LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
1.	ABACAVIR SULFATE (EQ 300MG BASE)	ZIAGEN TABLET MAL20001015ARZ	GLAXO SMITH KLINE PHARMACEUTICAL SA, POLAND GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
2.	ABIRATERONE ACETATE	ZYTIGA 500MG FILM-COATED TABLET MAL20116008ACZ	PATHEON FRANCE S.A., FRANCE
		ZYTIGA 250MG TABLET MAL12085056ACRZ	PATHEON INC, CANADA
3.	ABEMACICLIB	YULAREB 50MG FILM-COATED TABLETS MAL20046079ARZ	LILLY DEL CARIBE, INC (UNITED STATES)
		YULAREB 100MG FILM-COATED TABLETS MAL20046080ARZ	LILLY DEL CARIBE, INC (UNITED STATES)
		YULAREB 150MG FILM-COATED TABLETS MAL20046081ARZ	LILLY DEL CARIBE, INC (UNITED STATES)
4.	ACARBOSE	GLUCOBAY TABLET 100MG MAL19940746AZ	BAYER AG LEVERKUSEN, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
		GLUCOBAY TABLET 50MG MAL19940745AZ	BAYER AG LEVERKUSEN, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
5.	ACALABRUTINIB	CALQUENCE HARD CAPSULE 100MG MAL21106005AZ	ASTRA ZENECA AB, SWEDEN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
6.	ACEBUTOLOL HYDROCHLORIDE	SECTRAL TABLET 400MG MAL19870053A	MAY & BAKER LTD, MAY & BAKER LTD, DAGENHAM, ESSEX, RM107XS, ENGLAND
		SECTRAL CAPSULE 200MG MAL19870052A	MAY & BAKER LTD, MAY & BAKER LTD, DAGENHAM, ESSEX, RM107XS, ENGLAND
		SECTRAL CAPSULE 100MG MAL19870251A	MAY & BAKER LTD, MAY & BAKER LTD, DAGENHAM, ESSEX, RM107XS, ENGLAND
		SECTRAL 200MG CAPSULE MAL19920620A	RHONE-POULENC RORER, JL LAWANG GINTUNG, BOGUR, WEST JAVA, INDONESIA
7.	ACECLOFENAC	AIRTAL 100MG FILM-COATED TABLET MAL20026048AZ	INDUSTRIAS FARMACEUTICAS ALMIRALL, S.A. (IFA), SPAIN
8.	ACEMETACIN 60MG	RANTUDIL CAPSULE 60MG MAL19986936A	BAYER AG, GERMANY
9.	ACIPIMOX 250MG	OLBETAM CAPSULE 250 MG MAL19900589A	PHARMACIA S.P.A, ITALY
10.	ACITRETIN	NEOTIGASON CAPSULE 25 MG MAL06091393ACZ	PATHEON INC, CANADA
		NEOTIGASON CAPSULE 25 MG MAL21026035ACZ	CENEXI, FRANCE
		NEOTIGASON CAPSULE 10 MG MAL06091392ACZ	PATHEON INC, CANADA
		NEOTIGASON HARD GELATIN CAPSULE 25 MAL19921412A	ROCHE PRODUCTS LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	**MANUFACTURER**
		NEOTIGASON HARD GELATIN CAPSULE 10MG MAL19921411A	ROCHE PRODUCTS LTD, UNITED KINGDOM
11.	ACRIVASTINE	SEMPREX CAPSULE 8MG MAL19900013A	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
12.	ACYCLOVIR (*List 2*)	ZOVIRAX TABLET 800MG MAL19930258A	THE WELLCOME FOUNDATION LTD, UK
		ZOVIRAX TABLET 400MG MAL19880351A	THE WELLCOME FOUNDATION LTD, UK
		ZOVIRAX TABLET 200MG MAL19860860A	THE WELLCOME FOUNDATION LTD, UK
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 3/2015 – 9th December 2015: the BE requirement shall be imposed on generic immediate release product containing Acyclovir. This requirement is also applicable for registered products with renewal due date from 1st July 2017 onwards. The meeting has agreed to add the following products as additional comparator in Malaysia.	
		ACIC 800 TABLET MAL19986961ACZ	SALUTAS PHARMA, GERMANY
		ACIC 400 TABLET MAL19986960ACZ	SALUTAS PHARMA, GERMANY
		ACIC 200 TABLET MAL20000724ACZ	SALUTAS PHARMA, GERMANY
		ACYCLOVIR 800 STADA MAL19984317AZ	STADA ARZNEIMITTEL AG, GERMANY STADAPHARM GMBH, GERMANY
		ACYCLOVIR 400 STADA MAL19984318AZ	STADA ARZNEIMITTEL AG, GERMANY STADAPHARM GMBH, GERMANY
		ACYCLOVIR 200 STADA MAL19983993AZ	STADA ARZNEIMITTEL AG, GERMANY STADAPHARM GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		APO-ACYCLOVIR 800MG MAL19984323AZ	APOTEX INC, CANADA
		APO-ACYCLOVIR 400MG MAL19984322AZ	APOTEX INC, CANADA
		APO-ACYCLOVIR 200MG MAL19984321AZ	APOTEX INC, CANADA
		DRAVYR TABLET 400MG MAL19983967AZ	LISAPHARM, ITALY
		MEDOVIR 400MG TABLETS MAL09062118AZ	MEDOCHEMIE LTD, CYPRUS
13.	ADEFOVIR DIPIVOXIL 10MG	HEPSERA TABLET 10MG MAL20040907ARZ	GLAXOSMITHKLINE (TIANJIN) CO. LTD., CHINA
14.	AFATINIB DIMALEATE	GIOTRIF 50MG FILM-COATED TABLETS MAL14075071AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, GERMANY
		GIOTRIF 40MG FILM-COATED TABLETS MAL14075069AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, GERMANY
		GIOTRIF 30MG FILM-COATED TABLETS MAL14075070AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, GERMANY
		GIOTRIF 20MG FILM-COATED TABLETS MAL14075068AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, GERMANY
15.	AGOMELATINE 25MG	VALDOXAN 25MG FILM-COATED TABLETS MAL20091965AZ	LES LABS SERVIER INDUSTRIE (FRANCE)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

16.	ALENDRONATE SODIUM *(List 7)*	FOSAMAX TABLET 70MG MAL20013990AR	MERCK SHARP & DOHME (ITALIA) SPA, ITALY SAVIO INDUSTRIAL S.R.L, PAVIA, ITALY ROVI PHARMA INDUSTRIAL SERVICES S.A (SPAIN)
		FOSAMAX 10MG TABLET MAL19971268AR	MERCK SHARP & DOHME (ITALIA) SPA, ITALY
		Fosamax Tablet 70mg can be obtained from **Singapore**. (*Source of information: Merck Sharp & Dohme (Malaysia) Sdn Bhd, 2016*) Fosamax Tablet 70mg manufactured by Savio Industrial S.r.l, Pavia, Italy can be obtained from **Australia, Canada, Belgium/ Luxembourg , Croatia, Denmark/Norway, Germany, Italy, France , Ireland, Greece, Switzerland, Netherlands, Switzerland, Spain, UK, Portugal, Bosnia and Herzegovina, Saudi Arabia, Israel, Mexico, China.** (*Source of information: Merck Sharp & Dohme (Malaysia) Sdn Bhd, 2020*)	
17.	ALISKIREN HEMIFUMARATE	RASILEZ 300MG FILM-COATED TABLET MAL20081731ARZ	NOVARTIS PHARMA S.P.A, ITALY
		RASILEZ 150MG FILM-COATED TABLET MAL20081730ARZ	NOVARTIS PHARMA S.P.A, ITALY
18.	ALLOPURINOL	ZYLORIC TABLET 300MG MAL19972499AZ	ASPEN PORT ELIZABETH (PTY) LTD, SOUTH AFRICA.
		ZYLORIC 100MG TABLETS MAL19973571AZ	ASPEN PORT ELIZABETH (PTY) LTD, SOUTH AFRICA.
19.	ALPRAZOLAM *(List 9)*	XANAX TABLET 1MG MAL05121166ACRSZ	SANICO N.V., BELGIUM
		XANAX TABLET 0.5MG MAL05121161ACRSZ	SANICO N.V., BELGIUM
		XANAX TABLET 0.25MG MAL05121165ACRSZ	SANICO N.V., BELGIUM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		XANAX 1.0MG TABLETS MAL20021409A	PFIZER MANUFACTURING BELGIUM NV, BELGIUM
		XANAX 0.5MG TABLETS MAL20021408A	PFIZER MANUFACTURING BELGIUM NV, BELGIUM
		XANAX TABLET 0.25MG MAL19861297A	PFIZER MANUFACTURING BELGIUM NV, BELGIUM
		XANAX TABLET 1MG MAL19861299A	PFIZER PHARMACEUTICALS LLC, PUERTO RICO
		XANAX TABLET 0.5MG MAL19861301A	PFIZER PHARMACEUTICALS LLC, PUERTO RICO
		XANAX TABLET 0.25MG MAL19861296A	PFIZER PHARMACEUTICALS LLC, PUERTO RICO
20.	ALPELISIB	TREZILENT 50MG FILM-COATED TABLETS MAL20076006ARZ	NOVARTIS PHARMA STEIN AG(SWITZERLAND)
		TREZILENT 150MG FILM-COATED TABLETS MAL20076007ARZ	NOVARTIS PHARMA STEIN AG(SWITZERLAND)
		TREZILENT 200MG FILM-COATED TABLETS MAL20076008ARZ	NOVARTIS PHARMA STEIN AG(SWITZERLAND)
21.	ALVERIN CITRATE	SPASMAVERINE TABLET 0.04G MAL19871806A	LABORATOIR BELLON, FRANCE
		This product can be obtained from **Vietnam & Cambodia**. *(Source of information: Sanofi Aventis (Malaysia) Sdn Bhd, 2013)*	
22.	AMANTADINE HYDROCHLORIDE	SYMMETREL SOFT GELATIN CAPSULE 100 1986040644A	NOVARTIS PHARMA STEIN AG, SWITZERLAND CATALENTGERMANY SCHORNDORF GMBH, GERMANY
		This product manufactured by Catalent Germany can be obtained from **Australia, New Zealand, Singapore, Switzerland & Netherlands**. *(Source of information: Novartis Corporation (Malaysia) Sdn Bhd, 2024)*	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

23.	AMANTADINE SULPHATE 100MG	PK-MERZ TABLET 100MG MAL19860850AZ	MERZ PHARMA GMBH & CO. KGAA,GERMANY
24.	AMBRISENTAN	VOLIBRIS 10 MG FILM COATED TABLET MAL20102009ACRZ	PATHEON INC. CANADA
		VOLIBRIS 5 MG FILM COATED TABLET MAL20102008ACRZ	PATHEON INC. CANADA
25.	AMIODARONE HYDROCHLORIDE 200MG	CORDARONE 200MG MAL19987968ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE
26.	AMISULPRIDE	SOLIAN 400MG SCORED FILM-COATED TABLET MAL20032240ACZ	DELPHARM DIJON, FRANCE SANOFI WINTHROP INDUSTRIE, FRANCE
		SOLIAN 100MG SCORED TABLET MAL20032239ACZ	DELPHARM DIJON, FRANCE SANOFI WINTHROP INDUSTRIE, FRANCE
27.	AMITRIPTYLLINE HYDROCHLORIDE *(List 4)*	TRYPTANOL 25MG TABLET MAL19940012AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2012 – 13th September 2012: the following products are being added as additional comparator in Malaysia.	
		APO-AMITRIPTYLINE 25MG MAL19984711ARZ	APOTEX INC, CANADA
		APO-AMITRIPTYLINE 10MG TABLETS MAL19984714ARZ	APOTEX INC, CANADA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

28.	AMLODIPINE BESYLATE *(List 6)*	NORVASC TABLET 10 MG MAL19970268ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		NORVASC TABLET 5MG MAL19970269ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		NORVASC TABLET 10 MG MAL19910813A	PFIZER CORP (BELGIUM)
		NORVASC TABLET 5MG MAL19910812A	PFIZER CORP (BELGIUM)
		NORVASC TABLET 10MG MAL20020267ACZ	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
		NORVASC TABLET 5MG MAL20020266ACZ	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
29.	AMOXYCILLIN TRIHYDRATE *(List 8)*	OSPAMOX 1000MG FILM-COATED TABLET MAL19890613AZ	SANDOZ GMBH, AUSTRIA
		OSPAMOX 500MG FILM-COATED TABLET MAL19890612AZ	SANDOZ GMBH, AUSTRIA
		OSPAMOX 250MG CAPSULE MAL19890611AZ	SANDOZ GMBH, AUSTRIA
		MOXILEN CAPSULE 500MG MAL19860465AZ	MEDOCHEMIE LTD, CYPRUS
		MOXILEN CAPSULE 250MG MAL19860458AZ	MEDOCHEMIE LTD, CYPRUS
30.	AMPICILLIN TRIHYDRATE *(List 8)*	PAMECIL CAPSULE 500MG MAL19860396AZ	MEDOCHEMIE LTD, CYPRUS
		PAMECIL CAPSULE 250MG MAL19860391AZ	MEDOCHEMIE LTD, CYPRUS

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

31.	ANAGRELIDE HYDROCHLORIDE (EQ 0.5MG BASE) *(List 9)*	AGRYLIN 0.5MG CAPSULES MAL13055062ACRZ	PATHEON MANUFACTURING SERVICES LLC, UNITED STATES DSM PHARMACEUTICALS, INC., UNITED STATES
		AGRYLIN 0.5MG CAPSULES MAL20051337ACR	MALLINCKRODT INC, UNITED STATES
32.	ANASTROZOLE	ARIMIDEX TABLET 1MG MAL9987960ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
33.	APALUTAMIDE	ERLEADA 60MG FILM-COATED TABLET MAL20026041ARZ	JANSSEN ORTHO LLC (PUERTO RICO)
34.	APIXABAN	ELIQUIS 2.5MG FILM-COATED TABLETS MAL13085062ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND BRISTOL-MYERS SQUIBB MANUFACTURING COMPANY, UNITED STATES
		ELIQUIS 5MG FILM-COATED TABLETS MAL13085063ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND BRISTOL-MYERS SQUIBB MANUFACTURING COMPANY, UNITED STATES
35.	APREMILAST	OTEZLA FILM-COATED TABLETS 30MG MAL18116084ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND PATHEON INC., WHITBY, ONTARIO, CANADA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

36.		OTEZLA FILM-COATED TABLETS 20MG MAL18116085ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND PATHEON INC., WHITBY, ONTARIO, CANADA
		OTEZLA FILM-COATED TABLETS 10MG MAL18116086ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND PATHEON INC., WHITBY, ONTARIO, CANADA
		This product manufactured by **Patheon Inc., Whitby, Ontario, Canada** can be obtained from **Singapore, Japan, Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iran, Ireland, Israel, Italy, Kuwait, Lebanon, Lithuania, Luxembourg, Netherlands, Norway, Portugal, Poland, Qatar, Romania, Saudi Arabia, Slovakia, Slovenia, Spain, Switzerland, Taiwan, UAE, UK, US.** *(Source of information:* **Amgen Biopharmaceuticals Malaysia** *(Malaysia) Sdn Bhd 2025*	
37.	APREPITANT	EMEND 125MG CAPSULE MAL15065039ACRZ	ALKERMES PHARMA IRELAND LIMITED, IRELAND
		EMEND 80MG CAPSULE MAL15065038ACRZ	ALKERMES PHARMA IRELAND LIMITED, IRELAND
		EMEND 125MG CAPSULE MAL20040906AR	MERCK SHARP & DOHME CORP., UNITED STATES
		EMEND 80MG CAPSULE MAL20040905AR	MERCK SHARP & DOHME CORP., UNITED STATES
38.	ARIPIPRAZOLE *(List 9)*	ABILIFY TABLET 15MG MAL07021403ARS	OTSUKA PHARMACEUTICAL CO LTD., JAPAN
		ABILIFY TABLET 10MG MAL07021401ARS	OTSUKA PHARMACEUTICAL CO LTD., JAPAN
		ABILIFY TABLET 15MG MAL05023434AR	BRISTOL-MYERS SQUIBB MANUFACTURING COMPANY, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		ABILIFY TABLET 10MG MAL05023433AR	BRISTOL-MYERS SQUIBB MANUFACTURING COMPANY, UNITED STATES
		ARISA TABLET 5MG MAL23056004AZ	PHARMATHEN INTERNATIONAL S.A. (GREECE)
		Products can be obtained from **Australia, Canada, China, Egypt, Europe region including Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Hong Kong, Indonesia, Republic of Korea, Macao, Myanmar, New Zealand, Philippines, Singapore, South Africa, Taiwan, Tunisia, Turkey, United Kingdom and United States.** *(Source of information: **Otsuka Pharmaceuticals (Malaysia) Sdn. Bhd**. May 2026)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2019 – 19th November 2019: Abilify Tablets 10mg and Abilify Tablets 15mg manufactured by **Abdi Ibrahim Ilac San. Ve. Tic. A.S., Turkey** and **Second Tokushima Factory, Tokushima, Japan** are allowed to be used as comparator.	
39.	ATAZANAVIR SULFATE	REYATAZ CAPSULE 200MG MAL20061580AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		REYATAZ CAPSULE 150MG MAL20061579AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		REYATAZ CAPSULE 100MG MAL20061578AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		The product can be obtained from **Singapore** and **Thailand**. Kindly contact Idis Managed Access for further information. Idis Managed Access Email: MAPProgramAssociate@clinigengroup.com Website: www.clinigengroup.com *(Source of information: BMS Thailand, 2017)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2018 – 25th May 2018: Reyataz Capsule manufactured by **AstraZeneca Pharmaceuticals LP, United States** is allowed to be used as comparator products.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

40.	ATENOLOL *(List 4)*	TENORMIN TABLET 100MG MAL19870056ARZ	ASTRAZENECA UK LIMITED, UNITED KINGDOM
		TENORMIN TABLET 50MG MAL19870055ARZ	ASTRAZENECA UK LIMITED, UNITED KINGDOM
41.	ATOGEPANT	AQUIPTA TABLET 10MG MAL25046001ACRZ	FOREST LABORATORIES IRELAND LIMITED(IRELAND)
		AQUIPTA TABLET 60MG MAL25046002ACRZ	FOREST LABORATORIES IRELAND LIMITED(IRELAND)
42.	ATOMOXETINE HYDROCHLORIDE	STRATTERA 60MG CAPSULE MAL20051406ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A, MADRID, SPAIN
		STRATTERA 40MG CAPSULES MAL20051405ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A, MADRID, SPAIN
		STRATTERA 25MG CAPSULES MAL20051404ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A, MADRID, SPAIN
		STRATTERA 18MG CAPSULES MAL20051403ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A, MADRID, SPAIN
		STRATTERA 10MG CAPSULES MAL20051402ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A, MADRID, SPAIN
43.	ATORVASTATIN CALCIUM *(List 7)*	LIPITOR TABLET 80MG MAL20040226ARZ	PFIZER PHARMACEUTICAL LLC, UNITED STATES VIATRIS Pharmaceuticals LLC (UNITED STATES)
		LIPITOR TABLET 40MG MAL20034212 ARZ	PFIZER PHARMACEUTICAL LLC, UNITED STATES VIATRIS Pharmaceuticals LLC (UNITED STATES)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		LIPITOR TABLET 20MG MAL20034211 ARZ	PFIZER PHARMACEUTICAL LLC, UNITED STATES VIATRIS Pharmaceuticals LLC (UNITED STATES)
		LIPITOR TABLET 10MG MAL20034210 ARZ	PFIZER PHARMACEUTICAL LLC, UNITED STATES VIATRIS Pharmaceuticals LLC (UNITED STATES)
		LIPITOR TABLET 40MG MAL19985092A	GODECKE GMBH, GERMANY
		LIPITOR TABLET 20MG MAL19985091A	GODECKE GMBH, GERMANY
		LIPITOR TABLET 10MG MAL19985090A	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		ROTAQOR FILM COATED TABLET 10MG MAL24096051AZ	LEK S.A.(POLAND)
		ROTAQOR FILM COATED TABLET 20MG MAL24096052AZ	LEK S.A.(POLAND)
		ROTAQOR FILM COATED TABLET 40MG MAL24096053AZ	LEK S.A.(POLAND)
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2010 – 8th December 2010 : Both parent drug and active metabolite (2-hydroxy-atorvastatin acid) need to be analysed in BE study. However, should the BE study conducted prior to 8 December 2010 and the analysis was only done on parent drug, the BE report can still be considered for evaluation.	
44.	AXITINIB	INLYTA FILM-COATED TABLETS 1MG MAL13115126AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH (GERMANY)
		INLYTA FILM-COATED TABLETS 5MG MAL13115127AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH (GERMANY)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

45.	AZATHIOPRINE *(List 7)*	IMURAN 50MG TABLET MAL04103439AZ	ASPEN SA OPERATION PTY. LTD, SOUTH AFRICA
46.	AZITHROMYCIN DIHYDRATE *(List 6)*	ZITHROMAX TABLET 500MG MAL19985909ACZ	HAUPT PHARMA LATINA S.R.L., ITALY PFIZER ITALIA S.R.L., ITALY
		ZITHROMAX TABLET 250MG MAL19985908ACZ	HAUPT PHARMA LATINA S.R.L., ITALY PFIZER ITALIA S.R.L., ITALY
		ZITHROMAX TABLET 500MG MAL20040036ASZ	PFIZER AUSTRALIA PTY. LTD, AUSTRALIA.
		ZITHROMAX TABLET 250MG MAL20040039ASZ	PFIZER AUSTRALIA PTY. LTD, AUSTRALIA.
		ZITHROMAX CAPSULES 250MG MAL19970270AS	PFIZER PTY LTD, AUSTRALIA
		ZITHROMAX CAPSULES 250MG MAL19921615A	PFIZER LIMITED, UNITED KINGDOM
47.	BACLOFEN 10MG	LIORESAL 10MG TABLET MAL20000748ACRZ	NOVARTIS FARMA S.P.A., ITALY
48.	BALOXAVIR MARBOXIL 40MG	XOFLUZA FILM-COATED TABLET 40MG MAL20046078ACRZ	SHIONOGI PHARMA CO., LTD. (JAPAN)
49.	BEDAQUILINE	SIRTURO 100MG TABLETS MAL20076070ACZ	RECIPHARM PHARMASERVICES PRIVATE LIMITED, INDIA
50.	BENFLUOREX HYDROCHLORIDE 150MG	MEDIAXAL TABLET 150MG MAL19870176A	LES LABS SERVIER INDUSTRIE, FRANCE
51.	BENZHEXOL HYDROCHLORIDE 2MG	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**. *(Source of information: Pfizer (Malaysia) Sdn Bhd, 2013)*	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2017 – 27th September 2017: the following product is being added as additional comparator in Malaysia	
		APO-TRIHEX TABLET 2MG MAL19984756AZ	APOTEX INC, CANADA
52.	BENZTROPINE MESYLATE 2MG	COGENTIN TABLET 2MG MAL19870343AR COGENTIN 2MG TABLET MAL19940013AS	MERCK SHARP & DOHME INT, UNITED STATES MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (AUSTRALIA)
53.	BETAHISTINE DIHYDROCHLORIDE	BETASERC 24MG TABLET MAL07061394ACZ	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**. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2015)*	
54.	BETAHISTINE MESYLATE 6MG	MERISLON TABLET 6MG MAL19861236AZ	EISAI CO LTD, JAPAN
55.	BETAXOLOL HYDROCHLORIDE 20MG	KERLONE TABLET 20MG MAL19872264AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
56.	BICALUTAMIDE	CASODEX TABLET 50MG MAL19990958ACRZ	CORDEN PHARMA GMBH, GERMANY.

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		CASODEX 150MG TABLET MAL20040082AR	ASTRAZENECA GMBH, GERMANY
57.	BISOPROLOL FUMARATE	CONCOR 10 FILM-COATED TABLET MAL19890390AZ	MERCK HEALTHCARE KGAA, GERMANY
		CONCOR 5 FILM COATED TABLET MAL19890389AZ	MERCK HEALTHCARE KGAA, GERMANY
		CONCOR 2.5MG FILM COATED TABLET MAL20020792AZ	MERCK HEALTHCARE KGAA, GERMANY
58.	BILASTINE	BILAXTEN 20MG TABLETS MAL14085008ARZ	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L., ITALY FAES FARMA S.A. (SPAIN)
59.	BOSENTAN MONOHYDRATE	TRACLEER TABLET 125 MG MAL20041085ACRZ	PATHEON INC., CANADA
		TRACLEER TABLET 62.5 MG MAL20041084ACRZ	PATHEON INC., CANADA
60. .	BOSUTINIB DIHYDRATE	BOSNIB 500 (BOSUTINIB TABLETS 500 MG) MAL25056004AZ	MSN LABORATORIES PRIVATE LIMITED(INDIA)
		BOSNIB 100 (BOSUTINIB TABLETS 100 MG) MAL25056003AZ	MSN LABORATORIES PRIVATE LIMITED(INDIA)
61.	BREXPIPRAZOLE	REXULTI 4MG FILM-COATED TABLETS MAL20026047ARZ	OTSUKA PHARMACEUTICAL CO., LTD., JAPAN
		REXULTI 3MG FILM-COATED TABLETS MAL20026046ARZ	OTSUKA PHARMACEUTICAL CO., LTD., JAPAN
		REXULTI 2MG FILM-COATED TABLETS MAL20026045ARZ	OTSUKA PHARMACEUTICAL CO., LTD., JAPAN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		REXULTI 1MG FILM-COATED TABLETS MAL20026044ARZ	OTSUKA PHARMACEUTICAL CO., LTD., JAPAN
		REXULTI 0.5MG FILM-COATED TABLETS MAL20026043ARZ	OTSUKA PHARMACEUTICAL CO., LTD., JAPAN
		REXULTI 0.25MG FILM-COATED TABLETS MAL20026042ARZ	OTSUKA PHARMACEUTICAL CO., LTD., JAPAN
62.	BRIGATINIB	ALUNBRIG (BRIGATINIB) 180MG FILM COATED TABLET MAL21046007AZ	TAKEDA IRELAND LIMITED (IRELAND)
		ALUNBRIG (BRIGATINIB) 90MG FILM-COATED TABLET MAL21046006AZ	TAKEDA IRELAND LIMITED (IRELAND)
		ALUNBRIG (BRIGATINIB) 30MG FILM COATED TABLET MAL21046005AZ	TAKEDA IRELAND LIMITED (IRELAND)
63.	BROMAZEPAM *(List 9)*	LEXOTAN ROCHE TABLET 1.5MG MAL19861302ACRZ	DELPHARM MILANO S.R.L, ITALY AESICA PHARMACEUTICALS GMBH (GERMANY)
64.	BROMOCRIPTINE MESYLATE *(List 4)*	PARLODEL TABLET 2.5MG MAL19870437ARZ	NOVARTIS FARMA S.P.A., ITALY
		This product can be obtained from **Korea, Philippines & Switzerland**. *(Source of information: Novartis Corporation (Malaysia) Sdn Bhd 2019)*	
65.	BUMETANIDE	BURINEX TABLET 1MG MAL19913216AZ	LABORATOIRES LEO, FRANCE LEO PHARM PRODUCTS, DENMARK

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

66.	BUSULPHAN	MYLERAN TABLETS 2MG MAL05051050ACZ	EXCELLA GMBH & CO. KG, GERMANY
67.	BUTROPIUM BROMIDE	COLIOPAN TABLET 5MG MAL19910111ACZ	BORA PHARMACEUTICALS CO., LTD, TAIWAN EISAI TAIWAN INC, TAIWAN
68.	CABERGOLINE	DOSTINEX TABLET 0.5MG MAL19971775AZ	PFIZER ITALIA S.R.L., ITALY
69.	CABOZANTINIB (S)-MALATE	CABOMETYX 20MG FILM COATED TABLETS MAL21046002ACZ	PATHEON INC, CANADA
		CABOMETYX 40MG FILM COATED TABLETS MAL21046003ACZ	
		CABOMETYX 60MG FILM COATED TABLETS MAL21046004ACZ	
70.	CALCIFEDIOL	HIDROFEROL 0.266MG SOFT CAPSULES (CALCIFEDIOL MONOHYDRATE) MAL25036004ACZ	HC CLOVER PRODUCTOS Y SERVICIOS, S.L.(SPAIN)
71.	CANAGLIFLOZIN HEMIHYDRATE	INVOKANA 100MG FILM-COATED TABLETS MAL16045042ARZ	JANSSEN CILAG SPA, ITALY
		INVOKANA 300MG FILM-COATED TABLETS MAL16045038ARZ	
72.	CANDESARTAN CILEXETIL	ATACAND TABLET 32MG MAL09042471A	ASTRAZENECA AB, SWEDEN
		ATACAND TABLET 16MG MAL20001219ACRZ	ASTRAZENECA AB, SWEDEN
		ATACAND TABLET 8MG MAL20001218ACRZ	ASTRAZENECA AB, SWEDEN
		ATACAND TABLET 4MG MAL20001217A	ASTRAZENECA AB, SWEDEN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		BLOPRESS TABLET 16MG MAL20002653AZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		BLOPRESS TABLET 8MG MAL20002652ARZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		BLOPRESS TABLET 16MG MAL22036008ACZ	DELPHARM NOVARA S.R.L(ITALY)
		BLOPRESS TABLET 8MG MAL22036007ACZ	DELPHARM NOVARA S.R.L(ITALY)
73.	CAPECITABINE	XELODA TABLET 500 MG MAL19091001ACRSZ	SHANGHAI ROCHE PHARMACEUTICALS LTD, CHINA
		XELODA TABLETS 500MG MAL19096011ACRZ	EXCELLA GMBH & CO.KG, GERMANY
		XELODA TABLETS 150MG MAL19096016ACRZ	EXCELLA GMBH & CO.KG, GERMANY
		XELODA TABLET 500MG MAL20000002ARZ	PRODUCTOS ROCHE S.A DE C.V, MEXICO
		XELODA TABLET 150MG MAL20000001ARZ	PRODUCTOS ROCHE S.A DE C.V, MEXICO
74.	CAPIVASERTIB	TRUQAP 200MG FILM COATED TABLETS MAL25056002ARZ	ASTRA ZENECA AB(SWEDEN)
		TRUQAP 160MG FILM COATED TABLETS MAL25056001ARZ	ASTRA ZENECA AB(SWEDEN)
75.	CAPTOPRIL *(List 1)*	As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2009* – 19th Ogos 2009: the following products are being added as additional comparators in Malaysia.	
		APO-CAPTO 25MG TABLET MAL19987340ARZ	APOTEX INC., CANADA
		APO-CAPTO 12.5MG TABLET MAL19987341ARZ	APOTEX INC., CANADA
		KIMAFAN TABLET 25MG MAL19985969AZ	DUOPHARMA (M) SDN BHD
		KIMAFAN TABLET 12.5MG MAL19985970A	DUOPHARMA (M) SDN BHD

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

76.	CARBAMAZEPINE *(List 3)*	TEGRETOL 200MG TABLET MAL20000032ARZ	NOVARTIS FARMA S.P.A., ITALY
77.	CARBIMAZOLE	NEOMERCAZOLE® TABLET 5MG MAL12020025ACZ	CENEXI SAS, FRANCE
		NEOMERCAZOLE TABLET 5MG MAL05092230AC	APTUIT (EDINBURGH) LIMITED, UNITED KINGDOM
		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**. *(Source of information: Menarini Singapore Pte Ltd, 2015)*	
78.	CARVEDILOL *(List 6)*	DILATREND TABLET 25MG MAL19940581ACZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A, ITALY
		DILATREND TABLET 12.5MG MAL19991010ARZ	ROCHE S.P.A, ITALY
		DILATREND TABLET 6.25MG MAL19991009ACZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A, ITALY
79.	CEFACLOR	DISTACLOR CAPSULE 500MG MAL19962115A	ELI LILLY & CO (TAIWAN) INC, TAIWAN
		DISTACLOR CAPSULE 250MG MAL19962114A DISTACLOR 250MG CAPSULE MAL20020359A	ELI LILLY & CO (TAIWAN) INC, TAIWAN ELI LILLY ITALIA SPA (ITALY)
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2015* – 9th December 2015, Distaclor 250mg capsule from **China** and Distaclor 500mg capsule from **Greece** are allowed to be used as comparator products. i) DISTACLOR 250MG Capsule **Lilly Suzhou Pharmaceutical Co, Ltd** No. 6 Baiyu Road, Suzhou Industrial Park, Jiangsu Province, **China** ii) DISTACLOR 500MG Capsule	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		Vianex S.A, (Factory D) VI.PE Patras 250 18 Ag. Stefanos, **Greece** *(Source of information: Eli Lily (Malaysia) Sdn Bhd, 2015)* Distaclor 250mg capsule and Distaclor 500mg capsule are available in **China** and **Greece** under the brand name of Ceclor Capsule. *(Source of information: Eli Lily (Malaysia) Sdn Bhd, 2016)*	
80.	CEFADROXIL MONOHYDRATE	DURICEF TABLET 1GM MAL19940665A	BRISTOL-M BARCELONETA INC, PUERTO RICO, UNITED STATES
		DURICEF CAPSULE 500MG MAL19860523A	BRISTOL-M BARCELONETA INC, PUERTO RICO, UNITED STATES
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2014 – 18 August 2014: DURICEF capsule and DURICEF tablet from **Corden Pharmaceuticals Italy** is allowed to be used as a comparator. Duricef Capsule 500mg and Duricef Tablet 1gm can be obtained from **Belgium, Luxembourg, Bulgaria, Czech Rep, Estonia, Lithuania, Latvia**, and **Poland** and are sold under the brand name of Duracef. *(Source of information:- Valeant Pharmaceuticals, 2017)*	
81.	CEFDINIR	OMNICEF CAPSULE 100MG MAL19991688AC	DUOPHARMA MANUFACTURING (BANGI) SDN BHD UPHA PHARMACEUTICAL MFG. (M) SDN BHD
82.	CEFIXIME	SUPRAX TABLET	LEDERLE
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 3/2015 – 9th December 2015: SUPRAX TABLET from **Famar Lyon, France** and **Merck Pharma, Spain** are allowed to be used as comparator. It can be obtained from **United Kingdom** and **Canada**. *(Source of information: Sanofi Aventis (Malaysia) Sdn Bhd, 2015)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2020 – 28th December 2020: SUPRAX TABLET from **S.C. Zentiva, S.A., Romania** is allowed to be used as comparator. It can be obtained from **United Kingdom**. *(Source of information: Sanofi Aventis (Malaysia) Sdn Bhd, 2020)*	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

83.	CEFPROZIL	PROCEF TABLET 500MG MAL19940483A	BRISTOL-M BARCELONETA INC, UNITED STATES
		PROCEF TABLET 250MG MAL19940487A	BRISTOL-M BARCELONETA INC, UNITED STATES
84.	CEFTIBUTEN	CEDAX CAPSULE 400MG MAL19950227AZ	MERCK SHARP & DOHME CORP, UNITED STATES SIFI S.P.A., ITALY
		CEDAX CAPSULE 200MG MAL19950228A	SIFI S.P.A., ITALY
85.	CEFUROXIME AXETIL *(List 6)*	ZINNAT TABLET 250MG MAL19890137ARZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM SANDOZ GMBH(AUSTRIA)
		ZINNAT TABLET 125MG MAL19890136AZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		ZINNAT TABLET 500MG MAL22086003ARZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM SANDOZ GMBH(AUSTRIA)
86.	CELECOXIB	CELEBREX 400MG CAPSULES MAL08051748ARZ	PFIZER PHARMACEUTICAL LLC, USA VIATRIS PHARMACEUTICALS LLC,UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		CELEBREX CAPSULE 200MG MAL20000005ARZ	PFIZER PHARMACEUTICAL LLC, USA VIATRIS PHARMACEUTICALS LLC,UNITED STATES
		CELEBREX CAPSULE 100MG MAL20000004ARZ	PFIZER PHARMACEUTICAL LLC, USA VIATRIS PHARMACEUTICALS LLC,UNITED STATES
		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**. (*Source of information: Pfizer (Malaysia) Sdn Bhd, 2015)*	
87.	CEPHALEXIN *(List 8)*	OSPEXIN 1000MG FILM-COATED TABLET MAL19890610AZ	SANDOZ GMBH, AUSTRIA
		OSPEXIN 500MG F/C TABLET MAL19890448AZ	SANDOZ GMBH, AUSTRIA
		OSPEXIN CAPSULE 250MG MAL19890449AZ	SANDOZ GMBH, AUSTRIA
88.	CEPHRADINE	VELOSEF CAPSULE 500MG MAL19920468A	BRISTOL-MYERS SQUIBB AEBE, GREECE
89.	CETIRIZINE DIHYDROCHLORIDE 10MG *(List 6)*	ZYRTEC 10MG FILM COATED TABLET MAL19890575ACRZ	UCB FARCHIM S.A., SWITZERLAND
90.	CHLORAMBUCIL 2MG *(List 7)*	LEUKERAN TABLETS 2MG MAL04125474ACZ	EXCELLA GMBH & CO.KG, GERMANY
91.	CHLOROQUINE SULPHATE	NIVAQUINE TABLET 200MG MAL19912313A	MAY & BAKER LTD, UNITED KINGDOM
92.	CHLORPROMAZINE *(List 9)*	LARGACTIL TABLET 100MG PBKD8631345A	MAY & BAKER LTD, UNITED KINGDOM
		LARGACTIL TABLET 25MG PBKD861335A	MAY & BAKER LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		Products are available in **East Europe[(i)], Tunisia[(i)], Africa[(i)].** and **Australia**[(ii)] (Source of information: (i) Sanofi-Aventis (Malaysia) Sdn Bhd, (ii)JKKBE 02/2013) As agreed upon *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2013 – 2nd September 2013: Largactil® manufactured from **Sanofi Aventis, Spain** and **Famar Lyon, France** are allowed to be used as the comparator.	
93.	CHLORPROPAMIDE	DIABENESE TABLET 250MG MAL19986461A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		DIABINESE TABLET 250MG MAL19870382A	PFIZER PHARM DIV., PHILIPINES
94.	CHLORTETRACYCLINE	AUREOMYCIN CAPSULE 250MG MAL19871950A	INTERTHAI PHARMACEUTICAL MANUFACTURING LTD, THAILAND
95.	CILOSTAZOL	PLETAAL 100MG TABLETS MAL20061475AZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, KOREA
		PLETAAL 50MG TABLETS MAL20061476AZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, KOREA
96.	CIMETIDINE *(List 3)*	TAGAMET TABLET 200MG MAL19950282A	SIGMA PHARM PVT LTD, AUSTRALIA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2016, 16th June 2016: the following products are being added as additional comparator in Malaysia.	
		APO-CIMETIDINE TABLET400MG MAL19984723ARZ	APOTEX INC., CANADA
		APO-CIMETIDINE TABLET 200MG MAL19984721ARZ	APOTEX INC., CANADA
97.	CINACALCET HYDROCHLORIDE (EQ 25MG BASE)	REGPARA TABLETS 25MG MAL13025055ACZ	OHARA PHARMACEUTICAL CO., LTD (KAMI FACTORY), JAPAN
98.	CINACALCET HYDROCHLORIDE (EQ 30MG BASE)	CINACRED 30 MAL24096013AZ	DR. REDDY'S LABORATORIES LIMITED (INDIA)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

99.	CINACALCET HYDROCHLORIDE (EQ 60MG BASE)	CINACRED 60 MAL24096014AZ	DR. REDDY'S LABORATORIES LIMITED (INDIA)
100.	CINACALCET HYDROCHLORIDE (EQ 90MG BASE)	CINACRED 90 MAL 24096015AZ	DR. REDDY'S LABORATORIES LIMITED (INDIA)
101.	CINNARIZINE 25MG	STUGERON 25MG TABLET MAL19871481AZ	JANSSEN CILAG SPA, ITALY
102.	CIPROFIBRATE 100MG	MODALIM TABLET 100MG MAL19950391AZ	PT AVENTIS PHARMA, INDONESIA
103.	CIPROFLOXACIN *(List 5)*	CIPROBAY TABLET 750MG MAL19890627A	BAYER AG, GERMANY BAYER AG, WEST GERMANY
		CIPROBAY TABLET 500MG MAL19890626AZ	BAYER AG, GERMANY BAYER HEALTHCARE AG, GERMANY
		CIPROBAY TABLET 250MG MAL19890115AZ	BAYER AG, GERMANY BAYER HEALTHCARE AG, GERMANY
104.	CITALOPRAM HYDROBROMIDE *(List 9)*	CIPRAM TABLETS 40MG MAL19950392A	H. LUNDBECK A/S, DENMARK
		CIPRAM TABLETS 20MG MAL19950394AZ	H. LUNDBECK A/S, DENMARK
		CIPRAM TABLETS 10MG MAL19950393A	H. LUNDBECK A/S, DENMARK
105.	CLARITHROMYCIN *(List 5)*	KLACID TABLET 500MG MAL18106039ACZ	ABBVIE S.R.L, ITALY
		KLACID TABLET 500MG MAL19984348ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM
		KLACID 250MG TABLET MAL19940216A	ABBOTT S.P.A., ITALY
106.	CLADRIBINE	MAVENCLAD 10MG TABLETS MAL20096001ARZ	NERPHARMA S.R.L.(ITALY)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

107.	CLEMASTINE FUMARATE	TAVEGYL TABLET 1MG PBKD861195A	NOVARTIS PHARMA AG, SWITZERLAND
108.	CLINDAMYCIN HYDROCHLORIDE *(List 8)*	DALACIN C CAPSULES 300MG MAL19985498ACZ	FAREVA AMBOISE, FRANCE PFIZER, FRANCE PATHEON INC, CANADA
		DALACIN C CAPSULE 150MG MAL19871766ACZ	FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE
109.	CLOFAZIMINE 50MG	LAMPRENE CAPSULE 50MG MAL19860819A	NOVARTIS PHARMA STEIN AG (SWITZERLAND)
110.	CLOFAZIMINE 100MG	LAMPRENE CAPSULE 100MG MAL19860820A	NOVARTIS PHARMA STEIN AG (SWITZERLAND)
111.	CLOMIPHENE CITRATE 50MG	CLOMID TABLET 50MG MAL19950686AZ	ZENTIVA K.S., CZECH REPUBLIC PATHEON FRANCE S.A., FRANCE
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2016 – 16th Jun 2016: Both isomers (enclomiphene and zuclomiphene) need to be measured and analysed in BE study. However, BE study conducted prior to 16 June 2016 and the analysis was only done on parent drug, the BE report can still be considered for evaluation.	
112.	CLOMIPRAMINE HYDROCHLORIDE 25MG *(List 4)*	ANAFRANIL 25MG TABLET MAL20000270ACRZ	NOVARTIS FARMA S.P.A, ITALY
113.	CLONAZEPAM	RIVOTRIL ROCHE TABLET 2MG MAL19860962ACRZ	RECIPHARM LEGANÉS S.L.U., SPAIN ROCHE FARMA S.A., SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		RIVOTRIL ROCHE TABLET 0.5MG MAL19860961ACRZ	RECIPHARM LEGANÉS S.L.U., SPAIN ROCHE FARMA S.A., SPAIN
114.	CLONIDINE HYDROCHLORIDE	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
115.	CLOPIDOGREL HYDROGEN SULPHATE *(List 7)*	PLAVIX TABLET 300MG MAL10100020AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		PLAVIX TABLET 75MG MAL19992344AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
116.	CLORAZEPATE DIPOTASSIUM	TRANXENE CAPSULE 10MG PBKD861332AR	SANOFI WINTHROP INDUSTRIE, FRANCE
		TRANXENE CAPSULE 5MG PBKD861331AR	SANOFI WINTHROP INDUSTRIE, FRANCE
117.	CLOXACILLIN SODIUM *(List 8)*	MONOCLOX CAPSULE 250MG MAL19871957AZ	MEDOCHEMIE LTD, CYPRUS
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2015, 7th September 2015: the following products are being added as additional comparators in Malaysia.	
		CLOXACILLIN CAPSULE 500MG MAL07090901AZ	DYNAPHARM (M) SDN BHD, MALAYSIA
		CLOXACILLIN CAPSULE 250MG MAL19930225AZ	DYNAPHARM (M) SDN BHD, MALAYSIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		CLOXACILLA CAP 250MG MAL19890418AZ	IDAMAN PHARMA MANUFACTURING SDN BHD (SERI ISKANDAR), MALAYSIA
118.	CLOBAZAM 10MG *(List 9)*	FRISIUM TABLET 10MG MAL19861330ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE OPELLA HEALTHCARE INTERNATIONAL SAS, FRANCE
119.	CLOZAPINE *(List 7)*	CLOZARIL TABLET 100MG MAL20000747ACRZ	NOVARTIS SAGLIK, TURKEY NOVARTIS PHARMACEUTICALS UK LTD, HORSHAM, GREAT BRITAIN.
		CLOZARIL TABLET 25MG MAL19992681ACRZ	NOVARTIS SAGLIK, TURKEY NOVARTIS PHARMACEUTICALS UK LTD, HORSHAM, GREAT BRITAIN.
120.	CO-DERGOCRINE MESYLATE	HYDERGINE TABLET 4.5MG MAL19870111A	NOVARTIS PHARMA AG, SWITZERLAND
		HYDERGINE TABLET 1.5MG MAL19870106A	NOVARTIS PHARMA AG, SWITZERLAND
		HYDERGINE TABLET 1MG MAL19870102A	NOVARTIS FARMA S.P.A., ITALY
121.	CONJUGATED ESTROGEN	PREMARIN 0.3 TABLET MAL19991386ASZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
		PREMARIN TABLET 0.625MG MAL19870652AZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
122.	CRIZOTINIB	XALKORI 250MG HARD CAPSULES MAL12095103AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		XALKORI 200MG HARD CAPSULES MAL12095102AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
123.	CYCLOSPORIN	SANDIMMUN NEORAL CAPSULE 100MG	CATALENT GERMANY EBERBACH GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

	(List 1)	MAL19962140ACRZ	R.P. SCHERER GMBH & CO KG, GERMANY
		SANDIMMUN NEORAL CAPSULE 50MG MAL19962141AC	CATALENT GERMANY EBERBACH GMBH, GERMANY R.P. SCHERER GMBH & CO KG, GERMANY
		SANDIMMUN NEORAL CAPSULE 25MG MAL19962142ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY R.P. SCHERER GMBH & CO KG, GERMANY
		SANDIMMUN NEORAL 10MG CAPSULE MAL20001791ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY R.P. SCHERER GMBH & CO KG, GERMANY
124.	CYPROTERONE ACETATE 50MG	ANDROCUR 50MG TABLET MAL19993023ARZ	BAYER WEIMAR GMBH UND CO.KG, GERMANY DELPHARM LILLE S.A.S., FRANCE
125.	DABIGATRAN ETEXILATE 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
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsan* 1/2021 – 26 October 2021: bioequivalence studies conducted as per the EMA Dabigatran Etexilate Hard Capsule 75mg, 110mg and 150mg Product-Specific Bioequivalence Guidance are required for submission of new application starting 1st January 2022.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

126.	DACLATASVIR DIHYDROCHLORIDE	DAKLINZA 60MG FILM-COATED TABLETS MAL16045037ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
		DAKLINZA 30MG FILM-COATED TABLETS MAL16045046ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2020 – 28th December 2020: the following products are being added as additional comparator in Malaysia.	
		DASVIR 60 (DACLATASVIR TABLETS 60MG) MAL19056124AZ	HETERO LABS LIMITED, INDIA
		DASVIR 30 (DACLASTASVIR TABLETS 30 MG) MAL19056123AZ	HETERO LABS LIMITED, INDIA
127.	DACOMITINIB MONOHYDRATE	VIZIMPRO 15 MG FILM-COATED TABLETS MAL20076010AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		VIZIMPRO 30 MG FILM-COATED TABLETS MAL20076011AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		VIZIMPRO 45MG FILM-COATED TABLETS MAL20076012AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
128.	DANAZOL	LADOGAL CAPSULE 200MG MAL19987969A	SANOFI-SYNTHELABO LTD, UNITED KINGDOM
		LADOGAL CAPSULE 100MG MAL19987970A	SANOFI-SYNTHELABO LTD, UNITED KINGDOM
		LADOGAL CAPSULE 200MG PBKD870435A	NYCOMED PUERTO RICO INC, SPAIN
		LADOGAL CAPSULE 100MG PBKD870434A	NYCOMED PUERTO RICO INC, SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		LADOGAL CAPSULE 50MG PBKD870433A	NYCOMED PUERTO RICO INC, SPAIN
		These products can be obtained from **Taiwan & Philliphines**. *(Source of information: Sanofi-Aventis (Malaysia) Sdn Bhd, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2015, 21st April 2015: the following products are being added as additional comparators in Malaysia.	
		ANARGIL CAPSULE 200MG MAL19871961AZ	MEDOCHEMIE LTD, CYPRUS
		ANARGIL CAPSULE 100MG MAL19890682AZ	MEDOCHEMIE LTD, CYPRUS
129.	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	FORXIGA 10MG FILM-COATED TABLET MAL14015014ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
		FORXIGA 5MG FILM-COATED TABLET MAL14015013ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
130.	DAPAGLIFLOZIN MANNITOL	DAPAMAC 10 (DAPAGLIFLOZIN FILM COATED TABLETS 10MG) MAL25036002AZ	MACLEODS PHARMACEUTICALS LTD, INDIA
		DAPAMAC 5 (DAPAGLIFLOZIN FILM COATED TABLETS 5MG) MAL25036001AZ	MACLEODS PHARMACEUTICALS LTD, INDIA
131.	DAPOXETINE HYDROCHLORIDE	PRILIGY 60MG FILM COATED TABLETS MAL20102028AZ	MENARINI - VON HEYDEN GMBH, LEIPZIGER, GERMANY
		PRILIGY 30MG FILM COATED TABLETS MAL20102027AZ	MENARINI- VON HEYDEN GMBH, LEIPZIGER, GERMANY
132.	DARUNAVIR ETHANOLATE	PREZISTA 600MG FILM COATED TABLET MAL19046001ARZ	JANSSEN ORTHO LLC, UNITED STATES
		PREZISTA 300 MG FILM-COATED TABLETS MAL20081771AZ	JANSSEN CILAG SPA, ITALY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

133.	DASATINIB	SPRYCEL 70MG TABLET MAL20071697AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		SPRYCEL 50MG TABLET MAL20071696AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		SPRYCEL 20MG TABLET MAL20071695AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		These products can be obtained from Asia pacific (**Singapore, Thailand, Australia, News Zealand**) and Europe (**France, Netherland, Spain, Ireland, Greece, Denmark, Finland, Sweden**) *(Source of information: Bristol Myers Squibb, 2020)*	
134.	DEFERASIROX	EXJADE 90MG FILM-COATED TABLET MAL18016074ARZ	NOVARTIS PHARMA STEIN AG (SWITZERLAND) SANDOZ S.R.L, ROMANIA
		EXJADE 180MG FILM-COATED TABLET MAL18016073ARZ	NOVARTIS PHARMA STEIN AG (SWITZERLAND) SANDOZ S.R.L, ROMANIA
		EXJADE 360MG FILM-COATED TABLET MAL18016071ARZ	NOVARTIS PHARMA STEIN AG (SWITZERLAND) SANDOZ S.R.L, ROMANIA
135.	DEFERIPRONE	FERRIPROX 1000MG FILM-COATED TABLET MAL16065019AZ	APOTEX INC, ETOBICOKE SITE, CANADA
		FERRIPROX 500MG TABLET MAL20033480ACZ	APOTEX INC, ETOBICOKE SITE, CANADA
136.	DESLORATADINE 5MG	AERIUS TABLET 5MG MAL10053655AZ	ORGANON HEIST BV, BELGIUM
		AERIUS TABLET MAL20020876ARZ	SCHERING PLOUGH SPA, ITALY
137.	DESMOPRESSIN ACETATE	MINIRIN TABLET 0.2MG MAL19950097ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MINIRIN TABLET 0.1MG MAL19950096ARZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND
138.	DESOGESTREL 75MCG	CERAZETTE TABLET MAL20031939AZ	N.V ORGANON, NETHERLAND
139.	DEXKETOPROFEN TROMETAMOL	KETESSE 25MG FILM COATED TABLET MAL20061602AZ	A. MENARINI MANUFACTURING LOGISTIES AND SERVICES S.R.L, ITALY
140.	DIACEREIN	ARTRODAR MAL20041211AZ	TRB PHARMA S.A, ARGENTINA
141.	DIAZEPAM *(List 9)*	VALIUM ROCHE TABLET 10MG PBKD861274A	F. HOFFMAN-LA ROCHE., SWITZERLAND
		VALIUM ROCHE TABLET 5MG PBKD861263A	F. HOFFMAN-LA ROCHE., SWITZERLAND
		VALIUM ROCHE TABLET 2MG PBKD861254A	F. HOFFMAN-LA ROCHE., SWITZERLAND
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2013 – 13th March 2013: Valium Tablet from **France**, **USA** & **Spain** are allowed to be used as a comparator.	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2014 – 23 April 2014: the following products are being added as additional comparators in Malaysia.	
		DIAZEPAM 10MG TABLET MAL19860207AZ	IDAMAN PHARMA MANUFACTURING SDN BHD, MALAYSIA
		DIAZEPAM 5MG TABLET MAL19860211AZ	IDAMAN PHARMA MANUFACTURING SDN BHD, MALAYSIA
142.	DICLOFENAC POTASSIUM	CATAFLAM TABLET 50MG MAL19960971ARZ	NOVARTIS SAGLIK, TURKEY
		CATAFLAM 25MG TABLETS MAL19960970A	NOVARTIS FARMA S.P.A., ITALY
		VOLTAREN DOLO 12.5 MG FILM-COATED TABLETS MAL06071043AZ	NOVARTIS FARMACEUTICA S.A., SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

143.	DIDANOSINE	VIDEX TABLET 200MG MAL20020813A	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES
		VIDEX TABLET 100MG MAL19973595A	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES
		VIDEX TABLET 50MG MAL19973594A	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES
		VIDEX TABLET 25MG MAL19973593A	BRISTOL-MYERS SQUIBB U.S. PHARMACEUTICAL GROUP, UNITED STATES
144.	DIENOGEST	VISANNE 2MG TABLET MAL12105068ARZ	BAYER WEIMAR GMBH CO. KG, GERMANY
145.	DIGOXIN *(List 4)*	LANOXIN PG 62.5MCG TABLETS MAL19973575AZ	ASPEN BAD OLDESLOE GMBH, GERMANY GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
		LANOXIN 250 MICROGRAMS TABLET MAL19983999AZ	ASPEN BAD OLDESLOE GMBH, GERMANY GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
146.	DIHYDROCODEINE TARTRATE	DF 118 TABLET MAL19962828ARSZ	GLAXOSMITHKLINE S.A. (PTY) LTD, SOUTH AFRICA
		Product can be obtained from **Hong Kong & Kenya**. *(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2015)* DF 118 Tablet is manufactured by GSK S.A. (pty) Ltd. Epping and distributed by Aspen Pharmacare in **South Africa**. *(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2017)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2019 – 19th November 2019: the following product is being added as additional comparator in Malaysia.	
		SUNCODIN TABLET MAL05090018AZ	SUNWARD PHARMACEUTICAL SDN BHD, MALAYSIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

147.	DISODIUM CLODRONATE TETRAHYDRATE	BONEFOS 800MG TABLETS MAL19988452AZ	BAYER OY, FINLAND
		BONEFOS 400MG TABLETS MAL19988453A	BAYER OY, FINLAND
148.	DIFLUNISAL	DOLOBID TABLET 500MG MAL19890178AR	MERCK SHARP & DOHME INT, UNITED STATES
		DOLOBID TABLET 250MG MAL19861106AR	MERCK SHARP & DOHME INT, UNITED STATES
149.	DIHYDROERGOTAMINE MESYLATE 5MG	SEGLOR CAPSULE 5MG MAL19870274AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
150.	DILTIAZEM HYDROCHLORIDE *(List 5)*	HERBESSER 60 TABLET MAL19890319AZ	PT TANABE INDONESIA, INDONESIA
		HERBESSER TABLET 30MG MAL19861581AZ	PT TANABE INDONESIA, INDONESIA
151.	DIPHENIDOL HYDROCHLORIDE 25MG	CEPHADOL TABLET 25MG MAL19861237AZ	NIPPON SHINYAKU CO LTD, JAPAN
152.	DISOPYRAMIDE PHOSPHATE *(List 4)*	DISORYTHM CAPSULE 100MG MAL19861552A	ROYCE PHARMA MANUFACTURING SDN BHD, MALAYSIA
153.	DOLUTEGAVIR SODIUM (EQ 50MG BASE)	TIVICAY 50MG FILM-COATED TABLETS MAL14055050ACRZ	DELPHARM POZNAN SPOLKA AKCYJNA, POLAND GLAXO OPERATIONS UK LTD, UNITED KINGDOM
154.	DOMPERIDONE	MOTILIUM TABLET 10MG MAL19872254ARZ	JANSSEN CILAG, FRANCE
155.	DONEPEZIL HYDROCHLORIDE	ARICEPT TABLET 10MG MAL05020190ACZ	BORA PHARMACEUTICALS CO., LTD., TAIWAN EISAI TAIWAN INC, TAIWAN
		ARICEPT F.C. 5MG MAL20013565ACZ	BORA PHARMACEUTICALS CO., LTD., TAIWAN EISAI TAIWAN INC, TAIWAN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		These products can be obtained from **Indonesia, Taiwan, Sri Lanka, Hong Kong, Macao, Jordan and Dominican Republic**. *(Source of information: Eisai (M) Sdn Bhd, 2017)*	
156.	DOTHIEPIN HYDROCHLORIDE	PROTHIADEN TABLET 75MG MAL19861460A	THE BOOTS COMPANY PLC, UNITED KINGDOM
		PROTHIADEN CAPSULE 25MG MAL19861459A	THE BOOTS COMPANY PLC, UNITED KINGDOM
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2016 – 13th January 2017: the following product is being added as additional comparator in Malaysia.	
		DOTHEP 75MG TABLET MAL19970063AZ	ALPHAPHARM PTY LTD, AUSTRALIA
157.	DOTINURAD	URECE TABLETS 2MG MAL25096003ARZ	FUJI YAKUHIN CO., LTD. TOYAMA PLANT(JAPAN)
		URECE TABLETS 1MG MAL25096002ARZ	FUJI YAKUHIN CO., LTD. TOYAMA PLANT(JAPAN)
		URECE TABLETS 0.5MG MAL25096001ARZ	FUJI YAKUHIN CO., LTD. TOYAMA PLANT(JAPAN)
158.	DOXAZOSIN	CARDURA TABLET 2MG MAL19990562ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		CARDURA 1MG TABLET MAL19988456A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		CARDURA TABLET 4MG MAL19988455A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		CARDURA TABLET 8MG MAL19900624A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

159.	DOXOFYLLINE 400MG	PUROXAN (DOXOFYLLINE 400MG) TABLET MAL21066005ACZ	ABC FARMACEUTICI SPA, ITALY
160.	DOXYCYCLINE HYCLATE (EQ 100MG BASE) *(List 6)*	VIBRAMYCIN TABLET 100 MG MAL19860578AZ	PFIZER PHARMACEUTICALS LIMITED, CHINA VIATRIS PHARMACEUTICALS (DALIAN) CO., LTD. (CHINA)
		VIBRAMYCIN TABLET 100 MG MAL20000043ASZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
161.	DOXYCYCLINE 100MG	VIBRAMYCIN CAPSULE 100MG MAL19991715A	PFIZER PTY LTD (AUSTRALIA)
162.	DRONEDARONE HYDROCHLORIDE (EQ 400MG BASE)	MULTAQ 400MG FILM-COATED TABLETS MAL20102016AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
163.	DROTAVERINE HYDROCHLORIDE	NO-SPA TABLETS 40MG MAL19900596A	CHINOIN PHARMACEUTICAL & CHEMICAL WORKS PRIVATE CO LTD, HUNGARY
		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 (123 Nguyen khoai, District 4, Ho Chi Minh, Vietnam)** is allowed to be used as a comparator.	
164.	DULOXETINE HYDROCHLORIDE	CYMBALTA CAPSULE 60MG MAL05092474ARZ	LILLY DEL CARIBE INC(PUERTO RICO)
		CYMBALTA CAPSULE 30MG MAL05092473ARZ	LILLY DEL CARIBE INC(PUERTO RICO)
165.	DUTASTERIDE	AVODART SOFT GELATIN CAPSULES 0.5MG MAL20040194ARZ	GLAXOSMITHKLINE PHARMACEUTICALS, POLAND RP SCHERER SA, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

166.	DYDROGESTERONE	DUPHASTON TABLET 10MG MAL19920643AZ	ABBOTT BIOLOGICALS B. V., NETHERLANDS
167.	EBASTINE	KESTINE 20MG FILM-COATED TABLETS MAL19096026AZ	INDUSTRIAS FARMACEUTICAS ALMIRALL, S.A. (IFA), SPAIN
		KESTINE 10MG FILM-COATED TABLETS MAL19096029AZ	INDUSTRIAS FARMACEUTICAS ALMIRALL, S.A. (IFA), SPAIN
168.	EDOXABAN	LIXIANA 15MG FILM COATED TABLETS MAL21026001ARZ	DAIICHI SANKYO EUROPE GMBH (GERMANY)
		LIXIANA 30MG FILM COATED TABLETS MAL21026002ARZ	
		LIXIANA 60MG FILM COATED TABLETS MAL21026003ARZ	
169.	EFAVIRENZ	STOCRIN TABLETS 600MG MAL14035016ACRZ	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD, CHINA
		STOCRIN TABLET 200MG MAL14055020ACRZ	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD, CHINA
		STOCRIN TABLET 50MG MAL14055019ACRZ	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD, CHINA
		STOCRIN TABLETS 600MG MAL20032164A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		STOCRIN TABLET 200MG MAL07050912A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		STOCRIN TABLET 50MG MAL07050913A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		STOCRIN CAPSULE 200MG MAL19992039AR	BRISTOL-MYERS SQUIBB HOLDING PHARMA LTD, UNITED STATES
		STOCRIN CAPSULE 100MG MAL19992038AR	BRISTOL-MYERS SQUIBB HOLDING PHARMA LTD, UNITED STATES
		STOCRIN CAPSULE 50MG MAL19992037AR	BRISTOL-MYERS SQUIBB HOLDING PHARMA LTD, UNITED STATES
		These products can be obtained from **Australia, New Zealand and EU (Germany, France, Spain, Sweden, Denmark, Greece, Croatia, Cyprus, Belgium)** *(Source of information: Merck Sharp & Dohme Sdn Bhd, 2024)*	
170.	ELACESTRANT (AS DIHYDROCHLORIDE)	ORSERDU 86 MG FILM-COATED TABLETS MAL26066001ACRZ	CATALENT GREENVILLE INC. (UNITED STATES)
		ORSERDU 345 MG FILM-COATED TABLETS MAL26066002ACRZ	CATALENT GREENVILLE INC. (UNITED STATES)
171.	ELAFIBRANOR	IQIRVO 80MG FILM-COATED TABLET MAL26036114ACZ	DELPHARM MILANO S.R.L (ITALY)
172.	ELETRIPTAN HYDROBROMIDE	RELPAX 80MG TABLET MAL20021361A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		RELPAX 40MG TABLET MAL20021360A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		RELPAX 20MG TABLET MAL20021359A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
173.	ELOBIXIBAT MONOHYDRATE	GOOFICE 5MG FILM COATED TABLET MAL25046003AZ	EA PHARMA CO., LTD. FUKUSHIMA PLANT(JAPAN)
174.	ELTROMBOPAG OLAMINE	REVOLADE FILM COATED TABLET 50 MG MAL20102011ARZ	SIEGFRIED BARBERA, S.L. SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
175.		REVOLADE FILM COATED TABLET 25MG MAL20102010ARZ	NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
		REVOLADE FILM COATED TABLET 50 MG MAL20102011ACRZ	GLAXO OPERATIONS UK LIMITED, UNITED KINGDOM
		REVOLADE FILM COATED TABLET 25MG MAL20102010ACRZ	GLAXO OPERATIONS UK LIMITED, UNITED KINGDOM
176.	EMPAGLIFLOZIN	JARDIANCE 10MG FILM COATED TABLETS MAL15125055ARZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG (GERMANY) BOEHRINGER INGELHEIM SEIYAKU CO. LTD. (JAPAN)
		JARDIANCE 25MG FILM COATED TABLETS MAL15125056ARZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG (GERMANY) BOEHRINGER INGELHEIM SEIYAKU CO. LTD. (JAPAN) ROTTENDORF PHARMA GMBH (GERMANY)
177.	ENZALUTAMIDE	XTANDI 80 MG FILM-COATED TABLETS MAL25036133ACRZ	PATHEON INC.(CANADA)
		XTANDI 40 MG FILM-COATED TABLETS MAL25036132ACRZ	PATHEON INC.(CANADA)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		XTANDI 40MG SOFT CAPSULES MAL16045039ACRZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
		This product can be obtained from **Taiwan**. (Source of Information Astellas Pharma Malaysia Sdn. Bhd, 2026)	
178.	ENALAPRIL MALEATE *(List 2)*	RENITEC 20MG TABLET MAL19940017ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		RENITEC 10MG TABLET MAL19940016ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		RENITEC 5MG TABLET MAL19940015ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
179.	ENAVOGLIFLOZIN	ENVLO 0.3 MG FILM-COATED TABLETS MAL26076005AZ	DAEWOONG PHARMACEUTICAL CO., LTD. (KOREA, SOUTH)
180.	ENTACAPONE 200MG	COMTAN TABLET 200MG MAL19992996ARZ	ORION CORP, FINLAND
181.	ENTECAVIR	BARACLUDE TABLET 1MG, MAL20061503AR	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		BARACLUDE TABLET 0.5 MG MAL20061502ACRZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
182.	EPERISONE HYDROCHLORIDE 50MG	MYONAL TABLET 50MG MAL19940448ACZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN MISATO PLANT OF EISAI CO, JAPAN
183.	EPLERENONE	INSPRA 50MG FILM-COATED TABLETS MAL20081802ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		INSPRA 25MG FILM-COATED TABLETS MAL20081801ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
184.	ERDOSTEINE	ERDOMED® 300MG HARD CAPSULES MAL20076014ARZ	EDMOND PHARMA S.R.L, ITALY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

185.	ERLOTINIB HYDROCHLORIDE	TARCEVA FILM COATED TABLET 150MG MAL10100028ACRSZ	DELPHARM MILANO S.R.L, ITALY
		TARCEVA FILM COATED TABLET 100 MG MAL10100029ACRSZ	DELPHARM MILANO S.R.L, ITALY
		TARCEVA FILM COATED TABLET 25 MG MAL10100027ACRSZ	DELPHARM MILANO S.R.L, ITALY
		TARCEVA FILM-COATED TABLET 150 MG MAL20071625ARZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		TARCEVA FILM-COATED TABLET 100 MG MAL20071624ARZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		TARCEVA FILM-COATED TABLET 25 MG MAL20071623ARZ	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
186.	ERYTHROMYCIN ETHYLSUCCINATE *(List 8)*	E.E.S. 400 FILMTAB MAL19870265A	ABBOTT LABORATORIES, US
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2013 – 2nd September 2013: the following product is being added as additional comparator in Malaysia.	
		AXCEL ERYTHROMYCIN ES TABLET MAL20020154AZ	KOTRA PHARMA (M) SDN. BHD
187.	ESCITALOPRAM OXALATE *(List 9)*	LEXAPRO 20MG TABLET MAL20041162AZ	H. LUNDBECK A/S, DENMARK
		LEXAPRO 15MG TABLET MAL20041161AZ	H. LUNDBECK A/S, DENMARK
		LEXAPRO 10MG TABLET MAL20041160AZ	H. LUNDBECK A/S, DENMARK
		LEXAPRO 5MG TABLET MAL20041159AZ	H. LUNDBECK A/S, DENMARK

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

188.	ESLICARBAZEPINE	EXCARB TABLETS 200MG MAL25046014AZ	TORRENT PHARMACEUTICALS LTD.(INDIA)
		EXCARB TABLETS 400MG MAL25046015AZ	TORRENT PHARMACEUTICALS LTD.(INDIA)
		EXCARB TABLETS 600MG MAL25046017AZ	TORRENT PHARMACEUTICALS LTD.(INDIA)
		EXCARB TABLETS 800MG MAL25046016AZ	TORRENT PHARMACEUTICALS LTD.(INDIA)
189.	ESTRADIOL VALERATE	PROGYNOVA TABLET 2MG MAL09020972ARZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY DELPHARM LILLE S.A.S., FRANCE
		PROGYNOVA 1MG TABLET MAL09020971ARZ	BAYER WEIMAR GMBH UND CO. KG, GERMANY DELPHARM LILLE S.A.S., FRANCE
190.	ESTRAMUSTINE SODIUM PHOSPHATE	ESTRACYT CAPSULE 140MG MAL19990993A	PFIZER ITALIA S.R.L., ITALY
191.	ETHIONAMIDE	As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2019 – 3rd May 2019: the following product is being added as additional comparator in Malaysia.	
		ETHOMID TABLETS 250MG MAL06091362AZ	MACLEODS PHARMACEUTICALS LTD, INDIA
192.	ETOPOSIDE *(List 7)*	VEPESID CAPSULE 50MG MAL19972952A	R.P SCHERER GMBH & CO. KG, GERMANY
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2012 – 13th September 2012: the following products are being added as additional comparators in Malaysia.	
		LASTET CAPSULE 50 MAL19900067AZ	NIPPON KAYAKU CO. LTD, JAPAN
		LASTET CAPSULE 100 MAL19900068AZ	NIPPON KAYAKU CO. LTD, JAPAN
193.	ETORICOXIB	ARCOXIA 120MG TABLET MAL12065084ACRZ	ROVI PHARMA INDUSTRIAL SERVICES S.A SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			FROSST IBERICA S.A, SPAIN
		ARCOXIA 90MG TABLET MAL12065065ACRZ	ROVI PHARMA INDUSTRIAL SERVICES S.A, SPAIN FROSST IBERICA S.A, SPAIN
		ARCOXIA 60MG TABLET MAL12065082ACRZ	ROVI PHARMA INDUSTRIAL SERVICES S.A, SPAIN FROSST IBERICA S.A, SPAIN
		ARCOXIA 30MG TABLET MAL12065063ACRZ	ROVI PHARMA INDUSTRIAL SERVICES S.A, SPAIN FROSST IBERICA S.A, SPAIN
		ARCOXIA 120MG TABLET MAL20034182AR	MERCK & CO INC, UNITED STATES
		ARCOXIA 90MG TABLET MAL20034179AR	MERCK & CO INC, UNITED STATES
		ARCOXIA 60MG TABLET MAL20034170AR	MERCK & CO INC, UNITED STATES
194.	ETRAVIRINE	INTELENCE 100MG TABLETS MAL20091947AZ	JANSSEN-CILAG S.P.A, ITALY
195.	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

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		CERTICAN 0.5MG TABLETS MAL20071690ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		CERTICAN 0.25MG TABLETS MAL20071689ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
196.	EXEMESTANE	AROMASIN TABLET 25MG MAL08111847AZ	PFIZER ITALIA S.R.L., ITALY
		AROMASIN 25MG TABLETS MAL20013341A	PFIZER ITALIA S.R.L., ITALY
197.	EZETIMIBE	EZETROL 10MG MAL20034627ARZ	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, UNITED STATES SCHERING PLOUGH PRODUCTS, UNITED STATES MSD INTERNATIONAL GMBH (SINGAPORE BRANCH), SINGAPORE
198.	FAMCICLOVIR 250MG	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**. *(Source of information: Novartis Corporation (Malaysia) Sdn Bhd, 2015)*	
199.	FAMOTIDINE	PEPCIDINE 20MG TABLET MAL19900506A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2013– 2rd September 2013: the following products are being added as additional comparator in Malaysia.	
		FAMOPSIN 40 F. C TABLET MAL19920503AZ	REMEDICA LTD, CYPRUS

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		FAMOPSIN 20 F.C TABLET MAL19920504AZ	REMEDICA LTD., CYPRUS
		ULCERAN TABLET 40MG MAL19900021AZ	MEDOCHEMIE LTD., CYPRUS
		ULCERAN TABLET 20MG MAL19900020AZ	MEDOCHEMIE LTD., CYPRUS
200.	FAVIPIRAVIR	AVIGAN FILM COATED TABLETS 200MG MAL20116034	TOYAMA FACTORY, FUJIFILM TOYAMA CHEMICAL CO., LTD, JAPAN
201.	FEBUXOSTAT	FEBURIC 80MG FILM-COATED TABLETS MAL16075031ACRZ	PANTHEON FRANCE, FRANCE
202.	FENOFIBRATE	LIPANTHYL SUPRA 160MG FILM-COATED TABLET MAL20020488AZ	RECIPHARM FONTAINE, FRANCE
		This product can be obtained from **Singapore, Vietnam, Cambodia, Taiwan, Hong Kong and Macau**. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2021)*	
		LIPANTHYL PENTA 145 FILM COATED TABLET MAL10053648AZ	RECIPHARM FONTAINE, FRANCE FOURNIER LABORATORIES IRELAND LIMITED(IRELAND)
		LIPANTHYL MICRO CAPSULE MAL19983968AZ	LABS FOURNIER SA, FRANCE
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2018 – 14 January 2019: LIPANTHYL MICRO CAPSULE from **Rue Des Pres Potets, France** is allowed to be used as a comparator. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2018)* LIPANTHYL MICRO CAPSULE can be obtained from **Indonesia**, **Philippines (under the product name of Fibrafen 200M), Vietnam, Thailand, Singapore and Switzerland.** *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2021)*	
		LIPANTHYL MICRO 267 CAPSULE MAL20014486A	LABS FOURNIER SA, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		This product can be obtained from **Indonesia, Philippines, Singapore, Switzerland, Thailand & Vietnam**. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2013)*	
		LIPANTHYL CAPSULE 300MG MAL19930138A	LABS FOURNIER, FRANCE
		This product can be obtained from **Vietnam, Qatar & Egypt**. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2015)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2014– 18th August 2014: GEN-FENOFIBRATE MICRO 200MG CAPSULE (MAL20040063ACR) is being added as additional comparator in Malaysia.	
		GEN-FENOFIBRATE MICRO 200MG CAPSULE MAL20040063ACRZ	ALPHAPHARM PTY LTD, AUSTRALIA
203.	FEXOFENADINE HYDROCHLORIDE	TELFAST 180MG TABLET MAL20000715AZ	SANOFI-AVENTIS U.S. LLC, UNITED STATES PT AVENTIS PHARMA INDONESIA SANOFI VIETNAM SHAREHOLDING COMPANY(VIETNAM)
		TELFAST 120MG MAL20000714AZ	HOECHST MARION ROUSSEL INC, UNITED STATES PT AVENTIS PHARMA, INDONESIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		TELFAST 60MG TABLET MAL20051395ARZ	SANOFI-AVENTIS U.S. LLC, UNITED STATES AVENTIS PHARMA INC, UNITED STATES
		TELFAST 30MG TABLET MAL20031923AZ	SANOFI-AVENTIS U.S. LLC, UNITED STATES AVENTIS PHARMA INC, UNITED STATES
204.	FEXUPRAZAN HYDROCHLORIDE	FEXUCLUE 40MG FILM-COATED TABLETS MAL26066004AZ	DAEWOONG PHARMACEUTICAL CO., LTD. (KOREA, SOUTH)
205.	FEZOLINETANT	VEOZA 45MG FILM-COATED TABLETS MAL26036003ARZ	ASTELLAS PHARMA INC. YAIZU TECHNOLOGY CENTER (JAPAN)
206.	FIMASARTAN POTASSIUM TRIHYDRATE	KANARB FILM-COATED TABLETS 120MG MAL18026065ARZ	BORYUNG PHARMACEUTICAL CO LTD, SOUTH KOREA
		KANARB FILM-COATED TABLETS 60MG MAL18026063ARZ	BORYUNG PHARMACEUTICAL CO LTD, SOUTH KOREA
207.	FINASTERIDE	PROPECIA TABLET MAL19992040ACRZ	AIAC INTERNATIONAL PHARMA, LLC, UNITED STATES MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, PEURTO RICO
		PROSCAR 5MG TABLET MAL19985910ACRZ	AIAC INTERNATIONAL PHARMA, LLC, UNITED STATES MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, PEURTO RICO
		PROSCAR 5MG TABLET MAL19930510AR	MERCK SHARP & DOHME LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

208.	FINGOLIMOD HYDROCHLORIDE (EQ 0.5MG BASE)	GILENYA 0.5MG HARD CAPSULE MAL12015017ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
209.	FLAVOXATE HYDROCHLORIDE 200MG	URISPAS 200 TABLET MAL20033669AZ	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A., ITALY
210.	FLECAINIDE ACETATE 100MG	TAMBOCOR TABLET 100MG MAL21106012ACZ	3M HEALTHCARE LTD, UNITED KINGDOM UNIQUE PHARMACEUTICAL LABORATORIES (INDIA)
211.	FLUCONAZOLE *(List 7)*	DIFLUCAN CAPSULE 150MG MAL19913230ACZ	FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE
		DIFLUCAN CAPSULE 100MG MAL19920034ACZ	FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE
		DIFLUCAN CAPSULE 50MG MAL19913229ACZ	FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE
		DIFLUCAN CAPSULE 150MG MAL19984003ASZ	PFIZER AUSTRALIA PTY. LTD, AUSTRALIA
		DIFLUCAN CAPSULES 50MG MAL19984004ASZ	PFIZER AUSTRALIA PTY. LTD, AUSTRALIA
212.	FLUDARABINE PHOSPHATE	FLUDARA 10MG FILM COATED TABLETS MAL05051075ACZ	BAYER PHARMA AG, GERMANY
213.	FLUNARIZINE HYDROCHLORIDE (EQ 5MG BASE)	SIBELIUM CAPSULE 5MG MAL19880179ARZ	JANSSEN-CILAG S.P.A., ITALY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

214.		SIBELIUM TABLET 5 MG MAL09100238AZ	JANSSEN-CILAG S.P.A., ITALY
		These products can be obtained from **Turkey, Oman, Taiwan & Korea** *(Source of information: Johnson & Johnson Malaysia, 2014)*	
215.	FLUTAMIDE *(List 7)*	FUGEREL TABLET 250MG MAL19872265A	SCHERING CANADA INC, CANADA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2016 – 16th Jun 2016, FLUTA-cell 250mg Tablet is being added as additional comparator in Malaysia.	
		FLUTA-CELL 250MG TABLETS MAL06021302ACZ	ROTTENDORF PHARMA GMBH, GERMANY
216.	FLUVASTATIN SODIUM	LESCOL CAPSULE 40MG MAL19992683ACRZ	NOVARTIS FARMACEUTICA SA, SPAIN
		LESCOL CAPSULE 20MG MAL19992682ACRZ	NOVARTIS FARMACEUTICA SA, SPAIN
		LESCOL 40MG CAPSULE MAL19962845A	NOVARTIS PHARMA AG, SWITZERLAND
		LESCOL 20MG CAPSULE MAL19962844A	NOVARTIS PHARMA AG, SWITZERLAND
217.	FLUOXYMESTERONE	HALOTESTIN TABLETS 5MG (BELGIUM) MAL19920022A	PHARMACIA & UPJOHN S.A., BELGIUM
218.	FLUOXETINE HYDROCHLORIDE (EQ 20MG BASE) *(List 7)*	PROZAC CAPSULE 20MG MAL07031127ACZ	PATHEON FRANCE S.A, FRANCE
219.	FLUPENTIXOL DIHYDROCHLORIDE	FLUANXOL TABLETS 3MG MAL19890544A	H. LUNDBECK A/S, DENMARK
		FLUANXOL TABLETS 1MG MAL19900451A	H. LUNDBECK A/S, DENMARK
		FLUANXOL TABLET 0.5MG MAL19890543AZ	H. LUNDBECK A/S, DENMARK
		FLUANXOL 0.5MG FILM-COATED TABLETS MAL18086153AZ	H. LUNDBECK A/S, DENMARK

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

220.	FLURAZEPAM MONOHYDROCHLORIDE 15MG	DALMADORM 15MG CAPSULES MAL07050892AC	LABIANA PHARMACEUTICALS SLU, SPAIN
221.	FLURBIPROFEN	FROBEN TABLET 50MG MAL19861117A	THE BOOTS COMPANY PLC, UNITED KINGDOM
222.	FLUVOXAMINE MALEATE *(List 7)*	LUVOX 100MG FILM COATED TABLET MAL20021413ACZ	MYLAN LABORATORIES SAS, FRANCE SOLVAY PHARMACEUTICALS SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
		LUVOX 50MG FILM COATED TABLET MAL20021412ACZ	MYLAN LABORATORIES SAS, FRANCE SOLVAY PHARMACEUTICALS SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
223.	FOSINOPRIL SODIUM	MONOPRIL TABLET 10MG MAL19992695AS	PT BRISTOL-MYERS SQUIBB INDONESIA TBK, INDONESIA
		MONOPRIL TABLET 20MG MAL19950243A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		MONOPRIL TABLET 10MG MAL19950242A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
224.	FRUSEMIDE *(List 4)*	LASIX TABLET 40MG MAL19870226AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
225.	GABAPENTIN	NEURONTIN 400MG CAPSULE MAL19984785AZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		NEURONTIN 300MG CAPSULE MAL19984786ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		NEURONTIN 100MG CAPSULE MAL06071076ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY VIATRIS PHARMACEUTICALS LLC (UNITED STATES)
		NEURONTIN TABLET 800MG MAL20031748A	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		NEURONTIN TABLET 600MG MAL20031747ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		NEURONTIN 400MG CAPSULE MAL19962170A	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		NEURONTIN 300MG CAPSULE MAL19962169A	PFIZER PHARMACEUTICALS LLC, UNITED STATES
226.	GALANTAMINE HYDROBROMIDE	REMINYL TABLET 12MG MAL20020125A	JANSSEN CILAG SPA, ITALY
		REMINYL TABLET 8MG MAL20020124A	JANSSEN CILAG SPA, ITALY
		REMINYL TABLET 4MG MAL20020123A	JANSSEN CILAG SPA, ITALY
227.	GANCICLOVIR	CYMEVENE CAPSULE 250MG MAL19993019AR	ROCHE PRODUCTS LTD, UNITED KINGDOM
		CYMEVENE HARD-GELATIN CAPSULE 250MG MAL19970079A	SYNTEX PUERTO RICO INC, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

228.	GEFITINIB	IRESSA 250MG FILM-COATED TABLET MAL19086008ACRZ	KAGAMIISHI PLANT, NIPRO PHARMA CORPORATION, JAPAN
		IRESSA 250MG MAL20033931ARZ	ASTRAZENECA UK LIMITED, UNITED KINGDOM
229.	GEMFIBROZIL	LOPID 600MG TABLET MAL19984784AS	PARKE DAVIS PTY LTD, AUSTRALIA
		LOPID CAPSULE 300MG MAL19990998A	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 – 14th January 2019: LOPID CAPSULE 300MG and LOPID 600MG TABLET from **Pfizer Manufacturing Deutschland, GmbH, Freiburg, Germany** are allowed to be used as comparator. They 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, Taiwan, Trinidad and Tobago, Turkey, United Arab Emirates, Venezuela, Vietnam, United States, Thailand**. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2018)*	
		LOPID 450MG TABLET MAL19921617ARS	GOEDECKE A.G, WEST GERMANY
		This product can be obtained from **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 – 23rd April 2014: the following product is being added as additional comparator in Malaysia:	
		PHARMANIAGA GEMFIBROZIL CAPSULE 300MG MAL19972153AZ	PHARMANIAGA MANUFACTURING BERHAD MALAYSIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2018 – 14th 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	
230.	GEMIGLIPTIN TARTRATE SESQUIHYDRATE	ZEMIGLO 50MG FILM-COATED TABLET MAL25106001AZ	LG CHEM, LTD.(KOREA,SOUTH)
231.	GESTRINONE	DIMETRIOSE CAPSULE MAL19940494A	ROUSSEL LABS LTD, UNITED KINGDOM
232.	GLIBENCLAMIDE *(List 5)*	DAONIL TABLET 5 MG MAL19870392AZ	PT. AVENTIS PHARMA, INDONESIA
233.	GLICLAZIDE *(List 6)*	DIAMICRON TABLET 0.08G MAL19870422AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2009 – 19 Ogos 2009 : i) Gliclazide remain in BE list requirement. ii) For Generic immediate release, oral solid dosage form product which follows BP specification and bioequivalence study is not conducted, the label need to state **'The dose may need to be titrated if patient has been switched from a different brand of product containing Gliclazide'.** iii) For Generic immediate release, oral solid dosage form product which does not follow BP specification and bioequivalence study is also not conducted , the label need to include statement no. (ii). For Generic immediate release, oral solid dosage form product which performed BE study and found bioequivalent with Innovator product (Diamicron), there is no requirement to include the statement no. (ii).	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

234.	GLIMEPIRIDE *(List 6)*	AMARYL 6.0 MAL19990965A	SANOFI SPA, ITALY AVENTIS PHARMA S.P.A., ITALY
		AMARYL 4.0 MAL19990964A	SANOFI SPA, ITALY AVENTIS PHARMA S.P.A., ITALY
		AMARYL 3.0 MAL19990963AZ	SANOFI S.P.A., ITALY SANOFI-AVENTIS S.P.A., ITALY
		AMARYL 2.0 MAL19990962AZ	SANOFI S.P.A., ITALY SANOFI-AVENTIS S.P.A., ITALY
		AMARYL 1.0 MAL19990961A	SANOFI SPA, ITALY AVENTIS PHARMA S.P.A., ITALY
235.	GLIPIZIDE	MINIDIAB 5MG TABLET MAL19913361AZ	PFIZER ITALIA S.R.L., ITALY
236.	GRANISETRON HYDROCHLORIDE (EQ 1MG BASE)	KYTRIL TABLET 1MG MAL19940574ACRZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
237.	GRISEOFULVIN *(List 8)*	MEDOFULVIN 500 TABLET MAL19860848AZ	MEDOCHEMIE LTD, CYPRUS
		MEDOFULVIN TABLET 125MG MAL19860841AZ	MEDOCHEMIE LTD, CYPRUS
238.	HALOPERIDOL *(List 9)*	SERENACE TABLET 5MG PBKD861368A	SEARLE LABS, AUSTRALIA
		SERENACE TABLET 1.5MG PBKD861365A	SEARLE LABS, AUSTRALIA
		SERENACE TABLET 0.5MG PBKD861361A	SEARLE LABS, AUSTRALIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		These products can be obtained from **Aruba, Bahrain, Iran, Kuwait, Macau, Oman, Philippines, Qatar, South Africa, UAE**. *(Source of information: Pfizer (M) Sdn Bhd, 2011)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2014 – 18th August 2014: Serenace Tablet from **Piramal Healthcare UK Limited & Sigma Australia** are allowed to be used as a comparator.	
239.	HYDROXYCHLOROQUINE SULPHATE 200MG	PLAQUENIL TABLETS MAL04103442AZ	SANOFI-AVENTIS S.A., SPAIN
		PLAQUENIL TABLET MAL19991702AZ	SANOFI-SYNTHELABO LTD, UNITED KINGDOM
240.	HYOSCINE BUTYLBROMIDE 10MG	BUSCOPAN TABLET 10MG MAL09051577ACZ	DELPHARM REIMS, FRANCE
241.	HYDROXYUREA/ HYDROXYCARBAMIDE	HYDREA CAPSULE 500MG MAL19993027A	BRISTOL MYERS SQUIBB S.R.L, ITALY
		HYDREA CAPSULE 500MG MAL19962497A	BRISTOL MYERS SQUIBB US PHARMACEUTICAL GROUP, UNITED STATES
		These products can be obtained from **Australia, United Kingdom, United States**, **Ireland** and **France**. *(Source of information: Bristol Myers Asia Pacific, 2013)* As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2015 – 21st April 2015: Hyrea Capsule (MAL19993027A) from **Coden Pharma Latina Italy** is allowed to be used as a comparator.	
242.	HYDROCHLOROTHIAZIDE	DICHLOTRIDE 50MG TABLET MAL19940019AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		DICHLOTRIDE 25MG TABLET MAL19940018AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		DICHLOTRIDE TABLET 50MG MAL19870201AR	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		DICHLOTRIDE TABLET 25MG MAL19870271AR	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2013 – 2rd September 2013: the following products are being added as additional comparator in Malaysia.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		APO-HYDRO 50MG TABLET MAL19984688ARZ	APOTEX INC, CANADA
		APO-HYDRO 25MG TABLET MAL19984694ARZ	APOTEX INC, CANADA
243.	HYDROCORTISONE	CORTEF TABLET 10MG	CATALENT PHILADELPHIA
		Product can be obtained from **Bosnia, Canada, Georgia, Croatia, Hungary, Poland, Russia, Saudi Arabia, Thailand, Tunisia and United States**. *(Source of information: Pfizer (Malaysia) Sdn Bhd, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 2/2015 – 7th September 2015: the following product is being added to the existing list of comparator:-	
		HYDROCORTISON ORION 10MG TABLET MAL15085015AZ	ORION CORPORATION ORION PHARMA, FINLAND MERCK KGAA & CO, AUSTRIA
244.	HYDROXYZINE *(List 6)*	ATARAX FILM-COATED TABLET 25MG MAL19861219ARZ	UCB S.A. SECTOR PHARMA, BELGIUM
		ATARAX FILM-COATED TABLET 10MG MAL19861218A	UCB S.A. SECTOR PHARMA, BELGIUM
		Product can be obtained from Spain.	
245.	IBANDRONIC ACID	BONVIVA FILM-COATED TABLETS 150MG MAL21036035ACRZ	PENN PHARMACEUTICAL SERVICES LIMITED, UNITED KINGDOM
		BONVIVA FILM-COATED TABLETS 150 MG MAL20071629AZ	F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
		BONDRONAT FILM-COATED TABLET 50 MG MAL20071698ARZ	F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
246.	IBRUTINIB	IMBRUVICA 140MG CAPSULES MAL16025029ACRZ	CATALENT CTS, LLC., UNITED STATES
		IMBRUVICA 140MG CAPSULES MAL19056121ASZ	CILAG AG, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		IMBRUVICA 280 MG FILM-COATED TABLETS MAL22106002ARZ	CILAG AG, SWITZERLAND
		IMBRUVICA 420 MG FILM-COATED TABLETS MAL22106003ARZ	CILAG AG, SWITZERLAND
247.	IBUPROFEN *(List 6)*	NUROFEN 400 CAPLET MAL19993016AZ	RECKITT BENCKISER HEATHCARE MANUFACTURING (THAILAND) LIMITED, THAILAND
		NUROFEN CAPLET 200MG MAL19993015AZ	RECKITT BENCKISER HEATHCARE MANUFACTURING (THAILAND) LIMITED, THAILAND
		BRUFEN TABLET 600MG MAL08031341AZ	ABBOTS LAB, PAKISTAN
		BRUFEN TABLET 400MG MAL19861011A	THE BOOTS COMPANY LTD, UNITED KINGDOM
		BRUFEN TABLET 200MG MAL19860992A	THE BOOTS COMPANY LTD, UNITED KINGDOM
		Brufen Tablet manufactured by Famar SA, Greece is allowed to be used as comparator. (Source of information: Abbott Laboratories (M) Sdn Bhd, 2025)	
		NUROFEN EXPRESS 400MG LIQUID CAPSULES MAL18016016ACRZ	PATHEON SOFTGELS B.V., NETHERLANDS
		NUROFEN EXPRESS 200MG LIQUID CAPSULES MAL18016015ACRZ	PATHEON SOFTGELS B.V., NETHERLANDS
		Nurofen Express can be obtained from **Australia, Austria, Croatia, Cyprus, France, Germany, Hungary, Ireland, Malta, Maldova, Mongolia, Netherlands, Poland, Romania, Russia, Serbia, Singapore, Slovakia, Switzerland & Thailand** *(Source of information: RB (HEALTH) Malaysia Sdn Bhd, 2025)*	
		IBUSPAN 400MG TABLET MAL20020268AZ	SM PHARMACEUTICALS SDN. BHD.
		IBUSPAN TABLET 200MG MAL19991893AZ	SM PHARMACEUTICALS SDN. BHD.

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 01/2015- 23 Dec 2025: Ibuspan Tablets are being added as additional comparator in Malaysia.	
248.	IBUPROFEN LYSINE	NUROFEN EXPRESS 684MG CAPLET MAL13085061AZ	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM
		NUROFEN EXPRESS 342MG CAPLET MAL13085058AZ	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM
249.	IMATINIB MESYLATE	GLIVEC TABLET 400MG MAL06011681ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND NOVARTIS PHARMA PRODUKTIONS GMBH (GERMANY)
		GLIVEC TABLET 100MG MAL06011679ARZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GLIVEC 100MG CAPSULES MAL20020356A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		GLIVEC 50MG CAPSULES MAL20020355A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
250.	IMIDAPRIL HYDROCHLORIDE	TANATRIL 10MG TABLET MAL20034618AZ	PT MITSUBISHI TANABE PHARMA INDONESIA, INDONESIA PT TANABE INDONESIA, INDONESIA
		TANATRIL 5MG TABLET MAL20034617AZ	PT MITSUBISHI TANABE PHARMA INDONESIA, INDONESIA PT TANABE INDONESIA, INDONESIA
		TANATRIL 2.5MG TABLET MAL20034616A	PT TANABE INDONESIA, INDONESIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

251.	INAVOLISIB	ITOVEBI 3MG FILM-COATED TABLETS	F. HOFFMANN-LA ROCHE LTD (SWITZERLAND)
		ITOVEBI 9MG FILM-COATED TABLETS	F. HOFFMANN-LA ROCHE LTD (SWITZERLAND)
252.	INDAPAMIDE	NATRILIX TABLET 0.0025G MAL19870270ARZ	LES LABS SERVIER INDUSTRIE, FRANCE
		NATRILIX TABLET MAL19972491AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		This product can be obtained from **Australia, Bangladesh, China, India, Pakistan, France and United Kingdom**. *(Source of information: Servier (M) Sdn. Bhd, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 2/2015 – 7th September 2015: the following product is being added as additional comparator in Malaysia.	
		APO INDAPAMIDE 2.5MG TABLET MAL19986967AZ	APOTEX INC, CANADA
253.	INDINAVIR 400MG	CRIXIVAN CAPSULE 400MG MAL19970276AR	MERCK SHARP & DOHME CORP. (ELKTON), UNITED STATES MERCK & CO INC, UNITED STATES
254.	INDOMETHACIN	INDOCID CAPSULE 25MG MAL19930412AS	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
		INDOCID CAPSULE 25MG MAL19861080A	MERCK SHARP & DOHME INT, UNITED STATES
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2013 – 13th March 2013: the above products can be obtained from Australia and are manufactured by Aspen Pharmacare South Africa.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

255.	IPTACOPAN HYDROCHLORIDE MONOHYDRATE	FABHALTA 200MG HARD CAPSULES MAL25036129ARZ	NOVARTIS PHARMA PRODUKTIONS GMBH(GERMANY)
256.	IRBESARTAN *(List 7)*	APROVEL 300MG FILM-COATED TABLET MAL19990972AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		APROVEL 150MG FILM-COATED TABLETS MAL19990971AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		APROVEL TABLET 75MG MAL19990970AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
257.	ISONIAZID *(List 7)*	As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2009 – 19th Ogos 2009: the following products are being added as additional comparator in Malaysia.	
		PHARMANIAGA ISONIAZID TABLETS 400MG MAL19961322AZ	DUOPHARMA (M) SDN BHD., MALAYSIA PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
		PHARMANIAGA ISONIAZID TABLETS 100MG MAL19961323AZ	DUOPHARMA (M) SDN BHD., MALAYSIA PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
258.	ISOSORBIDE DINITRATE	ISORDIL ORAL TABLET 10MG MAL19871489A	WYETH CANADA
		As agreed upon *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2016 – 16th Jun 2016: Isordil Oral Tablet manufactured by **Interphil, Philippines** is allowed to be used as a comparator.	
259.	ISOSORBIDE-5-MONONITRATE	ELANTAN 40 TABLETS MAL19900070AZ	SCHWARZ GMBH MITTELSTRASSE 11-13 D-4019 MONHEIM, GERMANY
		ELANTAN 20 TABLETS MAL19900069AZ	SCHWARZ GMBH

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			MITTELSTRASSE 11-13 D-4019 MONHEIM, GERMANY
		IMDUR 30MG TABLET MAL19940091ACZ	LABORATORIOS ALCALA PHARMA, S.L., SPAIN
		IMDUR 60MG TABLET MAL19940090ACZ	LABORATORIOS ALCALA PHARMA, S.L., SPAIN
260.	ISOTRETINOIN	ROACCUTANE CAPSULE 20MG MAL19991721ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY R. P. SCHERER GMBH, GERMANY
		ROACCUTANE CAPSULE 10MG MAL19991720ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY R. P. SCHERER GMBH, GERMANY
		ROACCUTANE ROCHE CAPSULE 20MG PBKD861795A	F. HOFFMAN-LA ROCHE, SWITZERLAND
		ROACCUTANE ROCHE CAPSULE 10MG PBKD861794A	F. HOFFMAN-LA ROCHE, SWITZERLAND
261.	ITOPRIDE HYDROCHLORIDE 50MG	GANATON TABLET 50MG MAL20051433ACZ	KATSUYAMA PHARMACEUTICALS K.K., JAPAN
262.	ITRACONAZOLE 100MG *(List 6)*	SPORANOX CAPSULE 100MG MAL05072016AZ	JANSSEN CILAG SPA, ITALY
263.	IVABRADINE HYDROCHLORIDE	CORALAN 7.5MG FILM-COATED TABLETS MAL20081756AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		CORALAN 5MG FILM-COATED TABLETS MAL20081755AZ	LES LABS SERVIER INDUSTRIE, FRANCE
264.	IXAZOMIB	NINLARO HARD CAPSULE 2.3MG MAL19126003ACRZ	HAUPT PHARMA AMAREG GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		NINLARO HARD CAPSULE 3MG MAL19126004ACRZ	HAUPT PHARMA AMAREG GMBH, GERMANY
		NINLARO HARD CAPSULE 4MG MAL19126005ACRZ	HAUPT PHARMA AMAREG GMBH, GERMANY
265.	KETOCONAZOLE 200MG *(List 6)*	NIZORAL TABLET 200 MG MAL20002457AR	JANSSEN CILAG SPA, ITALY
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2017– 24th May 2017: the following products are being added as additional comparator in Malaysia.	
		KETOZOTAN TABLET 200MG MAL19987372AZ	DUOPHARMA (M) SDN. BHD., MALAYSIA
		YUCOMY TABLET 200MG MAL19986498AZ	Y.S.P. INDUSTRIES (M) SDN. BHD., MALAYSIA
266.	KETOROLAC TROMETHAMINE	TORADOL 10 MG FILM-COATED TABLET MAL19973601A	ROCHE FARMA S.A, SPAIN
		This product can be obtained from **Australia, Indonesia, Georgia, Canada, Italy, and Portugal**. *(Source of information: Roche (M) Sdn Bhd, 2015)*	
267.	KETOTIFEN HYDROGEN FUMARATE (EQ 1MG BASE)	ZADITEN 1MG TABLET MAL20000272ARZ	NOVARTIS PHARM UK LTD, UNITED KINGDOM
268.	LABETALOL HYDROCHLORIDE	TRANDATE TABLETS 200MG MAL06011678AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		TRANDATE TABLETS 100MG MAL06011677AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		TRANDATE TABLET 200MG MAL19870060A	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
		TRANDATE TABLET 100MG MAL19870059A	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
269.	LACIDIPINE	LACIPIL TABLET 4MG MAL19950006ARZ	GLAXO WELLCOME S.A., SPAIN
		LACIPIL TABLET 2MG MAL19950005A	GLAXO WELLCOME S.A., SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

270.	LACOSAMIDE	VIMPAT 200MG FILM-COATED TABLETS MAL12055010AZ	AESICA PHARMACEUTICALS GMBH, GERMANY
		VIMPAT 150MG FILM-COATED TABLETS MAL12055009AZ	AESICA PHARMACEUTICALS GMBH, GERMANY
		VIMPAT 100MG FILM-COATED TABLETS MAL12055008AZ	AESICA PHARMACEUTICALS GMBH, GERMANY
		VIMPAT 50MG FILM-COATED TABLETS MAL12055002AZ	AESICA PHARMACEUTICALS GMBH, GERMANY
		As agreed upon *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2021 – 26 October 2021: Vimpat Tablets manufactured by **Aesica Pharmaceuticals GmbH**, Alfred-Nobel Strasse 10, D-40789 Monheim am Rhein, Germany and **UCB Pharma S.A.**, Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium are allowed to be used as the comparator.	
271.	LAMOTRIGINE *(LIST 6)*	LAMICTAL TABLET 100MG MAL19930435ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND
		LAMICTAL TABLET 50MG MAL19930433ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND
272.	LAMIVUDINE	3TC TABLETS 150MG MAL19963153ARZ	GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		ZEFFIX TABLET 100MG MAL19992323ARZ	GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

273.	LANSOPRAZOLE 30MG	PREVACID 30MG CAPSULE MAL19961284AR	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		This product can be obtained from **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, 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**. *(Source of information: Invida, 2013)*	
274.	LAPATINIB DITOSYLATE	TYKERB FILM-COATED TABLETS 250MG MAL20071677ARZ	S.C. SANDOZ S.R.L., ROMANIA GLAXO OPERATIONS UK LTD, UNITED KINGDOM
275.	LAZERTINIB MESYLATE MONOHYDRATE	LAZCLUZE 80MG FILM-COATED TABLETS MAL26026005ARZ	JANSSEN CILAG SPA (ITALY)
		LAZCLUZE 240MG FILM-COATED TABLETS MAL26026004ARZ	JANSSEN CILAG SPA (ITALY)
276.	LEFLUNOMIDE	ARAVA TABLET 100MG MAL20001529AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		ARAVA 20MG TABLET MAL20001527AZ	SANOFI WINTHROP INDUSTRIE, FRANCE OPELLA HEALTHCARE INTERNATIONAL SAS (FRANCE)
		ARAVA 10MG TABLET MAL20001528ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			OPELLA HEALTHCARE INTERNATIONAL SAS (FRANCE)
277.	LENALIDOMIDE	REVLIMID (LENALIDOMIDE) CAPSULES 25MG MAL12040007ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		REVLIMID (LENALIDOMIDE) CAPSULES 15MG MAL12040004ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		REVLIMID (LENALIDOMIDE) CAPSULES 10MG MAL12040006ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		REVLIMID (LENALIDOMIDE) CAPSULES 5MG MAL12040005ARSZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		REVLIMID (LENALIDOMIDE) CAPSULE 25MG MAL20091854ACRZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM
		REVLIMID (LENALIDOMIDE) CAPSULE 15MG MAL20091853ACRZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM
		REVLIMID (LENALIDOMIDE) CAPSULE 10MG MAL20091852ACRZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM
		REVLIMID (LENALIDOMIDE) CAPSULES 5MG MAL20091851ACRZ	PENN PHARMACEUTICAL SERVICES, UNITED KINGDOM
278.	LENVATINIB MESILATE	LENVIMA 10MG HARD CAPSULES MAL16115029AZ	EISAI CO., LTD., JAPAN
		LENVIMA 4 MG HARD CAPSULES MAL16115028AZ	EISAI CO., LTD., JAPAN
279.	LERCANIDIPINE HYDROCHLORIDE	ZANIDIP 20MG, FILM-COATED TABLET MAL07050024AZ	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A., ITALY
		ZANIDIP 10MG FILM COATED TABLETS	RECORDATI CHIMICA E FARMACEUTICA S.P.A., ITALY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAL20041041AZ	
280.	LETROZOLE 2.5MG *(List 9)*	FEMARA 2.5MG FILM-COATED TABLET MAL19973303ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
281.	LEVAMISOLE HYDROCHLORIDE	ERGAMISOL TABLET 50MG MAL19990537A	JANSSEN PHARMACEUTICA N.V., BELGIUM
282.	LEVETIRACETAM	KEPPRA 1000MG FILM COATED TABLET MAL20031727ARZ	UCB PHARMA S.A., BELGIUM
		KEPPRA 500MG FILM COATED TABLET MAL20031726ARZ	UCB PHARMA S.A., BELGIUM
		KEPPRA 250MG FILM COATED TABLET MAL20031725ARZ	UCB PHARMA S.A., BELGIUM
283.	LEVOCETIRIZINE DIHYDROCHLORIDE 5MG	XYZAL 5MG FILM COATED TABLET MAL20051323ACRZ	UCB FARCHIM S.A., SWITZERLAND
284.	LEVOFLOXACIN *(List 8)*	CRAVIT 500MG MAL20041052AZ	PT KALBE FARMA TBK, INDONESIA
		CRAVIT 250MG MAL20041051AZ	PT KALBE FARMA TBK, INDONESIA
		CRAVIT TABLET 100MG MAL19985877A	DAIICHI SANKYO PROPHARMA CO., LTD., SHIZUOKA PLANT, JAPAN
285.	LEVONORGESTREL	POSTINOR-2 TABLET 0.75MG MAL19872263ARZ	GEDEON RICHTER PLC, HUNGARY
		ESCAPELLE TABLET 1.5MG MAL06030792AZ	GEDEON RICHTER PLC, HUNGARY
286.	LEVOTHYROXINE SODIUM / THYROXINE SODIUM	OROXINE 100MCG TABLET MAL06071058AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		OROXINE 50MCG TABLET MAL06030792AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		EUTHYROX 100MCG TABLET MAL19985514AZ	MERCK HEALTHCARE KGaA (GERMANY)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		EUTHYROX 50MCG TABLET MAL20032260AZ	MERCK HEALTHCARE KGaA (GERMANY)
		EUTHYROX 25MCG TABLET MAL20032259AZ	MERCK HEALTHCARE KGaA (GERMANY)
287.	LINAGLIPTIN 5MG	TRAJENTA 5MG FILM-COATED TABLETS MAL12045094ACZ	WEST-WARD COLUMBUS INC., UNITED STATES BOEHRINGER INGELHEIM ROXANE, INC, UNITED STATES BOEHRINGER INGELHEIM SEIYAKU CO. LTD. (JAPAN)
288.	LINEZOLID	ZYVOX 600MG TABLETS MAL20020874AZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES
		ZYVOX 400MG TABLETS MAL20020873AR	PFIZER PHARMACEUTICALS LLC, PUERTO RICO
289.	LISINOPRIL DUHYDRATE *(List 2)*	ZESTRIL 20MG TABLET MAL19890681AZ	ASTRAZENECA PHARMACEUTICAL CO., LTD., CHINA ASTRAZENECA UK LTD, UNITED KINGDOM
		ZESTRIL 10MG TABLET MAL19890680AZ	ASTRAZENECA PHARMACEUTICAL CO., LTD., CHINA ASTRAZENECA UK LTD, UNITED KINGDOM
		ZESTRIL 5MG TABLET MAL19890679AZ	ASTRAZENECA PHARMACEUTICAL CO., LTD., CHINA ASTRAZENECA UK LTD, UNITED KINGDOM
290.	LOMEFLOXACIN HYDROCHLORIDE	MAXAQUIN 400MG TABLET MAL19940539A	SEARLE DE MEXICO, MEXICO

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAXAQUIN 400MG TABLET MAL19940540AS	MONSANTO FRANCE SA, FRANCE
291.	LOMUSTINE	CEENU CAPSULE 40MG MAL19991719A	BRISTOL-MYERS SQUIBB S.R.L., ITALY
292.	LOPERAMIDE HYDROCHLORIDE	IMODIUM CAPSULE 2MG MAL19871473ARZ	JANSSEN CILAG, FRANCE
293.	LORATADINE *(List 6)*	CLARITYNE TABLET 10MG MAL19890576ACZ	SCHERING-PL LABO N.V., BELGIUM
		CLARITYNE TABLET 10MG MAL10070583ASZ	PT. BAYER INDONESIA, INDONESIA PT. MERCK SHARP DOHME PHARMA TBK, INDONESIA P.T SCHERING-PLOUGH INDONESIA TBK, INDONESIA
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 2/2008 – 04th December 2008 : Both parent drug and active metabolite (desloratadine) need to be analysed in BE study. However, should the BE study conducted prior to 1 January 2009 and the analysis was only done on parent drug, the BE report can still be considered for evaluation.	
294.	LORAZEPAM *(List 9)*	ATIVAN 1MG TABLET MAL19991389A	WYETH MEDICA IRELAND, IRELAND
		ATIVAN 0.5MG TABLET MAL19991388A	WYETH MEDICA IRELAND, IRELAND
		ATIVAN TABLET 0.5MG MAL19871462A	WYETH PHARMA GMBH, GERMANY
		These products can be obtained from **Europe**. *(Source of information: Pfizer (Malaysia) Sdn Bhd, 2011)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 3/2013– 2nd December 2013: the following product is being added as additional comparator in Malaysia.	

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295.		APO-LORAZEPAM TABLET 1MG MAL19984741ARZ	APOTEX INC, CANADA
296.	LOVASTATIN *(List 6)*	MEDOSTATIN 40MG TABLET MAL20021411AZ	MEDOCHEMIE LTD, CYPRUS
		MEDOSTATIN TABLET 20MG MAL19973311AZ	MEDOCHEMIE LTD, CYPRUS
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2010 – 8th Disember 2010 : Both parent drug and active metabolite (beta-hydroxyacid lovastatin) need to be analysed in BE study However, BE study conducted prior to 8 December 2010 and analysis was only done on parent drug, the BE report can still be considered for evaluation.	
297.	LOSARTAN POTASSIUM *(List 6)*	COZAAR 100MG TABLET MAL20021160ARZ	MERCK SHARP & DOHME LTD., UNITED KINGDOM ORGANON PHARMA LIMITED, UNITED KINGDOM
		COZAAR 50MG TABLET MAL19963142ARZ	MERCK SHARP & DOHME LTD., UNITED KINGDOM ORGANON PHARMA LIMITED, UNITED KINGDOM
298.	LURASIDONE 20MG	LATUDA 20MG FILM COATED TABLET MAL22126001ACRZ	BUSHU PHARMACEUTICALS LTD (JAPAN)
299.	LURASIDONE 40MG	LATUDA 40MG FILM COATED TABLET MAL22126002ACRZ	BUSHU PHARMACEUTICALS LTD (JAPAN)
300.	LURASIDONE 80MG	LATUDA 80MG FILM COATED TABLET MAL22126003ACRZ	BUSHU PHARMACEUTICALS LTD (JAPAN)29/4
301.	MACITENTAN 10 MG	OPSUMIT ® 10MG FILM-COATED TABLETS MAL20016146ACRZ	EXCELLA GMBH & CO.KG (GERMANY)
302.	MAPROTILINE HYDROCHLORIDE	LUDIOMIL TABLET50MG MAL19861465A	NOVARTIS FARMACEUTICA S.A., SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

	(List 9)	LUDIOMIL 25MG TABLETS MAL20001251A	NOVARTIS URUNLERI, TURKEY
303.	MARAVIROC	CELSENTRI FILM-COATED TABLETS 300MG MAL20081834AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY GODECKE GMBH, GERMANY
		CELSENTRI FILM-COATED TABLETS 150MG MAL20081833AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY GODECKE GMBH, GERMANY
304.	MARIBAVIR	LIVTENCITY FILM-COATED TABLET 200MG MAL26026003ACZ	CATALENT CTS, LLC. (UNITED STATES)
305.	MEBEVERINE	DUSPATALIN TABLET 135MG MAL19940428ACZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
		DUSPATALIN TABLET 100MG MAL19920644A	ABBOTT BIOLOGICALS B.V., NETHERLAND
306.	MEDROXYPROGESTERONE ACETATE	FARLUTAL TABLET 500MG MAL19991380A	PFIZER ITALIA S.R.L., ITALY
		FARLUTAL TABLET 100MG MAL19991379A	PFIZER ITALIA S.R.L., ITALY
		PROVERA TABLET 5MG MAL19872113A	PHARMACIA & UPJOHN CO, UNITED STATES
		PROVERA 10MG TABLET MAL20000997AZ	PFIZER ITALIA S.R.L., ITALY PFIZER PHARMACEUTICAL LLC, PUERTO RICO
		PROVERA 5MG TABLETS MAL06051306AZ	PFIZER ITALIA S.R.L., ITALY PFIZER PHARMACEUTICAL LLC, PUERTO RICO

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

307.	MEFLOQUINE HYDROCHLORIDE (EQ 250MG BASE)	LARIAM TABLET 250MG MAL19921123ARZ	F. HOFFMAN-LA ROCHE, SWITZERLAND
308.	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 –14th January 2019: the following product is being added as additional comparator in Malaysia.	
		APO-MEGESTROL 160MG MAL19988445AZ	APOTEX INC, CANADA
309.	MELOXICAM *(List 6)*	MOBIC CAPSULE 15 MG MAL19971272A	BOEHRINGER INGELHEIM PHARMA KG, GERMANY
		MOBIC CAPSULE 7.5 MG MAL11060027ACZ	BOEHRINGER INGELHEIM PHARMA KG, GERMANY
		MOBIC TABLET 15 MG MAL20000031A	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, GERMANY
		MOBIC TABLET 7.5 MG MAL19992696AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, GERMANY
		MOBIC TABLET 7.5 MG MAL11060027ASZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE
310.	MELPHALAN 2MG	ALKERAN TABLETS 2MG MAL07101257ACZ	EXCELLA GMBH & CO. KG, GERMANY
311.	MEMANTINE HYDROCHLORIDE	EBIXA FILM-COATED TABLET 20 MG MAL10120014ACRZ	ROTTENDORF PHARMA GMBH, GERMANY
		EBIXA FILM-COATED TABLET 10MG MAL20061488ACRZ	ROTTENDORF PHARMA GMBH, GERMANY
312.	MEQUITAZINE	PRIMALAN TABLET 5MG MAL19871736A	MAY & BAKER LTD, UNITED KINGDOM
313.	MERCAPTOPURINE	PURI-NETHOL TABLET 50MG MAL19861668A	THE WELLCOME FOUNDATION LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2015 – 9 September 2015: products manufactured by **Excella GmbH, Germany** and **DSM Pharmaceuticals, Inc, United State** are allowed to be used as a 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**. *(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2014)*	
314.	MESNA	UROMITEXAN TABLET 600MG MAL20014209AZ	TEMMLER PHARMA GMBH & CO KG, GERMANY
		UROMITEXAN TABLET 400MG MAL20014208AZ	TEMMLER PHARMA GMBH & CO KG, GERMANY
315.	MESTEROLONE	PROVIRONUM TABLET 25MG MAL09122025ACZ	SCHERING DO BRASIL QUIMICA E FARMACEUTICA LTDA., BRAZIL
316.	METFORMIN HYDROCHLORIDE *(List 5)*	GLUCOPHAGE 1000 MG TABLET MAL06021194AZ	MERCK SANTE S.A.S, FRANCE
		GLUCOPHAGE 850 MG TABLET MAL19992048AZ	MERCK SANTE S.A.S, FRANCE
		GLUCOPHAGE 500 MG TABLET MAL19992047AZ	MERCK SANTE S.A.S, FRANCE
317.	METHOTREXATE 2.5MG *(List 7)*	EMTHEXATE TABLET 2.5MG MAL19920203AZ	TEVA CZECH INDUSTRIES S.R.O. CZECH REPUBLIC PHARMACHEMIE B.V, NETHERLANDS
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2013 – 2nd September 2013: the following product is being added as additional comparator in Malaysia.	
		METHOTREXATE TABLET 2.5MG	HAUPT PHARMA GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		PFZ METHOTREXATE TABLET 2.5MG (new product name) MAL20000041ACZ	EXCELLA GMBH, GERMANY
318.	METHOXSALEN 10MG	OXSORALEN-ULTRA CAPSULES 10MG MAL19920052A	ICN PHARM INC, UNITED STATES
		MELADININE TABLET 10MG MAL05090015ACZ	LABOBORATOIRES MACORS, FRANCE
319.	METHYLPHENIDATE HYDROCHLORIDE	RITALIN TABLET 10MG MAL19910002ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
320.	METHYLPREDNISOLONE	MEDROL TABLET 16MG MAL19990559A	PHARMACIA & UPJOHN CO, UNITED STATES
		MEDROL TABLET 4MG MAL19990558A	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**. *(Source of information: Pfizer (Malaysia) Sdn Bhd, 2014)*	
321.	METOCLOPRAMIDE HYDROCHLORIDE	MAXOLON TABLET 10MG MAL19921400A	BEECHAM PHARM, UNITED KINGDOM
		This product can be obtained from **South Africa, Australia and Pakistan**. (*Source of information Glaxosmithkline Pharmaceutical Sdn. Bhd, 2012*) As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2014" – 23th April 2014: products manufactured by **GSK Karachi** and **GSK Cape Town** are allowed to be used as comparator.	
322.	METOPROLOL TARTRATE *(List 4)*	BETALOC TABLET 100MG MAL19988457AS	ASTRAZENECA PHARMACEUTICAL CO. LTD, CHINA INTERPHIL LABORATORIES, INC. PHILIPINES

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		BETALOC TABLET 50MG MAL19988458AZ	ASTRAZENECA PHARMACEUTICAL CO. LTD, CHINA INTERPHIL LABORATORIES, INC. PHILIPINES
323.	METRONIDAZOLE *(List 6)*	As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2008 – 23rd July 2008: Flagyl Tablet from different manufacturer (registered in other country) are allowed to be used as a comparator.	
324.	MEXILETINE HYDROCHLORIDE	MEXITIL CAPSULE 200MG PBKD861808A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY
		MEXITIL CAPSULE 100MG PBKD861807A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY
		MEXITIL CAPSULE 50MG PBKD861806A	BOEHRINGER INGELHEIM INTERNATIONAL GMBH, GERMANY
		MEXITIL CAPSULE 100MG MAL19989013A	BOEHRINGER INGELHEIM TAIWAN LTD., TAIWAN
325.	MIANSERIN HYDROCHLORIDE	TOLVON TABLET 60MG MAL19900639A	N.V. ORGANON, NETHERLANDS
		TOLVON TABLET 30MG MAL19900638A	N.V. ORGANON, NETHERLANDS
		TOLVON TABLET 10MG MAL19900637A	N.V. ORGANON, NETHERLANDS

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

326.		This product can be obtained from **Algeria, Argentina, Austria, Belgium, Chile, Czech Republic, Eqypt, Finland, Italy, Japan, Luxembourg, Netherlands, Norway, Pakistan, Poland, Portugal, Russian Federation, Serbia, South Africa, Spain, Switzerland, Turkey & Ukraine**. *(Source of information: Merck Sharp & Dohme (Malaysia) Sdn. Bhd., 2018)*	
327.	MIDAZOLAM MALEATE	DORMICUM ROCHE TABLET 7.5 MG MAL19890299ACRZ	RECIPHARM LEGANES S.L.U., SPAIN PRODUCTOS ROCHE MEXICO
		DORMICUM FILM-COATED TABLET 15MG MAL19920037A	F. HOFFMAN-LA ROCHE, SWITZERLAND
328.	MIDOSTAURIN	RYDAPT 25MG SOFT CAPSULE MAL19046009ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
329.	MIGLITOL	DIASTABOL 100MG MAL19990974A	BAYER AG, GERMANY
		DIASTABOL 50MG MAL19990973A	BAYER AG, GERMANY
330.	MILNACIPRAN HYDROCHLORIDE	IXEL 50MG HARD CAPSULES MAL20061612A	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
		IXEL 25MG HARD CAPSULES MAL20061611A	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
331.	MINOCYCLINE *(List 8)*	APO-MINOCYCLINE 100MG CAPSULE MAL19984324AZ	APOTEX INC, CANADA
		APO-MINOCYCLINE 50MG MAL19984325AZ	APOTEX INC, CANADA
332.	MINOXIDIL	LONITEN 10MG TABLETS MAL20014501AR	GLOBAL PHARM LTD, CANADA
		LONITEN 5MG TABLETS MAL20014500AR	GLOBAL PHARM LTD, CANADA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		LONITEN TABLET 10MG MAL19861623A	UPJOHN LTD, UNITED KINGDOM
		LONITEN TABLET 5MG MAL19861624A	UPJOHN LTD, UNITED KINGDOM
		This product can be obtained from **Australia, Brazil, Canada, France, Germany, Ireland, Italy, Netherlands, New Zealand, South Africa, Spain, Switzerland, Taiwan & United Kingdom**. *(Source of information: Zeullig Pharma Sdn. Bhd., Malaysia, 2013)*	
333.	MIRTAZAPINE *(List 9)*	REMERON 45MG TABLET MAL19990904A	N.V. ORGANON, NETHERLANDS
		REMERON 30MG TABLET MAL19990903A	N.V. ORGANON, NETHERLANDS
		REMERON 15MG TABLET MAL19990905A	N.V. ORGANON, NETHERLANDS
		This product can be obtained from Argentina, **Australia, Bahrain, Canada, Chile, China, Cyprus, Egypt, France, Germany, Greece, Ireland, Japan, South Korea, Kuwait, Montenegro, Netherlands, Norway, Oman, Saudi Arabia, South Africa, Spain, Switzerland, Turkey, UAE, United States, Venezuala, Vietnam & Yemen**. *(Source of information: Organon Malaysia Sdn. Bhd., 2023)*	
334.	MIROGABALIN BESILATE	TARLIGE FILM-COATED TABLETS 2.5MG MAL26016001ACRZ	TAIYO PHARMA TECH CO., LTD., TAKATSUKI PLANT(JAPAN)
		TARLIGE® FILM-COATED TABLETS 5MG MAL26016002ACRZ	TAIYO PHARMA TECH CO., LTD., TAKATSUKI PLANT(JAPAN)
		TARLIGE® FILM-COATED TABLETS 10MG MAL26016003ACRZ	TAIYO PHARMA TECH CO., LTD., TAKATSUKI PLANT(JAPAN)
		TARLIGE® FILM-COATED TABLETS 15MG MAL26016004ACRZ	TAIYO PHARMA TECH CO., LTD., TAKATSUKI PLANT(JAPAN)
335.	MISOPROSTOL 200MCG	CYTOTEC TABLET 200MCG MAL19890225ARZ	PIRAMAL HEALTHCARE UK LIMITED, UNITED KINGDOM
336.	MIZOLASTIN	MIZOLLEN TABLET 10MG MAL20001215A	SANOFI WINTHROP INDUSTRIE, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

337.	MOCLOBEMIDE	AURORIX FILM COATED TABLET 300MG MAL13035055ACZ	CENEXI, FRANCE
		AURORIX FILM COATED TABLET 150MG MAL13035054ACZ	CENEXI, FRANCE
		AURORIX FILM-COATED TABLET 300MG MAL19987972A	F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
		AURORIX FILM-COATED TABLET 150MG MAL19910811A	F. HOFFMANN-LA ROCHE LTD, SWITZERLAND
338.	MONTELUKAST SODIUM (EQ 10MG BASE)	SINGULAIR TABLET 10MG MAL19990957ARZ	ORGANON PHARMA (UK) LIMITED, UNITED KINGDOM MERCK SHARP & DOHME LTD, UNITED KINGDOM
339.	MORPHINE SULPHATE	KAPANOL CAPSULES 100MG MAL19984002AR	F.H. FAULDING & CO LTD, AUSTRALIA
		KAPANOL CAPSULES 50MG MAL19984001AR	F.H. FAULDING & CO LTD, AUSTRALIA
		KAPANOL CAPSULES 20MG MAL19984000AR	F.H. FAULDING & CO LTD, AUSTRALIA
340.	MOXIFLOXACIN HYDROCHLORIDE (EQ 400MG BASE)	AVELOX TABLET MAL20012664AZ	BAYER HEALTHCARE MANUFACTURING S.R.L, ITALY BAYER AG, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
341.	MOXONIDINE	PHYSIOTENS 0.4MG TABLET MAL20033337ACZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		PHYSIOTENS 0.3MG TABLET MAL20033336ACZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
		PHYSIOTENS 0.2MG TABLET MAL20033335ACZ	MYLAN LABORATORIES SAS, FRANCE ABBOTT HEALTHCARE SAS, FRANCE
342.	MYCOPHENOLATE MOFETIL *(List 7)*	CELLCEPT TABLET 500MG MAL06030804ACRSZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY
		CELLCEPT CAPSULE 250MG MAL06030803ACRSZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY
343.	NALTREXONE HYDROCHLORIDE	REVIA TABLET 50MG MAL20013367A	DUPONT PHARM COMPANY, UNITED STATES
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2017 – 27th September 2017: Revia Tablet from **Bristol-Myers Squibb Australia Pty Ltd, Australia** dan **Teva Canada Limited, Canada** are allowed to be used as a comparator.	
		TREXAN TABLET 50MG MAL19930054A	DU PONT PHARM INC, N. YORK, UNITED STATES
344.	NAPROXEN SODIUM *(List 6)*	SYNFLEX TABLETS 550MG MAL20020897ACZ	RECIPHARM LEGANES, SPAIN ROCHE PHARMA S.A, SPAIN FOURRTS (INDIA) LABORATORIES PRIVATE LIMITED (INDIA)
		SYNFLEX TABLETS 275MG MAL20020896ACZ	RECIPHARM LEGANES, SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			ROCHE PHARMA S.A, SPAIN FOURRTS (INDIA) LABORATORIES PRIVATE LIMITED (INDIA)
	NAPROXEN *(List 6)*	APO-NAPROXEN 250MG TABLET MAL19984792A	APOTEX INC., CANADA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2020 – 28th December 2020: the following products are being added as additional comparator in Malaysia.	
		SELADIN TABLET 500MG MAL19988494AZ	Y.S.P INDUSTRIES (M) SDN BHD, MALAYSIA
		SELADIN TABLET 250MG MAL19988495AZ	Y.S.P INDUSTRIES (M) SDN BHD, MALAYSIA
345.	NATEGLINIDE	STARLIX 120MG TABLET MAL20014477AR	NOVARTIS FARMA S.P.A., ITALY
		STARLIX 60MG TABLET MAL20014476A	NOVARTIS FARMA S.P.A., ITALY
346.	NEBIVOLOL HYDROCHLORIDE (EQ 5MG BASE)	NEBILET TABLET MAL20041163AZ	BERLIN-CHEMIE AG, GERMANY
347.	NELFINAVIR MESYLATE (EQ 250MG BASE)	VIRACEPT FILM-COATED TABLET 250MG MAL05032533A	ROCHE FARMA S.A, SPAIN
		VIRACEPT TABLETS 250MG MAL20020815AS	F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
348.	NEOSTIGMINE BROMIDE	PROSTIGMIN ROCHE TABLET 15MG MAL19871818A	ROCHE PRODUCTS LTD, UNITED KINGDOM
349.	NERATINIB MALEATE	NERLYNX (NERATINIB) FILMCOATED TABLETS 40 MG MAL20076009ACRZ	EXCELLA GMBH & CO.KG (GERMANY)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

350.	NEVIRAPINE 200MG *(List 5)*	VIRAMUNE TABLET 200MG MAL19992680AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE
		This product can be obtained from **Taiwan, Hong Kong, Singapore, Thailand, Germany, Serbia, Switzerland, Saudi Arabia, South Africa, Kenya, Oman, Israel, Turkey, Botswana, Zimbabwe, Germany, Bosnia And Herzegovina, Kazakhstan, Namibia, Cyprus, Slovakia, Iceland, Greece, Portugal, Spain, Austria, Italy, France, Luxembourg, Belgium, Netherlands, Ireland, United Kingdom, Sweden, Finland, Denmark, Norway, Latvia, Malta and Liechtenstein**. *(Source of information: Boehringer Ingelheim (M) Sdn Bhd, 2016)*	
351.	NIFEDIPINE *(List 1)*	ADALAT CAPSULE 10MG MAL19880104AZ	BAYER PHARMA AG, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
		ADALAT 5 CAPSULE MAL19880105AZ	BAYER PHARMA AG, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
352.	NILOTINIB HYDROCHLORIDE MONOHYDRATE	TASIGNA 200MG CAPSULE MAL20081780ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
		TASIGNA 150MG CAPSULE MAL11105040ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
		TASIGNA 50MG CAPSULES MAL19106015ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
353.	NIMODIPINE 30MG	NIMOTOP TABLET 30MG MAL19940001AZ	BAYER PHARMA AG, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
354.	NINTEDANIB ESILATE	OFEV SOFT CAPSULES 150MG MAL16065015ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
		OFEV SOFT CAPSULES 100MG MAL16065014ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
355.	NIRAPARIB TOSYLATE MONOHYDRATE	ZEJULA FILM-COATED TABLET 100MG MAL25036003ACRZ	CATALENT GREENVILLE INC. (UNITED STATES)
356.	NISOLDIPINE	SYSCOR CC TABLET 40MG MAL20000267AC	BAYER AG, GERMANY
		SYSCOR CC TABLET 30MG MAL20000266AC	BAYER AG, GERMANY
		SYSCOR CC TABLET 20MG MAL20000265AC	BAYER AG, GERMANY
		SYSCOR CC 10MG TABLET MAL20000264AC	BAYER AG, GERMANY
357.	NITROFURANTOIN 100MG *(List 8)*	APO-NITROFURANTOIN TABLET 100MG MAL19984749ARZ	APOTEX INC, CANADA
358.	NIZATIDINE 150MG	PU 3144 AXID CAPSULE 150MG MAL19950508AC	LILLY S.A., SPAIN
359.	NORETHISTERONE 5MG	PRIMOLUT-N TABLET 5MG MAL19900564A	SCHERING AG BERLIN, GERMANY
		PRIMOLUT N 5MG TABLET MAL08120874A	SCHERING GMBH & CO. PRODUKTIONS KG GERMANY BAYER WEIMAR GMBH UND CO.KG, GERMANY
		PRIMOLUT-N 5MG TABLET MAL20002234AS	PT SCHERING INDONESIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		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. *(Source of information: Bayer Co (M) Sdn Bhd, 2015)* Primolut N tablet can be obtained from **Singapore, Thailand, Australia and New Zealand**. *(Source of information: Bayer Co (M) Sdn Bhd, 2016)*	
	NORETHISTERONE 0.35MG	NORIDAY TABLET MAL19992549AZ	PIRAMAL HEALTHCARE UK LIMITED, UNITED KINGDOM
360.	NORFLOXACIN 400MG	UROBACID 400MG FILM-COATED TABLETS MAL20021380AZ	MERCK KOMMANDITGESELLSCHAFT AUF AKTEIN & CO.WERK, AUSTRIA
		TRIZOLIN 400 F.C. TABLETS MAL19913447A	REMEDICA LTD, CYPRUS
361.	NYSTATIN	MYCOSTATIN ORAL TABLET 500000 IU MAL19921327A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA BRISTOL-MYERS SQUIBB PTY LTD, MEXICO
		This product can be obtained from **Mexico**. *(Source of information: Bristol Myers Squibb, Asia Pacific, 2012)* As agreed upon JKKBE, this active ingredient has been given biowaiver consideration. Kindly refer biowaiver page on NPRA website for more information.	
362.	ODEVIXIBAT SESQUIHYDRATE	BYLVAY 200 MICROGRAMS HARD CAPSULES MAL26036005ACRZ	PATHEON FRANCE S.A. (FRANCE)
		BYLVAY 400 MICROGRAMS HARD CAPSULES MAL26036006ACRZ	PATHEON FRANCE S.A. (FRANCE)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		BYLVAY 600 MICROGRAMS HARD CAPSULES MAL26036007ACRZ	PATHEON FRANCE S.A. (FRANCE)
		BYLVAY 1200 MICROGRAMS HARD CAPSULES MAL26036008ACRZ	PATHEON FRANCE S.A. (FRANCE)
363.	OFLOXACIN 100MG *(List 5)*	TARIVID TABLET 100MG MAL19890577AZ	DAIICHI SANKYO PROPHARMA CO. LTD, TAKATSUKI PLANT, JAPAN DAIICHI SANKYO PROPHARMA CO. LTD, SHIZUOKA PLANT, JAPAN
364.	OLANZAPINE *(List 9)*	ZYPREXA TABLET 10MG MAL08061565AZ	LILLY S.A., SPAIN
		ZYPREXA TABLET 5MG MAL08061564AZ	LILLY S.A., SPAIN
		ZYPREXA TABLET 20MG MAL04125532AR	LILLY DEL CARIBE INC., UNITED STATES
		ZYPREXA TABLET 15MG MAL04125528AR	LILLY DEL CARIBE INC., UNITED STATES
		ZYPREXA 10MG TABLET MAL19986935AZ	LILLY DEL CARIBE INC., PUERTO RICO BASINGSTOKE UK
		ZYPREXA 5MG TABLET MAL19986933AZ	LILLY DEL CARIBE INC., PUERTO RICO BASINGSTOKE UK
		This Product can be obtained from **Canada, USA, Denmark** and **Sweden**. *(Source of information: Eli Lilly (Malaysia) Sdn Bhd, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2013 – 2nd September 2013: the following products are being added as additional comparator in Malaysia.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		OLEANZ 10 TABLET MAL10100143AZ	SUN PHARMACEUTICAL INDUSTRIES LTD., INDIA
		OLEANZ 5 TABLET MAL10100139AZ	SUN PHARMACEUTICAL INDUSTRIES LTD., INDIA
		OLENZA 10MG TABLET MAL10100148AZ	NORIPHARMA SDN. BHD., MALAYSIA
		OLENZA 5MG TABLET MAL10100149AZ	NORIPHARMA SDN. BHD., MALAYSIA
365.	OLAPARIB	LYNPARZA 100 MG FILM-COATED TABLET MAL19106011ACRZ	ABBVIE LTD, UNITED STATES
		LYNPARZA 150 MG FILM-COATED TABLET MAL19106013ACRZ	ABBVIE LTD, UNITED STATES
366.	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
367.	ONDANSETRON HYDROCHLORIDE DIHYDRATE	ZOFRAN TABLET 8MG MAL19950013ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
		ZOFRAN TABLET 4MG MAL19950007ACZ	ASPEN BAD OLDESLOE GMBH, GERMANY
368.	ORLISTAT	XENICAL CAPSULE 120MG MAL19992994ARZ	F. HOFFMANN, LA ROCHE LTD, SWITZERLAND
		XENICAL CAPSULE 120 MG MAL05032548ARSZ	ROCHE S.P.A., ITALY
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2014 – 18th 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	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		amount of fat excretion over a 24-hour period at steady state relative to the amount of daily ingested fat.	
369.	ORPHENADRINE CITRATE	NORFLEX TABLET 100MG MAL13055067ACRZ	ADCOCK INGRAM - A MEDREICH GROUP COMPANY, INDIA
		NORFLEX TABLET 100MG MAL19861502A	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
370.	OSELTAMIVIR PHOSPHATE *(List 8)*	TAMIFLU CAPSULES 75MG MAL20014188ACRZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
		TAMIFLU CAPSULE 45MG MAL09100496ACRZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY
		TAMIFLU CAPSULE 30MG MAL09100495ACRZ	DELPHARM MILANO S.R.L, ITALY ROCHE S.P.A., ITALY
		TAMIFLU CAPSULE 75MG MAL09082799ARSZ	CENEXI SAS, FRANCE
		TAMIFLU CAPSULES 75MG MAL11030079ACRSZ	CATALENT PHARMA SOLUTIONS, GERMANY
371.	OSIMERTINIB	TAGRISSO FILM COATED TABLET 40 MG MAL20172807AZ	ASTRA ZENECA AB, SWEDEN
		TAGRISSO FILM COATED TABLET 80 MG MAL20172808AZ	ASTRA ZENECA AB, SWEDEN
372.	OXCARBAZEPINE	TRILEPTAL 600 MG FILM-COATED TABLET MAL07050038ARSZ	NOVARTIS FARMA S.P.A., ITALY
		TRILEPTAL 300MG MAL20021155ARZ	NOVARTIS FARMA S.P.A., ITALY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		TRILEPTAL 600MG TABLETS MAL20021156A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		TRILEPTAL 150MG MAL20021154A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
373.	OXYBUTYNIN HYDROCHLORIDE	DRIPTANE TABLET 5MG MAL19991351ARZ	LABS FOURNIER SA, FRANCE
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2019 – 19th November 2019: DRIPTANE TABLET 5MG manufactured by Recipharm Fontaine, France is allowed to be used as a comparator. DRIPTANE TABLET manufactured by Astrea Fontane, Fontaine Les Dijon, France. is allowed to be used as a comparator. It can be obtained from **Turkmenistan, Armenia, Azerbaijan and Uzbekistan.** *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2026)*	
374.	OXYCODONE HYDROCHLORIDE	OXYNORM 20MG CAPSULES MAL10070562ACZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
		OXYNORM 10MG CAPSULES MAL10070561ACZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
		OXYNORM 5MG CAPSULES MAL10070560ACZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
375.	OXYMETHOLONE	ANAPOLON 50 TABLET MAL19870679A	SYNTEX INCORPORATED, CANADA
		ANAPOLON 50 TABLET MAL19870678A	SYNTEX PHARM LTD, UNITED KINGDOM
376.	PALBOCICLIB	IBRANCE CAPSULES 125MG MAL16065004AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		IBRANCE CAPSULES 100MG MAL16065003AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		IBRANCE CAPSULES 75MG MAL16065002AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		IBRANCE FILM-COATED TABLETS 100MG MAL23096009AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		IBRANCE FILM-COATED TABLETS 125MG MAL23096010AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
		IBRANCE FILM-COATED TABLETS 75MG MAL23096008AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
377.	PARICALCITOL	ZEMPLAR CAPSULES 4 MCG MAL20071710ACZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
		ZEMPLAR CAPSULES 2 MCG MAL20071709ACZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
		ZEMPLAR CAPSULES 1 MCG MAL20071708ACZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
378.	PAROXETINE HYDROCHLORIDE (EQ 20MG BASE)	SEROXAT 20MG TABLET MAL19930146A	GLAXO WELLCOME PRODUCTION, FRANCE
		This product can be obtained from **Hong Kong**, **Thailand** and **Philippines**. *(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2015)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2018 – 25th May 2018: Seroxat 20mg Tablet manufactured by **S.C Europharm S.A, Romania** and **GlaxoSmithKline Pharmaceuticals S.A, Poland** are allowed to be used as a comparator.	
379.	PAZOPANIB HYDROCHLORIDE	VOTRIENT FILM-COATED TABLET 400MG MAL20102072ARZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
		VOTRIENT FILM-COATED TABLET 200MG MAL20102071ARZ	GLAXO OPERATIONS UK LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			NOVARTIS PHARMACEUTICALS MANUFACTURING LLC (SLOVENIA)
380.	PENICILLAMINE 250MG	ARTAMIN CAPSULE 250MG MAL20021153ACZ	HAUPT PHARMA BERLIN GMBH, GERMANY
381.	PENTOSAN POLYSULFATE SODIUM	ELMIRON 100MG CAPSULE MAL20091881A	IVAX PHARMACEUTICALS INC., UNITED STATES
382.	PENTOXIFYLLINE 400MG	TRENTAL 400 TABLET MAL19990996AZ	SANOFI-AVENTIS DE MEXICO S.A. DE C.V., MEXICO
383.	PERPHENAZINE *(List 9)*	TRILAFON TABLET 4MG 1986043352A	SCHERING-PLOUGH PTY. LTD., AUSTRALIA
		TRILAFON TABLET 2MG 1986043353A	SCHERING-PLOUGH PTY. LTD., AUSTRALIA
384.	PERAMPANEL 2MG	FYCOMPA 2MG FILM COATED TABLET MAL14035002AZ	EISAI MANUFACTURING LIMITED (UNITED KINGDOM)
385.	PERAMPANEL 4MG	FYCOMPA 4MG FILM COATED TABLET MAL14035005AZ	EISAI MANUFACTURING LIMITED (UNITED KINGDOM)
386.	PERINDOPRIL ARGININE *(List 7)*	COVERSYL 10MG FILM-COATED TABLETS MAL20081838AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		COVERSYL 5MG FILM-COATED TABLETS (MAL20081837AZ)	LES LABS SERVIER INDUSTRIE, FRANCE
	PERINDOPRIL TERT-BUTYLAMINE *(List 7)*	COVERSYL 8MG TABLET MAL05061534AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		COVERSYL 4MG TABLET MAL19900370AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		COVERSYL 2MG TABLET MAL19900369ARZ	LES LABS SERVIER INDUSTRIE, FRANCE
		This product can be obtained from **Thailand**. (*Source of information: Servier, Malaysia, 2018)*	
		COVERSYL TABLET 8MG MAL09062148ACSZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		COVERSYL 4MG MAL04103437ACZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2019 – 3rd May 2019: the following product is being added as additional comparator in Malaysia.	
		PERINDOSYL 4MG TABLETS MAL11010008AZ	LEK PHARMACEUTICALS D.D., SLOVENIA NOVARTIS PHARMACEUTICAL MANUFACTURING LLC, SLOVENIA
387.	PHENOXYMETHYLPENICILLIN POTASSIUM	OSPEN (KV) 1000 FILM-COATED TABLET MAL19872227AZ	SANDOZ GMBH, AUSTRIA
		OSPEN TABLET 250MG MAL19860442AZ	SANDOZ GMBH, AUSTRIA BIOCHEMIE GMBH, AUSTRIA
388.	PHENTERMINE HYDROCHLORIDE	DUROMINE CAPSULE 30MG MAL14035007ACRZ	DOUGLAS MANUFACTURING LIMITED, NEW ZEALAND
		DUROMINE CAPSULE 15MG MAL14035017ACRZ	DOUGLAS MANUFACTURING LIMITED, NEW ZEALAND
		DUROMINE CAPSULE 30MG MAL18086158ACSZ	VALEANT PHARMACEUTICALS INTERNATIONAL INC, CANADA
		DUROMINE CAPSULE 15MG MAL18086157ACSZ	VALEANT PHARMACEUTICALS INTERNATIONAL INC, CANADA
		DUROMINE CAPSULE 30MG MAL19871774AR	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		DUROMINE CAPSULE 15MG MAL19871769AR	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.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		However, the label on the generic immediate release product of Phenterminemust include the following statement:- **'Not Interchangeable with Duromine and other brand of product Containing Phentermine Resin'.**	
389.	PHENYTOIN SODIUM *(List 4)*	DILANTIN CAPSULE 100MG MAL19860935ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER AUSTRALIA PTY LTD, AUSTRALIA
		DILANTIN CAPSULE 30MG MAL19860940ARZ	PFIZER PHARMACEUTICALS LLC, UNITED STATES PFIZER AUSTRALIA PTY LTD, AUSTRALIA
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2010 – 8th December 2010 : i) For Generic immediate release, oral solid dosage form product which follows USP/BP specification and bioequivalence study is not conducted, the label on the generic products of phenytoin tablet must include the statement **'Not interchangeable with Dilantin and other brands of product containing Phenytoin'.** ii) For generic immediate release, oral solid dosage form product which had performed BE study and found bioequivalent with Innovator product (Dilantin), there is no need to include such statement as in no.(i).	
390.	PINAVERIUM BROMIDE	DICETEL 100MG FILM-COATED TABLET MAL20122215ACZ	ABBOTT HEALTHCARE SAS, FRANCE MYLAN LABORATORIES SAS, FRANCE
		DICETEL 50MG FILM-COATED TABLET MAL12045092AZ	ABBOTT HEALTHCARE SAS, FRANCE
391.	PINDOLOL	VISKEN TABLET 10MG PBKD870074A	NOVARTIS PHARMA AG, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		VISKEN TABLET 5MG PBKD870587A	NOVARTIS PHARMA AG, SWITZERLAND
392.	PIOGLITAZONE HYDROCHLORIDE	ACTOS 30MG TABLET MAL20051431ACZ	BORA PHARMACEUTICAL LABORATORIES INC. (TAIWAN)
		ACTOS 15MG TABLETS MAL11100026ACZ	BORA PHARMACEUTICAL LABORATORIES INC. (TAIWAN)
		ACTOS 15MG TABLET MAL20051432AR	TAKEDA PHARMACEUTICAL LTD., JAPAN
393.	PIPEMIDIC ACID	URIXIN FILMTAB TABLET MAL19910050A	ABBOTT LABS, PHILIPPINES
		URIXIN FILMTAB 400MG MAL19871869A	ABBOTT LABS, PAKISTAN
		This product can be obtained from **Pakistan**. *(Source of information: Abbott Laboratories (M) Sdn Bhd, 2016)*	
394.	PIRACETAM	NOOTROPIL TABLET 1200 MG MAL07021409ARZ	UCB S.A. - SECTEUR PHARMA, BELGIUM
		NOOTROPIL TABLET 800 MG MAL07021408ARZ	UCB S.A. - SECTEUR PHARMA, BELGIUM
395.	PIRFENIDONE	ESBRIET HARD CAPSULES 267MG MAL16115027ACRZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
		ESBRIET 267MG FILM-COATED TABLETS MAL24036009ACRZ	DELPHARM MILANO S.R.L (ITALY)
		ESBRIET 801MG FILM-COATED TABLETS MAL24036008ACRZ	DELPHARM MILANO S.R.L (ITALY)
396.	PIROXICAM *(List 2)*	FELDENE CAPSULE 20MG MAL19985518AS	PFIZER, FRANCE
		FELDENE CAPSULE 10MG MAL19985517AS	PFIZER, FRANCE
		According to circular Bil (51) dlm.BPFK/02/5/1.3, the following products are being added as additional comparator in Malaysia.	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		UPHAXICAM 20 CAPSULE MAL19861112AZ	DUOPHARMA MANUFACTURING (BANGI) SDN BHD,MALAYSIA UPHA PHARMACEUTICAL MFG. (M) SDN. BHD., MALAYSIA
		UPHAXICAM 10 CAPSULE MAL19861109AZ	DUOPHARMA MANUFACTURING (BANGI) SDN BHD,MALAYSIA UPHA PHARMACEUTICAL MFG. (M) SDN. BHD., MALAYSIA
		FELXICAM 20 CAPSULE MAL19920515AZ	HOVID BERHAD, MALAYSIA
		AXCEL PIROXICAM-10 CAPSULE MAL19910832AZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA
397.	PIROXICAM-B-CYCLODEXTRIN	BREXIN TABLET MAL19992991AZ	CHIESI FARMACEUTICI S.P.A., ITALY
398.	PITAVASTATIN CALCIUM (AS HYDRATE)	LIVALO FILM COATED TABLET 2MG MAL20046082AZ	KOWA COMPANY LTD. NAGOYA FACTORY, JAPAN
		LIVALO FILM COATED TABLET 4MG MAL20046083AZ	KOWA COMPANY LTD. NAGOYA FACTORY, JAPAN
399.	PIZOTIFEN MALATE (EQ 0.5MG BASE)	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**. *(Source of information: Novartis Corporation (M) Sdn Bhd, 2015*) Sandomigran Tablet is made in Italy and distributed by AFT Pharmaceuticals Pty Ltd in **Australia** and **New Zealand**. (*Source of information: Novartis Corporation (M) Sdn Bhd, 2016*)	
400.	POMALIDOMIDE	POMALYST CAPSULES 4MG MAL16015080ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		POMALYST CAPSULES 3MG MAL16015079ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		POMALYST CAPSULES 2MG MAL16015078ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
		POMALYST CAPSULES 1MG MAL16015077ARZ	CELGENE INTERNATIONAL SARL, SWITZERLAND
401.	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	SIFROL TABLET 1MG MAL20000719AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		SIFROL TABLET 0.25MG MAL20000718AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		SIFROL TABLET 0.125MG MAL20000717AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
402.	PRASUGREL HYDROCHLORIDE	EFFIENT FILM-COATED TABLETS 10 MG MAL20102003ARZ	ELI LILLY AND COMPANY, USA
		EFFIENT FILM-COATED TABLETS 5 MG MAL20102002ARZ	ELI LILLY AND COMPANY, USA
403.	PRAVASTATIN SODIUM	PRAVACHOL TABLET 40MG MAL19991374A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		PRAVACHOL TABLET 20MG MAL19940250A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		PRAVACHOL TABLET 10MG MAL19940249A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		PRAVACHOL TABLET 20MG MAL20021397AS	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		PRAVACHOL TABLET 10MG MAL20032161A	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		PRAVACHOL TABLET 20MG MAL20013463AC	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
		PRAVACHOL TABLET 20MG	E.R. SQUIBB &SONS LTD

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		PBKD921379A	
		PRAVACHOL TABLET 10MG PBKD 921380A	E.R. SQUIBB &SONS LTD
		This product can be obtained from **Canada, France, Germany, Ireland and United Kingdom**. *(Source of information: Bristol Myers Squibb Asia Pacific, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2018 –25 May 2018: the following products are being added as additional comparator in Malaysia.	
		APO-PRAVASTATIN 40MG TABLETS MAL06030825AZ	APO-PRAVASTATIN 40MG TABLETS MAL06030825AZ
		APO-PRAVASTATIN 20MG TABLET MAL20040229ARZ	APOTEX INC, CANADA
404.	PRAZOSIN HYDROCHLORIDE	MINIPRESS TABLET 5MG MAL19870100AZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		MINIPRESS TABLET 2MG MAL19870098AZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		MINIPRESS TABLET 1MG MAL19870096AZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		MINIPRESS TABLET 5MG MAL19930150ACSZ	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
		MINIPRESS TABLET 2MG MAL19930149ACSZ	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
		MINIPRESS TABLET 1MG MAL19930148ACSZ	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
405.	PREGABALIN *(LIST 9)*	LYRICA 150MG CAPSULES MAL20081832ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		LYRICA 75MG CAPSULES MAL20081831ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		LYRICA 50MG CAPSULES MAL20081830ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY
		LYRICA CR 165MG TABLET MAL25046011ACRZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH(GERMANY)
		LYRICA CR 82.5MG TABLET MAL25046010ACRZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH(GERMANY)
406.	PRETOMANID	PRETOMID 200 (PRETOMANID TABLETS 200 MG) MAL25086001AZ	MACLEODS PHARMACEUTICALS LIMITED(INDIA)
		DOVPRELA (PRETOMANID TABLETS 200MG) MAL26066008AZ	MYLAN LABORATORIES LIMITED (INDIA)
407.	PROCATEROL HYDROCHLORIDE	MEPTIN TABLET 0.05MG MAL19890453ACZ	OTSUKA PHARMACEUTICAL CO., LTD, JAPAN
408.	PROGESTERONE	UTROGESTAN CAPSULE 100MG MAL19971796ACZ	CYNDEA PHARMA (SPAIN)
409.	PROGUANIL HYDROCHLORIDE	PALUDRINE TABLETS 100MG PBKD911193A	ASTRAZENECA UK LIMITED, UNITED KINGDOM
410.	PROPAFENONE HYDROCHLORIDE	RYTMONORM TABLET 150MG MAL19880156AZ	ABBOT GMBH & CO. KG, GERMANY
411.	PROPANTHELINE	PRO-BANTHINE TABLET 15MG PBKD861516A	SEARLE LABS, AUSTRALIA.
		PRO-BANTHINE TABLET 15MG PBKD861515A	G.D. SEARLE & CO, UNITED KINGDOM
412.	PROPRANOLOL HYDROCHLORIDE *(List 3)*	INDERAL TABLET 40MG MAL19870042ARZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA ASTRAZENECA UK LIMITED, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		INDERAL TABLET 10MG MAL19870030ARZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA ASTRAZENECA UK LIMITED, UNITED KINGDOM
413.	PROPIVERINE HYDROCHLORIDE 15MG	MICTONORM TABLET MAL20061584AZ	APOGEPHA ARZNEIMITTEL GMBH, GERMANY
414.	PRUCALOPRIDE SUCCINATE	RESOLOR 2MG FILM COATED TABLETS MAL12025076ACZ	JANSSEN CILAG SPA, ITALY SANICO NV(BELGIUM)
		RESOLOR 1MG FILM COATED TABLETS MAL12025075ACZ	JANSSEN CILAG SPA, ITALY SANICO NV(BELGIUM)
415.	PSEUDOEPHEDRINE	SUDAFED TABLET 60MG, MAL19870799A	WELLCOME AUSTRALIA LTD, AUSTRALIA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2013 – 13th March 2013: Sudafed Tablet 60mg from **GlaxoSmithKline Chittagong, Bangladesh** is allowed to be used as comparator.	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2014 – 18th August 2014: Sudafed Tablet 60mg from **GlaxoSmithKline Pulogadong, Indonesia** is allowed to be used as a comparator.	
416.	PYRAZINAMIDE *(List 7)*	PZA-CIBA 500MG TABLET MAL20041254A	NOVARTIS BANGLADESH LTD, BANGLADESH
417.	PYRIDOSTIGMINE BROMIDE	MESTINON TABLET 10MG MAL05090001ACRZ	LABIANA PHARMACEUTICALS, SL, SPAIN
		MESTINON DRAGEES 60MG MAL04112698ACRZ	LABIANA PHARMACEUTICALS, SL, SPAIN
		MESTINON 60MG TABLET MAL19861730A	F.HOFFMAN-LA ROCHE, SWITZERLAND
		MESTINON ROCHE TABLET 10MG	F.HOFFMAN-LA ROCHE, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAL19861729A	
		MESTINON 60MG TABLET MAL20041049A	ICN CANADA LTD, CANADA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2014 – 23rd April 2014: Currently Mestinon 10mg Tablet (MAL05090001ACR) is not commercialised actively in Malaysia. Kindly contact the manufacturer's person in charge for the sourcing of this product: Qualified Person Maria Merce Roca Solsona Mariamerce.roca@labiana.com Tel: 003493 622 29 00	
418.	QUETIAPINE FUMARATE *(List 9)*	SEROQUEL TABLET 300MG MAL06041484AZ	ASTRA ZENECA PHARMACEUTICAL CO. LTD., CHINA
		SEROQUEL TABLET 200MG MAL20000262ACZ	ASTRA ZENECA PHARMACEUTICAL CO. LTD., CHINA
		SEROQUEL TABLET 100MG MAL20000262	ASTRA ZENECA PHARMACEUTICAL CO. LTD., CHINA
		SEROQUEL TABLET 25MG MAL20000261ACZ	ASTRA ZENECA PHARMACEUTICAL CO. LTD., CHINA
419.	QUINAPRIL HYDROCHLORIDE *(List 7)*	ACCUPRIL 20MG TABLETS MAL19962574A	PFIZER GMBH, GERMANY
		ACCUPRIL 10MG TABLETS MAL19962573A	PFIZER GMBH, GERMANY
		ACCUPRIL 5MG TABLETS MAL19962575A	PFIZER GMBH, GERMANY
420.	RABEPRAZOLE SODIUM	PARIET TABLET 10MG MAL19992540ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY (JAPAN)
		PARIET TABLET 10MG MAL19992541ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY (JAPAN)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

421.	RACECADOTRIL	HIDRASEC 100MG HARD CAPSULE MAL13045047AZ	SOPHARTEX (FRANCE)
422.	RALOXIFENE HYDROCHLORIDE *(List 7)*	EVISTA TABLET 60MG MAL04125481AZ	LILLY S.A., SPAIN
423.	RALTEGRAVIR	ISENTRESS 400MG TABLET MAL20081777ARZ	MSD INTERNATIONAL GMBH, IRELAND MSD INTERNATIONAL GMBH (SINGAPORE BRANCH), SINGAPORE MERCK & CO INC., UNITED STATES
424.	RAMIPRIL *(List 7)*	TRITACE 10MG TABLET MAL20031929AZ	SANOFI-AVENTIS S.P.A, ITALY
		TRITACE 5MG TABLET MAL19986948AZ	SANOFI-AVENTIS S.P.A, ITALY
		TRITACE 2.5MG TABLET MAL19986949AZ	SANOFI-AVENTIS S.P.A, ITALY
425.	RANITIDINE HYDROCHLORIDE *(List 4)*	ZANTAC TABLET 300MG MAL19940613ASZ	GLAXOSMITHKLINE AUSTRALIA PTY LTD, AUSTRALIA
		ZANTAC TABLET 150MG MAL19871471ARZ	GLAXO WELLCOME S.A., SPAIN GLAXOSMITHKLINE (TIANJIN) CO. LTD, CHINA
		ZANTAC TABLET 75MG MAL19990987AZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		This product can be obtained from **Australia, Hong Kong, India, Indonesia, New Zealand, Philippines & Thailand**. *(Source of information: GSK Malaysia, 2014)*	
426.	RASAGILINE MESYLATE	RAGITAR TABLETS (RASAGILINE TABLETS 1 MG) MAL25106003AZ	ALKEM LABORATORIES LIMITED (INDIA)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

427.	REBAMIPIDE	MUCOSTA TABLETS 100 MG MAL20071711ARZ	KOREA OTSUKA PHARMACEUTICAL CO LTD, SOUTH KOREA
428.	REGORAFENIB MONOHYDRATE	STIVARGA 40MG FILM COATED TABLETS MAL13065048AZ	BAYER AG, GERMANY
429.	REPAGLINIDE	NOVONORM TABLET 2.0MG MAL20001009ACRZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		NOVONORM TABLET 1.0MG MAL20001008ACRZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		NOVONORM TABLET 0.5MG MAL20001007ACRZ	BOEHRINGER INGELHEIM PHARMA KG, WEST GERMANY
430.	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
431.	RIBOCICLIB SUCCINATE	KRYXANA 200MG FILM COATED TABLETS MAL18046001ARZ	NOVARTIS PHARMACEUTICAL MANUFACTURING LLC, SLOVENIA
432.	RIFABUTIN	MYCOBUTIN 150MG CAPSULES MAL19960957A	PFIZER ITALIA S.R.L., ITALY
433.	RIFAMPICIN *(List 5)*	RIMACTANE 150 CAPSULE MAL19860792AZ	SANDOZ PRIVATE LIMITED, INDIA
		This product can be obtained from **Switzerland, Netherland, Denmark, Norway and Sweden**. *(Source of information: Sandoz Pharm (M) Sdn Bhd, 2018)*	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

434.	RILUZOLE	RILUTEK TABLETS 50MG MAL20051294AZ	SANOFI WINTHROP INDUSTRIE, FRANCE OPELLA HEALTHCARE INTERNATIONAL SAS(FRANCE)
435.	RISEDRONATE SODIUM	ACTONEL 35MG TABLET MAL20034605ACZ	BALKANPHARMA DUPNITSA AD, BULGARIA NORWICH PHARMACEUTICALS INC., UNITED STATES
		ACTONEL 30MG TABLET MAL20012656AR	OSG NORWICH PHARM INC, UNITED STATES
		ACTONEL FILM-COATED TABLET 5MG MAL20012657ARZ	BALKANPHARMA DUPNITSA AD, BULGARIA OSG NORWICH PHARM INC, UNITED STATES
436.	RISPERIDONE *(List 6)*	RISPERDAL TABLET 4 MG MAL20002245ASZ	JANSSEN CILAG SPA, ITALY
		RISPERDAL TABLET 3 MG MAL20002244ASZ	JANSSEN CILAG SPA, ITALY
		RISPERDAL TABLET 2 MG MAL20002243AZ	JANSSEN CILAG SPA, ITALY
		RISPERDAL TABLET 1 MG MAL20002242AZ	JANSSEN CILAG SPA, ITALY
		RISPERDAL 4MG TABLET MAL19963158AZ	JANSSEN PHARMACEUTICA N.V., BELGIUM
		RISPERDAL 3MG TABLET MAL19963157AZ	JANSSEN PHARMACEUTICA N.V., BELGIUM
		RISPERDAL 2MG TABLET MAL19963156AZ	JANSSEN PHARMACEUTICA N.V., BELGIUM
		RISPERDAL 1MG TABLET MAL19963155AZ	JANSSEN PHARMACEUTICA N.V., BELGIUM
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2009 – 19th August 2009 :	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		Both parent drug and active metabolite (9-hydroxyrisperidone) need to be analysed in BE study based on justification that both parent drug and active metabolite contribute to anti-psychotic activity. However, BE study conducted prior to 19 Ogos 2009 and analysis was only done on parent drug, the BE report can still be considered for evaluation.	
437.	RITONAVIR *(List 5)*	NORVIR TABLET 100MG MAL13015040ARZ	ABBVIE DEUTSCHLAND GMBH & CO.KG, GERMANY
		NORVIR SEC 100MG MAL20001246ACRZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES CARDINAL HEALTH 409 INC, UNITED STATES
438.	RIVAROXABAN	XARELTO 20MG FILM-COATED TABLET MAL11115001AZ	BAYER AG, GERMANY BAYER BITTERFELD GMBH (GERMANY)
		XARELTO 15MG FILM-COATED TABLET MAL11115002AZ	BAYER AG, GERMANY BAYER BITTERFELD GMBH (GERMANY)
		XARELTO FILM-COATED TABLETS 10MG MAL20091883AZ	BAYER AG, GERMANY BAYER BITTERFELD GMBH (GERMANY)
		XARELTO FILM-COATED TABLETS 2.5 MG MAL20046076AZ	BAYER AG, GERMANY BAYER BITTERFELD GMBH (GERMANY)
439.	RIVASTIGMINE HYDROGEN TARTRATE	EXELON 6MG CAPSULES MAL19990979ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXELON 4.5MG CAPSULES MAL19990978ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
		EXELON 3MG CAPSULES MAL19990977ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		EXELON 1.5MG CAPSULES MAL19990976ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
440.	RIZATRIPTAN BENZOATE	MAXALT TABLET 10MG MAL20000250ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		MAXALT TABLET 5MG MAL20000249ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
441.	ROFLUMILAST	DAXAS 500 MCG FILM-COATED TABLETS MAL20112164ACZ	TAKEDA GMBH, GERMANY
442.	ROPINIROLE HYDROCHLORIDE	REQUIP TABLET 5MG MAL19990969AZ	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
		REQUIP TABLET 2MG MAL19990968AZ	SMITHKLINE BEECHAM PHARM, UNITED KINGDOM
		REQUIP TABLET 1MG MAL19990967ARZ	GLAXO WELLCOME SA, SPAIN
		REQUIP TABLET 0.25MG MAL19990966ARZ	GLAXO WELLCOME SA, SPAIN
443.	ROSIGLITAZONE MALEATE	AVANDIA TABLET 8MG MAL20000009ARZ	GLAXO WELLCOME S.A., SPAIN
		AVANDIA TABLET 4MG MAL20000008ARZ	GLAXO WELLCOME S.A., SPAIN
		AVANDIA TABLET 2MG MAL20000007A	GLAXO WELLCOME S.A., SPAIN
444.	ROSUVASTATIN CALCIUM	CRESTOR 20MG TABLET MAL20051357ARZ	IPR PHARMACEUTICALS INC, PUERTO RICO
		CRESTOR 10MG TABLET MAL20041089ARZ	IPR PHARMACEUTICALS INC, PUERTO RICO
		CRESTOR 5 MG TABLET MAL20051356ARZ	IPR PHARMACEUTICALS INC, PUERTO RICO
445.	ROXITHROMYCIN *(List 6)*	RULID TABLET 150 MG MAL19890574AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
		This product can be obtained from **Thailand** and **Cambodia**. *(Source of information: Sanofi Aventis (M) Sdn. Bhd, 2013)*	
446.		JAKAVI 20MG TABLETS	NOVARTIS PHARMA STEIN AG

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

	RUXOLITINIB PHOSPHATE	MAL13025061ARZ	(SWITZERLAND)
		JAKAVI 15MG TABLETS MAL13025060ARZ	NOVARTIS PHARMA STEIN AG (SWITZERLAND)
		JAKAVI 10MG TABLETS MAL16075030ARZ	NOVARTIS PHARMA STEIN AG (SWITZERLAND)
		JAKAVI 5MG TABLETS MAL13025059ARZ	NOVARTIS PHARMA STEIN AG (SWITZERLAND)
447.	SAFINAMIDE MESYLATE	EQUFINA FILM COATED TABLETS 50 MG MAL23126005ACRZ	MEIJI SEIKA PHARMA CO., LTD., ODAWARA PLANT,(JAPAN)
448.	SALBUTAMOL SULPHATE *(List 5)*	VENTOLIN TABLETS 4MG MAL19962831ACRZ	ASPEN BAD OLDESLOE GMBH, GERMANY GLAXO WELLCOME GMBH & CO, GERMANY
		VENTOLIN TABLET 2MG MAL19961269ACRZ	ASPEN BAD OLDESLOE GMBH, GERMANY GLAXO WELLCOME GMBH & CO, GERMANY
		This product manufactured by Aspen Bad Oldesloe GMBH Germany is withdrawn worldwide *(Source of information: GSK Pharmaceutical Sdn. Bhd, 2024*	
		VENTOLIN ROTACAPS 400MCG MAL19870730A	GLAXO WELLCOME OPERATIONS, UNITED KINGDOM
		VENTOLIN ROTACAPS 200MCG MAL19870729A	GLAXO WELLCOME OPERATIONS, UNITED KINGDOM
449.	SAQUINAVIR MESYLATE	INVIRASE FILM-COATED TABLET 500MG MAL07081488ARZ	ROCHE FARMA S.A, SPAIN
		INVIRASE HARD-GELATIN CAPSULE 200MG MAL19970498ARZ	ROCHE FARMA S.A, SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			F.HOFFMANN-LA ROCHE LTD, SWITZERLAND
450.	SAXAGLIPTIN HYDROCHLORIDE	ONGLYZA TABLET 5MG MAL20102020ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
		ONGLYZA TABLET 2.5MG MAL20102019ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
451.	SELEGILINE HYDROCHLORIDE	JUMEX TABLET 5MG MAL19950723AZ	CHINOIN PHARMACEUTICAL AND CHEMICAL WORKS PVT. CO. LTD., HUNGARY
		This product can be obtained from **Austria, Bulgaria, Croatia, Czech Republic, Georgia, Greece, Honduras, Pakistan, Ukraine** and **Venezuela**. *(Source of information: Sanofi Aventis (M) Sdn. Bhd, 2020)*	
452.	SERTRALINE HYDROCHLORIDE *(List 7)*	ZOLOFT TABLET 100MG MAL19971290A	PFIZER PTY LTD, AUSTRALIA
		ZOLOFT TABLET 50MG MAL19971291ARZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH., GERMANY PFIZER AUSTRALIA PTY LTD, AUSTRALIA
		ZOLOFT TABLET 100MG MAL19921118A	PFIZER LTD, UNITED KINGDOM
		ZOLOFT TABLET 50MG MAL19921117A	PFIZER LTD, UNITED KINGDOM
453.	SEVELAMER CARBONATE	RENVELA (SEVELAMER CARBONATE) TABLET 800MG MAL20102007AZ	GENZYME IRELAND LIMITED, IRELAND SANOFI WINTHROP INDUSTRIE, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		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	
454.	SILDENAFIL CITRATE	VIAGRA 100MG TABLET MAL19990544A	PFIZER INC, UNITED STATES
		VIAGRA 50MG TABLET MAL19990543A	PFIZER INC, UNITED STATES
		VIAGRA 25MG TABLET MAL19990542A	PFIZER INC, UNITED STATES
		VIAGRA 100MG TABLET MAL20012711ACRZ	FAREVA AMBOISE, FRANCE PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		VIAGRA 50MG TABLET MAL20012710ACRZ	FAREVA AMBOISE, FRANCE PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		VIAGRA 25MG TABLET MAL20012709ARSZ	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		REVATIO 20 MG FILM-COATED TABLET MAL20071716ACRZ	FAREVA AMBOISE, FRANCE
455.	SILODOSIN	URIEF FILM COATED TABLETS 4MG MAL17117022ARZ	KISSEI PHARM CO LTD, JAPAN
456.	SIMVASTATIN *(List 6)*	ZOCOR 80MG TABLET MAL20020352ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		ZOCOR 40MG TABLET MAL19985911ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		ZOCOR TABLETS 20MG MAL19921416ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		ZOCOR TABLETS 10 MG	MERCK SHARP & DOHME LTD, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAL19921415ARZ	
		ZOCOR TABLET 5 MG MAL19940138AR	MERCK SHARP & DOHME LTD, UNITED KINGDOM
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 1/2010 – 8th December 2010 : Both parent drug and active metabolite (beta-hydroxyacid simvastatin) need to be analysed in BE study. However, BE study conducted prior to 8 December 2010 and analysis was only done on parent drug, the BE report can still be considered for evaluation.	
457.	SIROLIMUS *(List 7)*	RAPAMUNE TABLET 2MG MAL07031064AR	WYETH PHARMACEUTICALS CO., UNITED STATES
		RAPAMUNE TABLET 1MG MAL20032403ARZ	PFIZER IRELAND PHARMACEUTICALS WYETH PHARMA COMPANY, PUERTO RICO
458.	SITAGLIPTIN PHOSPHATE	JANUVIA 100 MG TABLET MAL20071664ACRZ	ORGANON PHARMA (UK) LIMITED, UNITED KINGDOM MERCK SHARP & DOHME LTD, UNITED KINGDOM
		JANUVIA 50 MG TABLET MAL20071663ACRZ	ORGANON PHARMA (UK) LIMITED, UNITED KINGDOM MERCK SHARP & DOHME LTD, UNITED KINGDOM
		JANUVIA 25 MG TABLET MAL20071662ACRZ	ORGANON PHARMA (UK) LIMITED, UNITED KINGDOM MERCK SHARP & DOHME LTD, UNITED KINGDOM
459.	SODIUM FUSIDATE 250MG	FUCIDIN TABLET 250MG (FILM COATED) MAL19910821AZ	LABORATOIRES LEO, FRANCE LEO PHARM PRODUCTS, DENMARK
460.	SOLIFENACIN SUCCINATE	VESICARE 10MG (FILM COATED TABLET)	ASTELLAS PHARMA EUROPE B.V, NETHERLANDS

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAL20091964AZ	
		Vesicare 10mg Film Coated Tablet can be obtained from **Australia, Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Indonesia, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Philippines, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Thailand and United Kingdom**. *(Source of information: Astellas Pharma Malaysia Sdn. Bhd., 2022)*	
		VESICARE 5 MG (FILM COATED TABLET) MAL20091963AZ	ASTELLAS PHARMA EUROPE B.V, NETHERLANDS
461.	SOFOSBUVIR	SOVALDI 400MG FILM-COATED TABLETS MAL15095034AZ	GILEAD SCIENCES IRELAND UC, IRELAND
462.	SORAFENIB TOSYLATE (EQ 200MG BASE)	NEXAVAR FILM-COATED TABLETS 200 MG MAL20071668AZ	BAYER AG, GERMANY BAYER SCHERING PHARMA AG, LEVERKUSEN, GERMANY
463.	SOTALOL HYDROCHLORIDE	SOTACOR TABLET 160MG MAL19930232A	BRISTOL-MYERS CO LTD, UNITED KINGDOM
		SOTACOR TABLET 80MG MAL19930231A	BRISTOL-MYERS CO LTD, UNITED KINGDOM
		SOTACOR TABLET 160MG MAL19940602AS	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
		SOTACOR TABLET 80MG MAL19940601AS	BRISTOL-MYERS SQUIBB PTY LTD, AUSTRALIA
464.	SOTORASIB	LUMAKRAS FILM-COATED TABLET 120MG MAL23096003ACRZ	PATHEON INC.(CANADA)
465.	SPIRAMYCIN	ROVAMYCINE 3 M.I.U. TABLETS MAL19962132AZ	FAMAR LYON, FRANCE
		ROVAMYCINE TABLET 1.5 MILLION IU MAL19890558A	FAMAR LYON, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

466.	SPIRONOLACTONE	ALDACTONE TABLET 100MG MAL19870236A	SEARLE LABS, AUSTRALIA
		ALDACTONE TABLET 25MG 1986030413A	SEARLE LABS, AUSTRALIA
		These products can be obtained from **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**. *(Source of information: Pfizer (M) Sdn Bhd, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2017 – 24th May 2017: Aldactone Tablet 25mg which is manufactured by **Piramal Healthcare UK Ltd, United Kingdom** and distributed by **Pfizer Australia Pty. Ltd,** is allowed to be used as a comparator.	
		Aldactone Tablet manufactured by Astrea Fontane, Farmasierra Manufacturing, Madrid is allowed to be used as a comparator. (Source of information: Pfizer (Malaysia) Sdn Bhd 2026)	
467.	STAVUDINE *(List 5)*	VIROSTAV CAPSULES 40MG MAL20033355AZ	RANBAXY (MALAYSIA) SDN BHD, MALAYSIA
		VIROSTAV CAPSULES 30MG MAL20033354AZ	RANBAXY (MALAYSIA) SDN BHD, MALAYSIA
468.	SULINDAC	CLINORIL 200MG TABLET MAL19950546A	MERCK SHARP & DOHME (AUSTRALIA) PTY LTD, AUSTRALIA
469.	SULODEXIDE	VESSEL DUE F 250 LSU CAPSULE MAL19992679AZ	ALFASIGMA S.P.A., ITALY ALFA WASSERMANN S.P.A., ITALY
470.	SULPIRIDE *(List 5)*	DOGMATIL 200MG TABLET MAL19913453AZ	SANOFI WINTHROP INDUSTRIE, FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			DELPHARM DIJON, FRANCE
		DOGMATIL 50MG CAPSULE MAL19930596AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
471.	SULTAMICILLIN TOSYLATE	UNASYN TABLET MAL19910104ARZ	PFIZER GLOBAL SUPPLY JAPAN INC, JAPAN
		UNASYN ORAL TABLET 375MG MAL20020026ACSZ	PHARMANIAGA MANUFACTURING BERHAD
472.	SUMATRIPTAN SUCCINATE	IMIGRAN TABLET 50MG MAL19973576ARZ	GLAXOSMITHKLINE PHARMACEUTICALS SA, POLAND
		This product can be obtained from **Cyprus, Croatia, Egypt, Singapore, Hong Kong, Thailand, Philippines, Republic of Korea, Great Britain, Germany, Greece, Norway, Poland, Turkey, Lithuania & Switzerland** *(Source of information: GlaxoSmithKline Pharmaceutical Sdn Bhd, 2019)*	
		IMIGRAN TABLET 100MG MAL19950008AZ	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
		This product is available in **Great Britain, Germany, Greece, Norway, Poland, Turkey & Lithuania**. *(Source of information: GlaxoSmithKline Pharmaceutical Sdn Bhd, 2019)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2019 – 3rd May 2019: Imigran Tablet 100mg manufactured by **GlaxoSmithKline Pharmaceuticals SA-Poznan, Poland** is allowed to be used as a comparator.	
473.	SUNITINIB MALATE	SUTENT 50MG CAPSULE MAL20071634AZ	PFIZER ITALIA S.R.L., ITALY
		SUTENT 25MG CAPSULE MAL20071633AZ	PFIZER ITALIA S.R.L., ITALY
		SUTENT 12.5MG CAPSULE MAL20071632AZ	PFIZER ITALIA S.R.L., ITALY
		This product is available in **Albania, Algeria, Argentina, Australia, Austria, Bahrain, Bangladesh, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Croatia, Republik Chech, Denmark, Finland,**	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		France, Germany, Greece, Hungary, India, Indonesia, Ireland, Italy, Jamaica, Jordan, Kuwait, Mexico, Nepal, Netherlands, New Zealand, Nigeria, Norway, Pakistan, Philipines, Poland, Portugal, Qatar, Saudi Arabia, Slovenia, Spain, Sri Lanka, Switzerland, Ukraine, United Kingdom, United States, Vietnam. *(Source of information: Pfizer (M) Sdn Bhd, 2023)*	
474.	TACROLIMUS *(List 7)*	PROGRAF CAPSULE 5MG MAL19990221AZ	ASTELLAS IRELAND CO. LTD, IRELAND
		PROGRAF CAPSULE 1MG MAL19990220AZ	ASTELLAS IRELAND CO. LTD, IRELAND
		PROGRAF CAPSULE 0.5MG MAL20031738AZ	ASTELLAS IRELAND CO. LTD, IRELAND
475.	TADALAFIL	CIALIS 20MG FILM COATED TABLET MAL20034166ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN
		CIALIS 10MG FILM COATED TABLET MAL20034164ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN
		CIALIS 5MG FILM-COATED TABLETS MAL14125149ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A., SPAIN
		CIALIS 2.5MG FILM-COATED TABLETS MAL14125151AZ	LILLY DEL CARIBE INC., PUERTO RICO
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2018 – 14th January 2019: bioequivalence studies conducted in both fasting and fed state are required for submission of new application starting 1st January 2020.	
476.	TAMOXIFEN CITRATE (EQ 20MG BASE) *(List 6)*	NOLVADEX-D TABLET 20MG MAL19870703ARZ	ASTRAZENECA UK LIMITED, UNITED KINGDOM
477.	TEGAFUR	FUTRAFUL CAPSULE 200MG MAL19861648A	TAIHO PHARM CO LTD, JAPAN
478.	TEGOPRAZAN	K-CAB 25MG FILM-COATED TABLET MAL26066005AZ	HK INNO. N CORPORATION (KOREA, SOUTH)

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

479.	TELBIVUDINE	SEBIVO 600 MG TABLETS MAL20071671ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
480.	TELITHROMYCIN	KETEK 400MG TABLET MAL20033479AZ	AVENTIS PHARMA S.P.A, ITALY
481.	TELMISARTAN	MICARDIS TABLET 80MG MAL19992674AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		MICARDIS TABLET 40MG MAL19992673AZ	BOEHRINGER INGELHEIM ELLAS A.E, GREECE BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
		MICARDIS TABLET 20MG MAL20014487A	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, WEST GERMANY
482.	TEMOZOLOMIDE	TEMODAL CAPSULES 250 MG MAL06071051ACRS	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 100MG MAL07082881ACRZ	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 20 MG MAL06071049ACRSZ	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 20MG MAL07082880ACRZ	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 5 MG MAL06071048ACRS	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 5MG MAL07082878ACR	ORION CORPORATION, ORION PHARMA, FINLAND
		TEMODAL CAPSULES 5MG MAL20032407AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES
		TEMODAL CAPSULES 250MG MAL20032410AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		TEMODAL CAPSULES 100MG MAL20032409AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES
		TEMODAL CAPSULES 20MG MAL20032408AR	INTEGRATED THERAPEUTICS GROUP INC, UNITED STATES
		These products can be obtained from **Canada, United Kingdom and EU (Austria, Belgium, Czech Republic, Germany, Switzerland, Serbia, Slovenia)** *(Source of information: Merck Sharp & Dohme Sdn Bhd, 2024)*	
483.	TENOFOVIR ALAFENAMIDE FUMARATE (EQ 25MG BASE)	VEMLIDY (TENOFOVIR ALAFENAMIDE 25MG) FILM-COATED TABLETS MAL18056111ACZ	PATHEON INC., CANADA
484.	TENOFOVIR DISOPROXIL FUMARATE 300MG	TENVIR FILM-COATED TABLET MAL20091933AZ	CIPLA LTD, INDIA
485.	TENOXICAM	TILCOTIL`ROCHE`LACQ-COATED TAB 20MG MAL19890224A	F. HOFFMAN-LA ROCHE, SWITZERLAND
		As agreed upon *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2016 – 16th June 2016: Tilcotil Tablet manufactured by **Cenexi SAS, France** is allowed to be used as comparator.	
486.	TERAZOSIN HYDROCHLORIDE	HYTRIN 5MG TABLET MAL20014490ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM
		HYTRIN 2MG TABLET MAL20014489ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM
		HYTRIN 1MG TABLET MAL20014488ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM
		HYTRIN TABLET 5MG MAL19970936A	ABBOTT AUSTRALIA P/L, AUSTRALIA
		HYTRIN TABLET 2MG MAL19970935A	ABBOTT AUSTRALIA P/L, AUSTRALIA
		HYTRIN TABLET 1MG MAL19970934A	ABBOTT AUSTRALIA P/L, AUSTRALIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		HYTRIN 5MG MAL19920458A	ABBOTT LABORATORIES, UNITED STATES
		HYTRIN 2MG TABLET MAL19920457A	ABBOTT LABORATORIES, UNITED STATES
		HYTRIN 1MG TABLET MAL19920456A	ABBOTT LABORATORIES, UNITED STATES
487.	TERBINAFINE HYDROCHLORIDE *(List 8)*	LAMISIL 250MG TABLET MAL20000273ACRZ	NOVARTIS PHARM UK LTD, UNITED KINGDOM
		LAMISIL 125MG TABLET MAL19930423A	NOVARTIS PHARM UK LTD, UNITED KINGDOM
		Lamisil Tablet 250mg is no longer marketed in Malaysia. It can be obtained from **Singapore, Hong Kong, China and Australia**. *(Source of information: Novartis (M) Sdn.Bhd, 2014)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2017 – 24th May 2017: Lamisil 250mg Tablet manufactured by **Novartis Pharma Produktions GmbH, Wehr, Germany** is allowed to be used as a comparator.	
488.	TERBUTALINE SULPHATE *(List 4)*	BRITALINE TABLET 2.5MG MAL19890080AZ	DUOPHARMA (M) SDN BHD, MALAYSIA
		PHARMANIAGA TERBUTALINE TABLET 2.5MG MAL19920521AZ	PHARMANIAGA MANUFACTURING SDN BHD, MALAYSIA
489.	TERIFLUNOMIDE 14MG	AUBAGIO 14MG FILM-COATED TABLETS MAL15045075AZ	SANOFI WINTHROP INDUSTRIE, FRANCE OPELLA HEALTHCARE INTERNATIONAL SAS, FRANCE
490.	TESTOSTERONE UNDECANOATE 40MG	ANDRIOL TESTOCAPS CAPSULES 40MG MAL05032535ACZ	CATALENT FRANCE BEINHEIM SA, FRANCE
		ANDRIOL CAPSULE 40MG MAL19870663A	R.P SCHERER GMBH & CO KG, GERMANY
491.	TETRACYCLINE HYDROCHLORIDE 250MG	TETRACYCLINE MC CAPSULE 250MG MAL19860535AZ	MEDOCHEMIE LTD, CYPRUS

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

	(List 8)		
492.	THALIDOMIDE	DOMIDE 50MG CAPSULE, MAL20102065AZ	TTY BIOPHARM COMPANY LIMITED, TAIWAN
493.	THEOPYLLINE *(List 3)*	NUELIN TABLET 125MG MAL19872131A	INOVA PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA * FORMERLY KNOWN AS 3M PHARMACEUTICALS (AUSTRALIA) PTY LTD, AUSTRALIA
		NEULIN TABLET 200MG MAL19872136A	3M PHARMACEUTICALS PTY LTD, AUSTRALIA
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 2/2015 – 7th September 2015: the following product is being added as additional comparator in Malaysia:	
		PHARMANIAGA THEOPHYLLINE TABLET 125MG MAL19872133AZ	PHARMANIAGA MANUFACTURING BERHAD, MALAYSIA
494.	THIOGUANINE 40MG	LANVIS TABLETS 40MG MAL13065045ACZ	EXCELLA GMBH & CO. KG, GERMANY
		LANVIS TABLETS 40MG MAL05032537ACR	DSM PHARMACEUTICALS INC, UNITED STATES
495.	TIBOLONE 2.5MG	LIVIAL TABLET 2.5MG MAL19913394AZ	N.V. ORGANON, NETHERLANDS
496.	TICAGRELOR	BRILINTA 90MG FILM-COATED TABLET MAL20112115ARZ	ASTRAZENECA AB, SWEDEN ASTRAZENECA PHARMACEUTICAL CO. LTD. (CHINA)
		BRILINTA 60 MG FILM-COATED TABLET MAL18046135AZ	ASTRAZENECA AB, SWEDEN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

			ASTRAZENECA PHARMACEUTICAL CO. LTD. (CHINA)
497.	TICLOPIDINE HYDROCHLORIDE 250MG *(List 6)*	TICLID FILM COATED TABLET 250 MG MAL19930512ARZ	SANOFI-AVENTIS, S.A, SPAIN
498.	TINIDAZOLE *(List 8)*	SPORINEX TABLET 500MG MAL19900273A	MEDOCHEMIE LTD, CYPRUS
		TINIREM 500 TABLETS MAL19900270A	REMEDICA LTD, CYPRUS
499.	TALAZOPARIB TOSYLATE	TALZENNA 1MG HARD CAPSULES MAL21086004ACRZ	EXCELLA GMBH & CO.KG，GERMANY
		TALZENNA 0.25MG HARD CAPSULES MAL21086003ACRZ	EXCELLA GMBH & CO.KG，GERMANY
		TALZENNA 0.1MG HARD CAPSULES MAL26096001ACRZ	EXCELLA GMBH & CO.KG (GERMANY)
500.	TOFACITINIB CITRATE	XELJANZ FILM-COATED TABLETS 5MG MAL14075067AZ	PFIZER MANUFACTURING DEUTSCHLAND GMBH, GERMANY
501.	TOLTERODINE L-TARTRATE 2MG	DETRUSITOL TABLET 2MG MAL19991686ARZ	PFIZER ITALIA S.R.L., ITALY
502.	TOPIRAMATE *(List 7)*	TOPAMAX TABLET 200MG MAL20013559AZ	CILAG AG, SWITZERLAND
		TOPAMAX TABLET 100MG MAL20013561AZ	CILAG AG, SWITZERLAND
		TOPAMAX TABLET 50MG MAL20013560AZ	CILAG AG, SWITZERLAND
		TOPAMAX TABLET 25MG MAL20013558AZ	CILAG AG, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

503.	TOPOTECAN HYDROCHLORIDE	HYCAMTIN 1 MG HARD CAPSULES MAL20091961ACZ	GLAXOSMITHKLINE MANUFACTURING S.P.A, ITALY
		HYCAMTIN 0.25MG HARD CAPSULES MAL20091960ACZ	GLAXOSMITHKLINE MANUFACTURING S.P.A, ITALY
504.	TOLVAPTAN	SAMSCA TOLVAPTAN TABLET 15MG MAL22066001ACZ	KOREA OTSUKA PHARMACEUTICAL CO LTD (KOREA,SOUTH)
		JINARC TABLETS 15 MG MAL24036007ARZ	OTSUKA PHARMACEUTICAL CO., LTD (JAPAN)
		JINARC TABLETS 30 MG MAL24036006ARZ	OTSUKA PHARMACEUTICAL CO., LTD (JAPAN)
		JINARC 45 MG AND JINARC 15 MG TABLETS MAL24036005ARZ	OTSUKA PHARMACEUTICAL CO., LTD (JAPAN)
		JINARC 60 MG AND JINARC 30 MG TABLETS MAL24036004ARZ	OTSUKA PHARMACEUTICAL CO., LTD (JAPAN)
		JINARC 90 MG AND JINARC 30 MG TABLETS MAL24036003ARZ	OTSUKA PHARMACEUTICAL CO., LTD (JAPAN)
		Tolvaptan is currently registered in Malaysia under two distinct brand names: **Samsca®** and **Jinarc®**. Both products are registered for significantly different therapeutic indications and dosing regimens. The selection of the Malaysia Comparator Product (MCP) must be indication-specific.	
505.	TRANEXAMIC ACID 250MG	TRANSAMIN CAPSULE 250MG MAL19890202ACZ	CMIC CMO CO. LTD, JAPAN
506.	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**. *(Source of information: Grunenthal Gmbh, Germany, 2013)*	

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2015 – 21st April 2015: Tramal Capsule (MAL19921516A) from **Farmaceutici Formenti S.P.A, Via di Vittorio 2, 21040 Oriddio, Italy** is allowed to be used as comparator.	
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2015" – 21 April 2015: Tramadolor 50 Capsule (MAL19985903AC) and Tramox Capsule 50mg (MAL08042453AC) are being added as additional comparator in Malaysia.	
		TRAMADOLOR 50 CAPSULE MAL19985903ACZ	SALUTAS PHARMA GMBH, GERMANY
		TRAMOX CAPSULE 50MG MAL08042453ACZ	DELORBIS PHARMACEUTICALS, CYPRUS AEGIS LTD, CYPRUS
507.	TRETINOIN 10MG	VESANOID SOFT-GELATIN CAPSULE 10MG MAL19960996ACRZ	CATALENT GERMANY EBERBACH GMBH, GERMANY
508.	TRIAZOLAM 0.25MG	SOMESE TABLET 0.25 MG MAL07050020ARZ	PFIZER ITALIA S.R.L., ITALY SANICO N.V., BELGIUM
509.	TRIENTINE DIHYDROCHLORIDE 250MG	COCHEL 250MG CAPSULES MAL25086002AZ	MSN LABORATORIES PRIVATE LIMITED (INDIA)
510.	TRIFLUOPERAZINE HYDROCHLORIDE *(List 9)*	STELAZINE TABLET 5MG PBKD861379A	SMITH KLINE & FRENCH (AUST) LTD, AUSTRALIA
		STELAZINE TABLET 1MG PBKD861375A	SMITH KLINE & FRENCH (AUST) LTD, AUSTRALIA
		STELAZINE CAPSULE 2MG MAL19871465A	SMITH KLINE & FRENCH LABS, UNITED KINGDOM
		These products can be obtained from Singapore. *(Source of information: Mesyuarat JKKBE 02/2011)*	
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2017" – 24 May 2017, the following product is being added as additional comparator in Malaysia.	
		APO-TRIFLUOPERAZINE 5MG MAL19984755AZ	APOTEX INC, CANADA
511.	TRIFLUSAL 300MG	GRENDIS 300MG CAPSULE MAL20051420AZ	J. URIACH Y COMPAÑÍA, S.A, SPAIN

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

512.	TRIMEBUTINE MALEATE	DEBRIDAT TABLET 1990040029A	JOUVEINAL LABS, FRANCE
513.	TRIMETAZIDINE HYDROCHLORIDE/ TRIMETAZIDINE DIHYDROCHLORIDE	VASTAREL COATED TABLET 20MG MAL19870169AZ	LES LABS SERVIER INDUSTRIE, FRANCE
514.	TRIMETHOPRIM *(List 8)*	ALPRIM 300 TABLET MAL19940099AZ	ALPHAPHARM PTY LTD, AUSTRALIA
		Alprim 300mg Tablet can be obtained from **Australia** and **New Zealand**. *(Source of information: Pahang Pharmacy (M) Sdn Bhd, 2015)*	
515.	ULIPRISTAL ACETATE	ELLA TABLET 30MG MAL12035079ACZ	CENEXI, FRANCE
		ESMYA 5MG TABLETS MAL15025044ACZ	CENEXI, FRANCE
516.	URSODEOXYCHOLIC ACID 250MG	URSOFALK CAPSULE 250MG MAL19990011ACSZ	LOSAN PHARMA GMBH, GERMANY
517.	VALACICLOVIR HYDROCHLORIDE *(List 7)*	VALTREX TABLET 500MG MAL19962817ARZ	GLAXO WELLCOME S.A, SPAIN
		VALTREX 250MG TABLET MAL20020133A	GLAXO WELLCOME OPERATIONS UK LTD, UNITED KINGDOM
518.	VALGANCICLOVIR HYDROCHLORIDE (EQ 450MG BASE)	VALCYTE TABLETS 450MG MAL20040021ARZ	PATHEON INC, CANADA
519.	VALSARTAN *(List 7)*	DIOVAN 320MG FILM-COATED TABLET MAL07050032ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		DIOVAN 160MG FILM-COATED TABLET MAL20021003A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		DIOVAN 80MG FILM-COATED TABLET MAL20021002A	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		DIOVAN 40MG FILM-COATED TABLET	NOVARTIS PHARMA STEIN AG, SWITZERLAND

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAL06051320A	
		DIOVAN 160MG FILM-COATED TABLET MAL09042431ARZ	NOVARTIS FARMA S.P.A. (ITALY)
		DIOVAN 80MG FILM-COATED TABLET MAL09042430ARZ	NOVARTIS FARMA S.P.A. (ITALY)
		DIOVAN 40MG FILM-COATED TABLET MAL09042429ARZ	NOVARTIS FARMA S.P.A. (ITALY)
520.	VANCOMYCIN HYDROCHLORIDE	VANCOCIN MATRIGEL CAPSULE 250MG MAL19930570A	ELI LILLY & CO, UNITED STATES
		VANCOCIN MATRIGEL CAPSULE 125MG MAL19930569AR	ELI LILLY & CO, UNITED STATES
		As agreed upon in *Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan* 1/2021 – 26 October 2021: Vancocin Capsule from **ANI Pharmaceuticals**, which is available in the United States is allowed to be used as comparator. Bioequivalence study is not required due to local effect. However, *in vitro* study is required to support the interchangeability between the test and comparator product as per USFDA Draft Guidance on Vancomycin Hydrochloride and EMA Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally acting products in the gastrointestinal tract.	
521.	VARENICLINE 0.5MG	CHAMPIX 0.5MG FILM COATED TABLET MAL20081740AZ	PFIZER ITALIA S.R.L (ITALY)
522.	VARENICLINE 1.0MG	CHAMPIX 1.0MG FILM COATED TABLET MAL20081741AZ	PFIZER ITALIA S.R.L (ITALY)
		Champix can be obtained from **United Kingdom**, **Romania**, **New Zealand**, and **Thailand**. (Source: Pfizer Malaysia Sdn Bhd 2026)	
523.	VIGABATRIN	SABRIL 500MG TABLET MAL19961357AZ	PATHEON FRANCE S.A., FRANCE

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

524.	VILDAGLIPTIN	GALVUS 50MG TABLETS MAL20081792ARZ	NOVARTIS FARMACEUTICA S.A, SPAIN LEK PHARMACEUTICALS D.D. (SLOVENIA)
525.	VINORELBINE TARTRATE	NAVELBINE 30MG SOFT CAPSULE MAL20071636AZ	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
		NAVELBINE 20MG SOFT CAPSULE MAL20071635AZ	PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE
526.	VONOPRAZAN FUMARATE	VOCINTI 20MG FILM-COATED TABLET MAL19056003ARZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
		VOCINTI 10MG FILM-COATED TABLET MAL19056002ARZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
527.	VORICONAZOLE	VFEND 200MG TABLET MAL20040543ARZ	PFIZER ITALIA S.R.L ITALY PFIZER MANUFACTURING DEUTSHLAND GMBH, GERMANY
		VFEND 50MG TABLET MAL20040542ARZ	PFIZER ITALIA S.R.L ITALY PFIZER MANUFACTURING DEUTSHLAND GMBH, GERMANY
528.	VORINOSTAT 100MG	ZOLINZA 100MG CAPSULE MAL20102001ACRZ	PATHEON INC., CANADA
529.	VORTIOXETINE HYDROBROMIDE	BRINTELLIX 20MG FILM-COATED TABLETS MAL15045163AZ	H. LUNDBECK A/S, DENMARK
		BRINTELLIX 15MG FILM-COATED TABLETS MAL15045162AZ	H. LUNDBECK A/S, DENMARK
		BRINTELLIX 10MG FILM-COATED TABLETS	H. LUNDBECK A/S, DENMARK

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		MAL15045160AZ	
		BRINTELLIX 5MG FILM-COATED TABLETS MAL15045161AZ	H. LUNDBECK A/S, DENMARK
530.	VENETOCLAX	VENCLEXTA TABLET 10MG MAL18061001ARZ	ABBVIE IRELAND NL B.V, IRELAND
		VENCLEXTA TABLET 50MG MAL18061002ARZ	ABBVIE IRELAND NL B.V, IRELAND
		VENCLEXTA TABLET 100MG MAL18061003ARZ	ABBVIE IRELAND NL B.V, IRELAND
531.	WARFARIN SODIUM *(List 4)*	COUMADIN TABLET 5MG MAL19880128A	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, UNITED STATES
		COUMADIN TABLET 2MG MAL19880127A	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, UNITED STATES
		COUMADIN 1MG TABLET MAL19992058AS	BRISTOL-MYERS SQUIBB HOLDINGS PHARMA LTD, UNITED STATES
		APO-WARFARIN 5MG MAL20021396AZ	APOTEX INC, CANADA
		APO- WARFARIN 2MG TABLET MAL20021395AZ	APOTEX INC, CANADA
		APO-WARFARIN 1MG TABLET MAL20021394AZ	APOTEX INC, CANADA
		ORFARIN 5MG TABLET MAL20041004AZ	ORION CORPORATION, FINLAND
		ORFARIN TABLET 3MG MAL19921323AZ	ORION CORPORATION, FINLAND
532.	ZIDOVUDINE	RETROVIR CAPSULE 100MG MAL19880248AZ	S.C. EUROPHARM S.A, ROMANIA GLAXOSMITHKLINE PHARMACEUTICALS SA POLAND SMITHKLINE BEECHAM PHARM, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

		RETROVIR TABLET 300MG MAL19983998A	GLAXO WELLCOME OPERATIONS, UNITED KINGDOM
		This product can be obtained from **Singapore**, **Taiwan** & **Indonesia**. *(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2013)*	
		As agreed upon in *Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan* 2/2013 – 2nd September 2013: the following products are being added as additional comparators in Malaysia.	
		ZIDOVUDINE CAPSULES USP 100MG MAL10053660AZ	M/S AUROBINDO PHARMA LTD, INDIA
		ZIDOVUDINE TABLETS USP 300MG MAL08051751AZ	M/S AUROBINDO PHARMA LTD, INDIA
		ZIDOVUDINE TABLETS 300MG MAL12070004AZ	MYLAN LABORATORIES LIMITED, INDIA MATRIX LABORATORIES LTD, INDIA
533.	ZIPRASIDONE HYDROCHLORIDE *(List 9)*	ZELDOX CAPSULE 80MG MAL20032625AZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		ZELDOX CAPSULE 60MG MAL20032624ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		ZELDOX CAPSULE 40MG MAL20032623ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND PFIZER AUSTRALIA PTY. LTD., AUSTRALIA
		ZELDOX CAPSULE 20MG MAL20032622A	PFIZER AUSTRALIA PTY. LTD., AUSTRALIA

LIST OF COMPARATOR PRODUCTS FOR IMMEDIATE RELEASE TABLET OR CAPSULE (SINGLE INGREDIENT)

534.	ZOFENOPRIL CALCIUM	BIFRIL 30 MAL20061470AZ	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L., ITALY
535.	ZOLPIDEM TARTRATE 10MG *(List 9)*	STILNOX 10MG FILM COATED TABLET MAL19940650ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE
536.	ZONISAMIDE 100MG	ZONEGRAN 100MG TABLETS MAL15085074ACZ	BORA PHARMACEUTICALS CO.,LTD.(TAIWAN)
537.	ZOPICLONE *(List 9)*	IMOVANE TABLET 7.5MG MAL19900140AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
538.	ZUCLOPENTHIXOL	CLOPIXOL TABLET 10MG MAL19890537A	H. LUNDBECK A/S, DENMARK

Note:
This list is non-exhaustive and will be updated from time to time. For further clarification, kindly email to be_sug@npra.gov.my

Updated on 17/11/2026.