetron hydrochloride	KYTRIL TABLET 1MG MAL19940574AR	ROCHE S.P.A., ITALY F. HOFFMANN-LA ROCHE LTD, SWITZERLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
136.	Hydroxychloroquine	PLAQUENIL TABLET MAL19991702AZ PLAQUENIL TABLETS MAL04103442AZ	SANOFI-SYNTHELABO LTD, UNITED KINGDOM SANOFI-AVENTIS, S.A., SPAIN
137.	Hyoscine butylbromide	BUSCOPAN TABLET 10MG MAL09051577AZ	DELPHARM REIMS, FRANCE
138.	Hydroxyurea/ Hydroxycarbamide	HYDREA CAPSULE 500MG, MAL19962497A HYDREA CAPSULE 500MG, MAL19993027A	BRISTOL MYERS SQUIBB US BRISTOL MYERS SQUIBB S.R.L, ITALY
		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.	
139.	Hydrochlorothiazide	DICHLOTRIDE TABLET 25MG, MAL19870271AR DICHLOTRIDE TABLET 50MG, MAL19870201AR DICHLOTRIDE 25MG TABLET, MAL19940018AS DICHLOTRIDE 50MG TABLET, MAL19940019AS APO-HYDRO 50MG TABLET MAL19984688ARZ APO-HYDRO 25MG TABLET MAL19984694ARZ	MERCK SHARP & DOHME UNITED KINGDOM MERCK SHARP & DOHME UNITED KINGDOM MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA APOTEX INC, CANADA

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013	
140.	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
141.	Ibandronic acid	BONDRONAT FILM-COATED TABLET 50 MG MAL20071698ARZ BONVIVA FILM-COATED TABLETS 150 MG MAL20071629AZ	F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
142.	Ibuprofen Lysine	NUROFEN EXPRESS 342MG CAPLET MAL13085058AZ NUROFEN EXPRESS 684MG CAPLET MAL13085061AZ	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM
143.	Imatinib mesylate	GLIVEC 50MG CAPSULES MAL20020355A GLIVEC 100MG CAPSULES	NOVARTIS PHARMA STEIN AG, SWITZERLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL20020356A GLIVEC TABLET 100MG MAL06011679ARZ GLIVEC TABLET 400MG MAL06011681ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY NOVARTIS PHARMA STEIN AG, SWITZERLAND NOVARTIS PHARMA STEIN AG, SWITZERLAND
144.	Imidapril hydrochloride	TANATRIL 2.5MG TABLET MAL20034616A TANATRIL 5MG TABLET MAL20034617AZ TANATRIL 10MG TABLET MAL20034618AZ	PT TANABE INDONESIA, INDONESIA PT TANABE INDONESIA, INDONESIA PT TANABE INDONESIA, INDONESIA
145.	Indapamide	NATRILIX TABLET MAL19972491AZ NATRILIX TABLET 0.0025G MAL19870270ARZ	LES LABS SERVIER INDUSTRIE, FRANCE
		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
146.	Indomethacin	INDOCID CAPSULE 25MG MAL19930412AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		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	
147.	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.	
148.	Isosorbide-5-mononitrate	ELANTAN 20MG TABLET MAL19900069AZ ELANTAN 40MG TABLET MAL19900070AZ	SCHWARZ GMBH MITTELSTRASSE 11-13 D-4019 MONHEIM, GERMANY
149.	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

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
150.	Itopride Hydrochloride	GANATON TABLET 50MG MAL20051433ACZ	MYLAN EPD G.K., JAPAN
151.	Ivabradine Hydrochloride	COROLAN 5MG FILM-COATED TABLETS MAL20081755AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		COROLAN 7.5MG FILM-COATED TABLETS MAL20081756AZ	LES LABS SERVIER INDUSTRIE, FRANCE
152.	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)	
153.	Ketotifen fumarate	ZADITEN 1MG TABLET MAL20000272ARZ	NOVARTIS PHARM UK LTD, UNITED KINGDOM
154.	Labetalol	TRANDATE TABLET 100MG, MAL19870059A	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
		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
155.	Lacidipine	LACIPIL TABLET 2MG MAL19950005A	GLAXO WELLCOME S.A.SPAIN
		LACIPIL TABLET 4MG MAL19950006ARZ	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
156.	Lacosamide	VIMPAT 50MG FILM-COATED TABLETS MAL12055002AZ VIMPAT 100MG FILM-COATED TABLETS MAL12055008AZ VIMPAT 150MG FILM-COATED TABLETS MAL12055009AZ VIMPAT 200MG FILM-COATED TABLETS MAL12055010AZ	AESICA PHARMACEUTICALS GMBH, GERMANY
157.	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)	
158.	Lapatinib ditosylate	TYKERB FILM-COATED TABLETS 250MG MAL20071677ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
159.	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
160.	Lenalidomide	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 REVLIMID (LENALIDOMIDE) CAPSULES 15MG MAL12040004ARSZ REVLIMID (LENALIDOMIDE) CAPSULES 25MG MAL12040007ARSZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM 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

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
161.	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
162.	Levamisole hydrochloride	ERGAMISOL TABLET 50MG MAL19990537A	JANSSEN PHARMACEUTICA N.V., BELGIUM
163.	Levetiracetam	KEPPRA 250MG FILM COATED TABLET MAL20031725ARZ KEPPRA 500MG FILM COATED TABLET MAL20031726ARZ KEPPRA 1000MG FILM COATED TABLET MAL20031727ARZ	UCB S.A. SECTOR PHARMA, BELGIUM UCB S.A. SECTOR PHARMA, BELGIUM UCB S.A. SECTOR PHARMA, BELGIUM
164.	Levocetirizine dihydrochloride	XYZAL 5MG FILM COATED TABLET MAL20051323ARZ	UCB FARCHIM S.A., SWITZERLAND
165.	Levonorgestrel	POSTINOR-2 TABLET 0.75MG MAL19872263ARZ ESCAPELLE TABLET 1.5MG MAL06030792AZ	GEDEON RICHTER PLC, HUNGARY 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.	
166.	Levothyroxine sodium	OROXINE 100MCG TABLET MAL06071058AZ	ASPEN BAD OLDESLOE GMBH, GERMANY

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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
167.	Linagliptin	TRAJENTA 5MG FILM-COATED TABLETS MAL12045094ACZ	BOEHRINGER INGELHEIM ROXANE, INC, UNITED STATES
168.	Linezolid	ZYVOX 400MG TABLETS MAL20020873AR ZYVOX 600MG TABLETS MAL20020874AZ	PFIZER PHARMACEUTICALS LLC, PUERTO RICO PFIZER PHARMACEUTICALS LLC, UNITED STATES
169.	Lomefloxacin hydrochloride	MAXAQUIN 400MG TABLET MAL19940539A	SEARLE DE MEXICO, MEXICO
		MAXAQUIN 400MG TABLET MAL19940540AS	MONSANTO FRANCE SA, FRANCE
170.	Lomustine	CEENU CAPSULE 40MG MAL19991719A	BRISTOL-MYERS SQUIBB S.R.L., ITALY
171.	Loperamide	IMODIUM CAPSULE 2MG MAL19871473ARZ	JANSSEN CILAG, FRANCE
172.	Mebeverine	DUSPATALIN TABLET 100MG MAL19920644A	ABBOTT BIOLOGICALS B.V., NETHERLAND
		DUSPATALIN TABLET 135MG MAL19940428ACZ	ABBOTT HEALTHCARE SAS, FRANCE
173.	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

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		PROVERA 10MG TABLET MAL20000997AZ PROVERA 5MG TABLET MAL06051306AZ	PFIZER ITALIA S.R.L., ITALY PFIZER PHARMACEUTICAL LLC, PUERTO RICO
174.	Mefloquine hydrochloride	LARIAM TABLET 250MG MAL19921123ARZ	F. HOFFMAN-LA ROCHE, SWITZERLAND
175.	Megestrol acetate	MEGACE TABLET 160MG MAL19962089A	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, AUSTRALIA
		MEGACE TABLET 40MG MAL19962090A	HAUPT PHARMA REGENSBURG GMBH, GERMANY
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2018”, 14 January 2019, the following products are being added to the existing list of comparator:-	
		APO-MEGESTROL 160MG MAL19988445AZ	APOTEX INC, CANADA
176.	Melphalan	ALKERAN TABLETS 2MG MAL07101257ACZ	EXCELLA GMBH, GERMANY
177.	Memantine hydrochloride	EBIXA FILM-COATED TABLET 10MG MAL20061488ACRZ	ROTTENDORF PHARMA GMBH, GERMANY
		EBIXA FILM-COATED TABLET 20 MG MAL10120014ACRZ	ROTTENDORF PHARMA GMBH, GERMANY
178.	Mequitazine	PRIMALAN TABLET 5MG MAL19871736A	MAY & BAKER LTD, UNITED KINGDOM
179.	Mercaptopurine	PURI-NETHOL TABLET 50MG MAL19861668A	THE WELLCOME FOUNDATION LTD, UNITED KINGDOM

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		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, 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)	
180.	Mesna	UROMITEXAN TABLET 400MG MAL20014208AZ UROMITEXAN TABLET 600MG MAL20014209AZ	TEMMLER PHARMA GMBH & CO KG, GERMANY TEMMLER PHARMA GMBH & CO KG, GERMANY
181.	Mesalazine	SALOFALK 500 ENTERIC-COATED TABLET MAL19987336ACSZ SALOFALK 250 ENTERIC-COATED TABLET MAL19987335ACSZ	LOSAN PHARMA GMBH, GERMANY
182.	Mesterolone	PROVIRONUM TABLET 25MG MAL09122025ACZ	SCHERING DA BRASIL QUIMICAE FARMACEUTICA LTDA., BRAZIL
183.	Methoxsalen	OXSORALEN-ULTRA CAPSULES 10MG MAL19920052A	ICN PHARM INC, UNITED STATES

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MELADININE TABLET 10MG MAL05090015ACZ	LABOBORATOIRES MACORS, FRANCE
184.	Methylphenidate hydrochloride	RITALIN TABLET 10MG MAL19910002ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
185.	Methylprednisolone	MEDROL TABLET 4MG MAL19990558A MEDROL TABLET 16MG MAL19990559A	PHARMACIA & UPJOHN CO, UNITED STATES
		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 15 th January 2014 from Pfizer, Malaysia)	
186.	Metoclopramide hydrochloride	MAXOLON TABLET 10MG MAL19921400A	BEECHAM PHARM, UNITED KINGDOM
		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) 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.	
187.	Mexiletine Hydrochloride	MEXITIL CAPSULE 50MG PBKD861806A MEXITIL CAPSULE 200MG PBKD861808A MEXITIL CAPSULE 100MG PBKD861807A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MEXITIL CAPSULE 100MG MAL19989013A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY BOEHRINGER INGELHEIM TAIWAN LTD., TAIWAN
188.	Mianserin hydrochloride	TOLVON TABLET 10MG MAL19900637A TOLVON TABLET 30MG MAL19900638A TOLVON TABLET 60MG MAL19900639A	N.V. ORGANON, NETHERLANDS N.V. ORGANON, NETHERLANDS N.V. ORGANON, NETHERLANDS
		This product can be obtained from Algeria, Argentina, Austria, Belgium, Chile, Czech Republic, Egypt, Finland, Italy, Japan, Luxembourg, Netherlands, Norway, Pakistan, Poland, Portugal, Russian Federation, Serbia, South Africa, Spain, Switzerland, Turkey & Ukraine (Information obtained from Merck Sharp & Dohme (Malaysia) Sdn. Bhd. dated 20 th June 2018 via an email)	
189.	Midazolam	DORMICUM ROCHE TABLET 7.5 MG MAL19890299ARZ DORMICUM FILM-COATED TABLET 15MG MAL19920037A	PRODUCTOS ROCHE MEXICO F.HOFFMAN-LA ROCHE, SWITZERLAND
190.	Miglitol	DIASTABOL 50MG MAL19990973A DIASTABOL 100MG MAL19990974A	BAYER AG, GERMANY
191.	Milnacipran hydrochloride	IXEL 25MG HARD CAPSULES MAL20061611A IXEL 50MG HARD CAPSULES MAL20061612A	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
192.	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)	
193.	Misoprostol	CYTOTEC TABLET 200MCG MAL19890225ARZ	PIRAMAL HEALTHCARE UK LIMITED, UNITED KINGDOM
194.	Mizolastin	MIZOLLEN TABLET 10MG MAL20001215A	SANOFI WINTHROP INDUSTRIE, FRANCE
195.	Moclobemide	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
196.	Montelukast sodium	SINGULAIR TABLET 10MG MAL19990957ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
197.	Morphine sulphate	KAPANOL CAPSULES 20MG MAL19984000AR KAPANOL CAPSULES 50MG MAL19984001AR KAPANOL CAPSULES 100MG MAL19984002AR	F.H. FAULDING & CO LTD, AUSTRALIA
198.	Moxifloxacin hydrochloride	AVELOX TABLET MAL20012664AZ	BAYER PHARMA AG, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
199.	Moxonidine	PHYSIOTENS 0.2MG TABLET MAL20033335ACZ PHYSIOTENS 0.3MG TABLET MAL20033336ACZ PHYSIOTENS 0.4MG TABLET MAL20033337ACZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
200.	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
201.	Nateglinide	STARLIX 60MG TABLET MAL20014476A STARLIX 120MG TABLET MAL20014477AR	NOVARTIS FARMA S.P.A., ITALY NOVARTIS FARMA S.P.A., ITALY

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
202.	Nebivolol	NEBILET TABLET MAL20041163AZ	BERLIN-CHEMIE AG, GERMANY
203.	Neostigmine bromide	PROSTIGMIN ROCHE TABLET 15MG MAL19871818A	ROCHE PRODUCTS LTD, UNITED KINGDOM
204.	Nilotinib hydrochloride monohydrate	TASIGNA 150MG CAPSULE MAL11105040ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
205.	Nimodipine	NIMOTOP TABLET 30MG MAL19940001AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
206.	Nisoldipine	SYSCOR CC 10MG TABLET MAL20000264AC SYSCOR CC TABLET 20MG MAL20000265AC SYSCOR CC TABLET 30MG MAL20000266AC SYSCOR CC TABLET 40MG MAL20000267AC	BAYER AG, WEST GERMANY
207.	Nizatidine	PU 3144 AXID CAPSULE 150MG MAL19950508AC	LILLY S.A., SPAIN
208.	Norethisterone 5mg	PRIMOLUT-N TABLET 5MG MAL19900564A	SCHERING AG BERLIN, GERMANY
		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

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2014 – 18th August 2014: 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) 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). This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer biowaiver page on NPRA website for more information.	
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2016 – 13th January 2017: 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.	
209.	Norethisterone 0.35mg	NORIDAY TABLET MAL19992549AZ	PIRAMAL HEALTHCARE UK LIMITED
		This active ingredient has been granted biowaiver based on Biopharmaceutical Classification System (BCS). Kindly refer biowaiver page on NPRA website for more information.	
210.	Nystatin	MYCOSTATIN ORAL TABLET 500000 IU MAL19921327A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		This product can be obtained from Mexico. (Information obtained via email dated 13th December 2012 from Bristol Myers Squibb, Asia Pacific) As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan" 1/2013 – 13 March, bioequivalence study can be waived due	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		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.	
		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.	
211.	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
212.	Ondansetron hydrochloride dihydrate	ZOFRAN TABLET 4MG MAL19950007ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		ZOFRAN TABLET 8MG MAL19950013ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
213.	Orlistat	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 th 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.	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
214.	Orphenadrine citrate	NORFLEX TABLET 100MG MAL19861502A NORFLEX TABLET 100MG MAL13055067ACRZ	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA ADCOCK INGRAM, INDIA
215.	Oxcarbazepine	TRILEPTAL 600 MG FILM-COATED TABLET MAL07050038ARSZ TRILEPTAL 600MG TABLETS MAL20021156A	NOVARTIS FARMA S.P.A., ITALY NOVARTIS PHARMA STEIN AG, SWITZERLAND
		TRILEPTAL 300MG MAL20021155ARZ TRILEPTAL 600 MG FILM-COATED TABLET MAL07050038ARSZ	NOVARTIS FARMA S.P.A., ITALY
216.	Oxybutynin hydrochloride	DRIPTANE TABLET 5MG MAL19991351ARZ	LABS FOURNIER SA, FRANCE
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2019 – 19 November 2019: DRIPTANE TABLET 5MG from Recipharm Fontaine, France can also be used as a comparator. It can be obtained from Algeria, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Lebanon, Moldova, Philippines, Russian Federation, Tajikistan, Turkmenistan, Ukraine dan Uzbekistan. (Information obtained from Abbott Malaysia via an email dated 11 November 2019).	
217.	Oxycodone hydrochloride	OXYNORM 5MG CAPSULES MAL10070560ACZ OXYNORM 10MG CAPSULES MAL10070561ACZ OXYNORM 20MG CAPSULES MAL10070562ACZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
218.	Oxymetholone	ANAPOLON 50 TABLET MAL19870679A	SYNTEX INCORPORATED, CANADA
		ANAPOLON 50 TABLET MAL19870678A	SYNTEX PHARM LTD, UNITED KINGDOM
219.	Pantoprazole	CONTROLOC 20MG TABLET MAL20032151AZ	TAKEDA GMBH, GERMANY
		CONTROLOC 40MG TABLET MAL19972093ARZ	NYCOMED GMBH, GERMANY TAKEDA GMBH, GERMANY NYCOMED GMBH, GERMANY
220.	Paricalcitol	ZEMPLAR CAPSULES 1 MCG MAL20071708ACZ	CALENT PHARMA SOLUTIONS, LLC, UNITED STATES
		ZEMPLAR CAPSULES 2 MCG MAL20071709ACZ	
221.	Pazopanib Hydrochloride	ZEMPLAR CAPSULES 4 MCG MAL20071710ACZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
		VOTRIENT FILM-COATED TABLET 200MG MAL20102071ACRZ	
222.	Penicillamine	VOTRIENT FILM-COATED TABLET 400MG MAL20102072ACRZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM
		ARTAMIN CAPSULE 250MG MAL20021153ACZ	HAUPT PHARMA BERLIN GMBH, GERMANY
223.	Pentoxifylline	TRENTAL 400 TABLET MAL19990996AZ	SANOFI-AVENTIS DE MEXICO SA DE CV

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
224.	Phentermine Hydrochloride	DUROMINE CAPSULE 15MG MAL19871769AR	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		DUROMINE CAPSULE 30MG MAL19871774AR	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		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. 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:- 'Not Interchangeable with Duromine and other brand of product Containing Phentermine Resin'.	
225.	Phthalylsulphathiazole	THALAZOLE TABLET 500MG 1986040494A	MAY & BAKER LTD, UNITED KINGDOM
226.	Pinaverium bromide	DICETEL 50MG FILM-COATED TABLET MAL12045092AZ	ABBOTT HEALTHCARE SAS, FRANCE
		DICETEL 100MG FILM-COATED TABLET MAL20122215AZ	MYLAN LABORATORIES SAS, FRANCE
227.	Pindolol	VISKEN TABLET 5MG PBKD870587A	NOVARTIS PHARMA AG, SWITZERLAND
		VISKEN TABLET 10MG PBKD870074A	NOVARTIS PHARMA AG, SWITZERLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
228.	Pioglitazone	ACTOS 15MG TABLET MAL20051432AR ACTOS 30MG TABLET MAL20051431ARZ ACTOS 15MG TABLETS MAL11100026ACRZ	TAKEDA PHARMACEUTICAL LTD., JAPAN TAKEDA PHARMACEUTICAL LTD., JAPAN DAITO PHARMACEUTICAL TOYOMA, JAPAN
229.	Pipemidic acid	URIXIN FILMTAB TABLET MAL19910050A URIXIN FILMTAB 400MG MAL19871869A	ABBOTT LABS, PHILIPPINES 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)	
230.	Piracetam	NOOTROPIL TABLET 800 MG MAL07021408ARZ NOOTROPIL TABLET 1200 MG MAL07021409ARZ	UCB S.A. - SECTEUR PHARMA, BELGIUM
231.	Piroxicam-B- Cyclodextrin	BREXIN TABLET MAL19992991AZ	CHIESI FARMACEUTICI S.P.A., ITALY
232.	Pizotifen malate	SANDOMIGRAN TABLET 0.5MG MAL19860378A	NOVARTIS FARMA S.P.A., ITALY
		This product 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). 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).	

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
233.	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
234.	Prasugrel Hydrochloride	EFFIENT FILM-COATED TABLETS 10 MG MAL20102003AZ EFFIENT FILM-COATED TABLETS 5 MG MAL20102002AZ	ELI LILLY AND COMPANY, USA
235.	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 product 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)	

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 in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2018”, 25 May 2018, the following products are being added to the existing list of comparator: -	
		APO-PRAVASTATIN 20MG TABLET MAL20040229ARZ APO-PRAVASTATIN 40MG TABLET MAL06030825AZ	APOTEX INC, CANADA
236.	Prazosin	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
237.	Primidone	MYSOLINE 250MG TABLETS	UNITED KINGDOM
238.	Procaterol hydrochloride	MEPTIN TABLET 0.05MG MAL19890453ACZ	OTSUKA PHARMACEUTICAL CO., LTD, JAPAN
239.	Progesterone	UTROGESTAN CAPSULE 100MG MAL19971796AZ	BESINS MANUFACTURING BELGIUM, 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
240.	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.	
241.	Propafenone	RYTMONORM TABLET 150MG MAL19880156AZ	ABBOT GMBH & CO. KG, GERMANY
242.	Propantheline	PRO-BANTHINE TABLET 15MG PBKD861516A PRO-BANTHINE TABLET 15MG PBKD861515A	SEARLE LABS, AUSTRALIA. G.D. SEARLE & CO, UNITED KINGDOM
243.	Propiverine	MICTONORM TABLET MAL20061584AZ	APOGEPHA ARZNEIMITTEL GMBH, GERMANY
244.	Prucalopride succinate	RESOLOR 1MG FILM COATED TABLETS MAL12025075AZ	JANSSEN CILAG SPA, ITALY
		RESOLOR 2MG FILM COATED TABLETS MAL12025076AZ	JANSSEN CILAG SPA, ITALY
245.	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.	

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
246.	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	
247.	Ranolazine	RANEZA 375MG PROLONGED- RELEASE TABLETS MAL16035014AZ	MENARINI-VON HEYDEN GMBH, GERMANY
		RANEZA 500MG PROLONGED- RELEASE TABLETS MAL16035012AZ	
		RANEZA 750MG PROLONGED- RELEASE TABLETS MAL16035015AZ	
248.	Rebamipide	MUCOSTA TABLETS 100 MG MAL20071711ARZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, SOUTH KOREA

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
249.	Repaglinide	NOVONORM TABLET 0.5MG MAL20001007ACRZ	BOEHRINGER INGELHEIM PHARMA KG, WEST GERMANY
		NOVONORM TABLET 1.0MG MAL20001008ACRZ NOVONORM TABLET 2.0MG MAL20001009ACRZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
250.	Reserpine	SERPASIL TABLET 0.10MG 1986044940A SERPASIL TABLET 0.25MG 1986044921A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
251.	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
252.	Rifabutin	MYCOBUTIN 150MG CAPSULES MAL19960957A	PFIZER ITALIA S.R.L.
253.	Riluzole	RILUTEK TABLETS 50MG MAL20051294AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
254.	Risedronate sodium	ACTONEL FILM-COATED TABLET 5MG MAL20012657ARZ	OSG NORWICH PHARM INC, UNITED STATES
		ACTONEL 30MG TABLET MAL20012656AR	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		ACTONEL 35MG TABLET MAL20034605ACRZ	NORWICH PHARMACEUTICALS INC., UNITED STATES
255.	Rivaroxaban	XARELTO 20MG FILM-COATED TABLET MAL11115001AZ XARELTO 15MG FILM-COATED TABLET MAL11115002AZ	BAYER PHARMA AG, GERMANY BAYER PHARMA AG, GERMANY
256.	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
257.	Rizatriptan benzoate	MAXALT TABLET 5MG MAL20000249ARZ MAXALT TABLET 10MG MAL20000250ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
258.	Roflumilast	DAXAS 500 MCG FILM-COATED TABLETS MAL20112164ACZ	TAKEDA GMBH, GERMANY
259.	Ropinirole hydrochloride	REQUIP TABLET 0.25MG MAL19990966ARZ REQUIP TABLET 1MG MAL19990967ARZ REQUIP TABLET 2MG MAL19990968AZ	GLAXO WELLCOME SA, SPAIN GLAXO WELLCOME SA, SPAIN

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		REQUIP TABLET 5MG MAL19990969AZ	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
260.	Rosiglitazone	AVANDIA TABLET 2MG MAL20000007A AVANDIA TABLET 4MG MAL20000008ARZ AVANDIA TABLET 8MG MAL20000009ARZ	GLAXO WELLCOME S.A., SPAIN
261.	Rosuvastatin calcium	CRESTOR 5 MG TABLET MAL20051356ARZ CRESTOR 10MG TABLET MAL20041089ARZ CRESTOR 20MG TABLET MAL20051357ARZ	IPR PHARMACEUTICALS INC, PUERTO RICO
262.	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)	
263.	Saxagliptin	ONGLYZA TABLET 2.5MG MAL20102019ARZ	ASTRAZENECA PHARMACEUTICALS LP, 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
		ONGLYZA TABLET 5MG MAL20102020ARZ	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
264.	Selegiline	JUMEX TABLET 5MG MAL19950723AZ	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PVT. CO. LTD., HUNGARY
265.	Sevelamer Carbonate	RENVELA (SEVELAMER CARBONATE) TABLETS MAL20102007AZ	GENZYME IRELAND LIMITED, IRELAND
		As agreed upon in Mesyuarat Dasar Regulatori 1/2013 dated 20th 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	
266.	Sildenafil citrate	VIAGRA 25MG TABLET MAL19990542A VIAGRA 50MG TABLET MAL19990543A VIAGRA 100MG TABLET MAL19990544A	PFIZER INC, UNITED STATES
		VIAGRA 25MG TABLET MAL20012709ARSZ VIAGRA 50MG TABLET MAL20012710ACRZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA FAREVA AMBOISE, 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
		VIAGRA 100MG TABLET MAL20012711ACRZ REVATIO 20 MG FILM-COATED TABLET MAL20071716ACRZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA FAREVA AMBOISE, FRANCE PFIZER AUSTRALIA PTY. LTD., AUSTRALIA FAREVA AMBOISE, FRANCE
267.	Sitagliptin	JANUVIA 25 MG TABLET MAL20071662ARZ JANUVIA 50 MG TABLET MAL20071663ARZ JANUVIA 100 MG TABLET MAL20071664ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
268.	Sodium Iodide	SODIUM IODIDE (1311) THERAPY CAPSU* MAL19930360AZ	GE HEALTHCARE LIMITED, UNITED KINGDOM
269.	Sodium fusidate	FUCIDIN TABLET 250MG (FILM COATED) MAL19910821AZ	LEO PHARM PRODUCTS, DENMARK
270.	Sodium rabeprazole	PARIET TABLET 10MG MAL19992540ACRZ PARIET TABLET 20MG MAL19992541ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN EISAI CO LTD, JAPAN
271.	Solifenacin Succinate	VESICARE 5 MG (FILM COATED TABLET) MAL20091963AZ	ASTELLAS PHARMA EUROPE B.V, NETHERLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		VESICARE 10MG (FILM COATED TABLET) MAL20091964AZ	
272.	Sofosbuvir	SOVALDI 400MG FILM-COATED TABLETS MAL15095034AZ	GILEAD SCIENCES IRELAND UC, IRELAND
273.	Sorafenib tosylate	NEXAVAR FILM-COATED TABLETS 200 MG MAL20071668AZ	BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
274.	Sotalol hydrochloride	SOTACOR TABLET 80MG MAL19930231A	BRISTOL-MYERS CO LTD, UNITED KINGDOM
		SOTACOR TABLET 160MG MAL19930232A	
		SOTACOR TABLET 80MG MAL19940601AS SOTACOR TABLET 160MG MAL19940602AS	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
275.	Spiramycin	ROVAMYCINE TABLET 1.5 MILLION IU MAL19890558A	FAMAR LYON, FRANCE
		ROVAMYCINE 3 M.I.U. TABLETS MAL19962132AZ	FAMAR LYON, FRANCE
276.	Spirolactone	ALDACTONE TABLET 100MG MAL19870236A	SEARLE LABS, AUSTRALIA
		ALDACTONE TABLET 25MG 1986030413A	SEARLE LABS, AUSTRALIA

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		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. (Information obtained from Pfizer Malaysia dated 10th June 2013 via an email) 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.	
277.	Sulindac	CLINORIL 200MG TABLET MAL19950546A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
278.	Sulodexide	VESSEL DUE F 250 LSU CAPSULE MAL19992679AZ	ALFA WASSERMANN S.P.A., ITALY
279.	Sulphasalazine	SALAZOPYRIN EN TABLET 500MG MAL19950470AZ	KEMWELL AB, SWEDEN
280.	Sultamicillin tosylate	UNASYN TABLET MAL19910104AZ	PFIZER JAPAN INC
		UNASYN ORAL TABLET 375MG MAL20020026ACSZ	PHARMANIAGA MANUFACTURING BERHAD
281.	Sumatriptan succinate	IMIGRAN TABLET 50MG MAL19973576ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND
		This product is available in Cyprus, Croatia, Egypt, Singapore, Hong Kong, Thailand, Philippines, Republic of Korea, Great Britain, Germany, Greece, Norway, Poland, Turkey, Lithuania & Switzerland (Information obtained from GlaxoSmithKline Pharmaceutical Sdn. Bhd. dated 14th January 2019 via an email)	

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		IMIGRAN TABLET 100MG MAL19950008AZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		This products is available in Great Britain, Germany, Greece, Norway, Poland, Turkey & Lithuania (Information obtained from GlaxoSmithKline Pharmaceutical Sdn. Bhd. dated 14th January 2019 via an email)	
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2019' – 3rd May 2019: Imigran Tablet 100mg manufactured by GlaxoSmithKline Pharmaceuticals SA-Poznan, Poland can also be used as a comparator.	
282.	Sunitinib Malate	SUTENT 12.5MG CAPSULE MAL20071632AZ SUTENT 25MG CAPSULE MAL20071633AZ SUTENT 50MG CAPSULE MAL20071634AZ	PFIZER ITALIA S.R.L., ITALY PFIZER ITALIA S.R.L., ITALY PFIZER ITALIA S.R.L., ITALY
283.	Tadalafil	CIALIS 2.5MG FILM-COATED TABLETS MAL14125151AZ CIALIS 5MG FILM-COATED TABLETS MAL14125149AZ CIALIS 10MG FILM COATED TABLET MAL20034164AZ CIALIS 20MG FILM COATED TABLET MAL20034166AZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2018' – 14 January 2019', starting 1 st January 2020, bioequivalence study are required in fasting and fed state.	
284.	Tamsulosin	HARNAL OCAS 400MCG FILM-COATED TABLET MAL20091914AZ	ASTELLAS PHARMA EUROPE B.V., NETHERLANDS
285.	Tegafur	FUTRAFUL CAPSULE 200MG MAL19861648A	TAIHO PHARM CO LTD, JAPAN
286.	Telbivudine	SEBIVO 600 MG TABLETS MAL20071671ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
287.	Telithromycin	KETEK 400MG TABLET MAL20033479AZ	AVENTIS PHARMA S.P.A, ITALY
288.	Telmisartan	MICARDIS TABLET 20MG MAL20014487A MICARDIS TABLET 40MG MAL19992673AZ MICARDIS TABLET 80MG MAL19992674AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY BOEHRINGER INGELHEIM ELLAS A.E., GREECE BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY BOEHRINGER INGELHEIM ELLAS A.E., GREECE
289.	Temozolomide	TEMODAL CAPSULES 5MG MAL07082878ACR TEMODAL CAPSULES 5 MG MAL06071048ACRS TEMODAL CAPSULES 20MG	ORION CORPORATION, ORION PHARMA, FINLAND

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		MAL07082880ACRZ TEMODAL CAPSULES 20 MG MAL06071049ACRSZ TEMODAL CAPSULES 100MG MAL07082881ACRZ TEMODAL CAPSULES 250 MG MAL06071051ACRS	
		TEMODAL CAPSULES 20MG MAL20032408AR TEMODAL CAPSULES 100MG MAL20032409AR TEMODAL CAPSULES 250MG MAL20032410AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES
290.	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.	
291.	Terazosin hydrochloride	HYTRIN 1MG TABLET MAL20014488ACZ HYTRIN 2MG TABLET MAL20014489ACZ HYTRIN 5MG TABLET MAL20014490ACZ HYTRIN TABLET 1MG MAL19970934A HYTRIN TABLET 2MG MAL19970935A	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM ABBOTT AUSTRALIA P/L, AUSTRALIA

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
		HYTRIN TABLET 5MG MAL19970936A HYTRIN 1MG TABLET MAL19920456A HYTRIN 2MG TABLET MAL19920457A HYTRIN 5MG MAL19920458A	ABBOTT LABORATORIES, UNITED STATES
292.	Teriflunomide	AUBAGIO 14MG FILM-COATED TABLETS MAL15045075AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
293.	Testosterone Undecanoate	ANDRIOL TESTOCAPS CAPSULES 40MG MAL05032535ACZ ANDRIOL CAPSULE 40MG MAL19870663A	CATALENT FRANCE BEINHEIM SA, FRANCE R.P SCHERER GMBH & CO KG, GERMANY
294.	Thalidomide	DOMIDE 50MG CAPSULE, MAL20102065AZ	TTY BIOPHARM COMPANY LIMITED, TAIWAN
		As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2013 – 2 September 2013	
295.	Thioguanine	LANVIS TABLETS 40MG MAL05032537ACR LANVIS TABLETS 40MG MAL13065045ACZ	DSM PHARMACEUTICALS INC, UNITED STATES EXCELLA GMBH & CO. KG, GERMANY
296.	Thyroxine sodium	ELTROXIN TABLET 0.05 MG MAL19890455A ELTROXIN TABLET 0.1MG MAL19890456A	GLAXO WELLCOME OPERATIONS UK LTD

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
297.	Tibolone	LIVIAL TABLET 2.5MG MAL19913394AZ	N.V. ORGANON, NETHERLANDS
298.	Ticagrelor	BRILINTA 90MG FILM-COATED TABLET MAL20112115ARZ	ASTRAZENECA AB, SWEDEN
299.	Tolterodine l-tartrate	DETRUSITOL TABLET 2MG MAL19991686AZ	PFIZER ITALIA S.R.L., ITALY
300.	Topotecan hydrochloride	HYCAMTIN 0.25MG HARD CAPSULES MAL20091960ACZ HYCAMTIN 1 MG HARD CAPSULES MAL20091961ACZ	GLAXOSMITHKLINE MANUFACTURING S.P.A, ITALY
301.	Tranexamic Acid	TRANSAMIN CAPSULE 250MG MAL19890202ACZ TRANSAMIN CAPSULE 250MG	CMIC CMO CO. LTD, JAPAN DAIICHI PHARMACEUTICAL LTS, JAPAN
302.	Tramadol hydrochloride	TRAMAL CAPSULE MAL19921516A	GRUNENTHAL GMBH, WEST GERMANY
		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) 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 Origgio, Italy can also be used as a comparator.	

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(DECEMBER 2019)

Bil.	TEST PRODUCTS (Pharmaceutical name)	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
303.	Tretinoin	VESANOID SOFT-GELATIN CAPSULE 10MG MAL19960996ACZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
304.	Triazolam	SOMESE TABLET 0.25 MG MAL07050020AZ	PFIZER ITALIA S.R.L., ITALY SANICO N.V., BELGIUM
305.	Triflusal	GRENDIS 300MG CAPSULE MAL20051420AZ	J. URIACH & CIA,S.A., SPAIN
306.	Trimebutine maleate	DEBRIDAT TABLET 1990040029A	JOUEVINAL LABS, FRANCE
307.	Trimetazidine hydrochloride/ Trimetazidine Dihydrochloride	VASTAREL COATED TABLET 20MG MAL19870169AZ	LES LABS SERVIER INDUSTRIE, FRANCE
308.	Ulipristal Acetate	ELLA TABLET 30MG MAL12035079ACZ ESMYA 5MG TABLETS MAL15025044ACZ	CENEXI, FRANCE CENEXI, FRANCE
309.	Ursodeoxycholic acid	URSOFALK CAPSULE 250MG MAL19990011ACSZ	LOSAN PHARMA GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(DECEMBER 2019)

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
310.	Valganciclovir	VALCYTE TABLETS 450MG MAL20040021ARZ	PATHEON INC, CANADA
311.	Vigabatrin	SABRIL 500MG TABLET MAL19961357AZ	PATHEON FRANCE S.A., FRANCE
312.	Vildagliptin	GALVUS 50MG TABLETS MAL20081792ARZ	NOVARTIS FARMACEUTICA S.A, SPAIN
313.	Vinorelbine tartrate	NAVELBINE 20MG SOFT CAPSULE MAL20071635AZ NAVELBINE 30MG SOFT CAPSULE MAL20071636AZ	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
314.	Voriconazole	VFEND 50MG TABLET MAL20040542ARZ VFEND 200MG TABLET MAL20040543ARZ	PFIZER ITALIA S.R.L ITALY PFIZER MANUFACTURING DEUTSHLAND GMBH, GERMANY
315.	Vorinostat	ZOLINZA 100MG CAPSULE MAL20102001ACRZ	PATHEON INC. CANADA
316.	Ziprasidone hydrochloride	ZELDOX CAPSULE 20MG MAL20032622A ZELDOX CAPSULE 40MG MAL20032623AZ ZELDOX CAPSULE 60MG MAL20032624AZ ZELDOX CAPSULE 80MG MAL20032625AZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
317.	Zofenopril calcium	BIFRIL 30 MAL20061470AZ	A. MENARINI MANUFACTURING

LIST OF COMPARATOR PRODUCTS FOR BIOEQUIVALENCE STUDIES
(DECEMBER 2019)

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products	
		Trade Mark/Registration No./ Reference No.	Manufacturer
			LOGISTICS AND SERVICES S.R.L., ITALY
318.	Zuclopenthixol	CLOPIXOL TABLET 10MG MAL19890537A	H.LUNDBECK A/S, DENMARK

Note:

If you need further clarification, kindly email to be_sug@npra.gov.my

Updated on 31/12/2019