

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
1.	ACEMETACIN	RANTUDIL RETARD 90MG CAPSULE MAL19992054AZ	BAYER SCHERING PHARMA AG, GERMANY
2.	ALFUZOSIN 10MG	XATRAL XL 10MG TABLET MAL20020894AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
3.	BAZEDOXIFENE ACETATE (EQ 20MG BASE) AND CONJUGATED ESTROGENS 0.45MG	DUAVIVE 20 MG/0.45 MG MODIFIED – RELEASE TABLETS MAL16105047AZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
4.	BENSERAZIDE HYDROCHLORIDE 25MG AND LEVODOPA 100MG	MADOPAR 'ROCHE' HBS CAPSULE MAL19900240ACRZ	DELPHARM MILANO S.R.L, ITALY
5.	BUDESONIDE 9MG	CORTIMENT PROLONGED RELEASE TABLETS 9MG MAL18066050ACZ	COSMO S.P.A., ITALY
6.	BUPROPION HYDROCHLORIDE 150MG	WELLBUTRIN SR TABLETS MAL20081803ARZ	GLAXOSMITHKLINE LLC, UNITED STATES
		Product is available in United States, Hong Kong, Singapore, Latvia and Slovakia. <i>(Source of information: GlaxoSmithKline Pharmaceutical Sdn. Bhd, 2021)</i>	
7.	CARBAMAZEPINE 400MG	TEGRETOL CR 400MG TABLETS MAL20000269ACRZ	NOVARTIS FARMA S.P.A., ITALY
	CARBAMAZEPINE 400MG	TEGRETOL CR 200MG TABLETS MAL20000749ACRZ	NOVARTIS FARMA S.P.A., ITALY
8.	CARBIDOPA 50MG AND LEVODOPA 200MG	SINEMET CR 50/200 CONTROLLED-RELEASE TABLET MAL12125048ACRZ	MYLAN PHARMACEUTICALS INC., UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
9.	CETIRIZINE DIHYDROCHLORIDE 5MG AND PSEUDOEPHEDRINE HYDROCHLORIDE 120MG	ZYRTEC-D TABLET MAL06061671ARZ	UCB FARCHIM S.A., SWITZERLAND
10.	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (EQ 10MG BASE) AND METFORMIN HYDROCHLORIDE 1000MG	XIGDUO XR TABLET 10/1000MG MAL16045040AZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (EQ 10MG BASE) AND METFORMIN HYDROCHLORIDE 500MG	XIGDUO XR TABLET 10/500MG MAL16045044AZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
	DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (EQ 5MG BASE) AND METFORMIN HYDROCHLORIDE 1000MG	XIGDUO XR TABLET 5/1000MG MAL16045043AZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
11.	DARIFENACIN HYDROBROMIDE (EQ 15MG BASE)	ENABLEX 15MG PROLONGED-RELEASE TABLETS MAL20081779AZ	ASPEN BAD OLDESLOE GMBH, GERMANY
	DARIFENACIN HYDROBROMIDE (EQ 7.5MG BASE)	ENABLEX 7.5MG PROLONGED-RELEASE TABLETS MAL20081778AZ	ASPEN BAD OLDESLOE GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
12.	DESLORATADINE 2.5MG AND PSEUDOEPHEDRINE SULPHATE 120 MG	AERIUS D-12 MODIFIED RELEASE TABLET MAL11050002ACRZ	PATHEON INC., CANADA
13.	DESVENLAFAXINE SUCCINATE (EQ 100MG BASE)	PRISTIQ 100 MG EXTENDED-RELEASE TABLETS MAL20091919AZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
	DESVENLAFAXINE SUCCINATE (EQ 50MG BASE)	PRISTIQ 50 MG EXTENDED-RELEASE TABLETS MAL20091918ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
14.	DEXLANSOPRAZOLE 60MG	DEXILANT DELAYED RELEASE CAPSULES 60MG MAL14015010AZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
	DEXLANSOPRAZOLE 30MG	DEXILANT DELAYED RELEASE CAPSULES 30MG MAL14015012AZ	TAKEDA PHARMACEUTICAL COMPANY LIMITED, JAPAN
15.	DICLOFENAC SODIUM 100MG	VOLTAREN SR 100 TABLET MAL19861070ARZ	NOVARTIS FARMA S.P.A., ITALY
	DICLOFENAC SODIUM 75MG	VOLTAREN SR 75MG FILM COATED TABLET MAL19930374ARZ	NOVARTIS FARMA S.P.A., ITALY
	DICLOFENAC SODIUM 50MG	VOLTAREN TABLET 50MG MAL19861068ARZ	NOVARTIS SAGLIK, TURKEY NOVARTIS FARMA S.P.A., ITALY
	DICLOFENAC SODIUM 25MG	VOLTAREN TABLET 25MG MAL19861069AZ	NOVARTIS SAGLIK, TURKEY NOVARTIS FARMA S.P.A., ITALY
16.	DIDANOSINE 400MG	VIDEX EC DELAYED-RELEASE CAPSULE 400MG MAL20021391A	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	DIDANOSINE 250MG	VIDEX EC DELAYED-RELEASE CAPSULE 250MG MAL20021390A	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
	DIDANOSINE 200MG	VIDEX EC DELAYED-RELEASE CAPSULE 200MG MAL20021389A	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
	DIDANOSINE 125MG	VIDEX EC DELAYED-RELEASE CAPSULE 125MG MAL20021388A	BRISTOL-MYERS SQUIBB COMPANY, UNITED STATES
17.	DILTIAZEM HYDROCHLORIDE 90MG	HERBESSER 90 SR CAPSULE MAL19920505AZ	PT MITSUBISHI TANABE PHARMA INDONESIA
	DILTIAZEM HYDROCHLORIDE 200MG	HERBESSER R200 SUSTAINED RELEASE CAPSULE MAL20000016ARZ	mitsubishi tanabe pharma factory ltd., onoda plant, JAPAN
	DILTIAZEM HYDROCHLORIDE 100MG	HERBESSER R100 SUSTAINED RELEASE CAPSULE MAL20000015ARZ	mitsubishi tanabe pharma factory ltd., onoda plant, JAPAN
18.	DIMETHYL FUMARATE 240MG	TECFIDERA 240MG GASTRO-RESISTANT HARD CAPSULES MAL15085078ACRZ	VIFOR SA, SWITZERLAND
	DIMETHYL FUMARATE 120MG	TECFIDERA 120 MG GASTRO-RESISTANT HARD CAPSULES MAL15085076ACRZ	VIFOR SA, SWITZERLAND
		Product can be obtained from Singapore.	
19.	DOXAZOSIN MESYLATE (EQ 4MG BASE)	CARDURA-XL TABLET 4MG MAL20040550ARZ	PFIZER PHARMACEUTICALS LLC (PFIZER BARCELONETA), PUERTO RICO
20.	DULOXETINE HYDROCHLORIDE (EQ 60MG BASE)	CYMBALTA CAPSULE 60MG MAL05092474ARZ	LILLY DEL CARIBE INC., PUERTO RICO
			LILLY S.A, SPAIN

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	DULOXETINE HYDROCHLORIDE (EQ 30MG BASE)	CYMBALTA CAPSULE 30MG MAL05092473ARZ	LILLY DEL CARIBE INC., PUERTO RICO LILLY S.A, SPAIN
21.	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (EQ 40MG BASE)	NEXIUM MUPS TABLET 40MG MAL20020239ARZ	ASTRAZENECA AB, SWEDEN
	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (EQ 40MG BASE)	NEXIUM MUPS TABLET 20MG MAL20020238ARZ	ASTRAZENECA AB, SWEDEN
22.	FELODIPINE 10MG	PLENDIL 10MG ER TABLETS (9MM) MAL19972985AZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA
	FELODIPINE 5MG	PLENDIL 5 ER TABLETS (9MM) MAL19972986AZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA
	FELODIPINE 2.5MG	PLENDIL 2.5MG ER TABLET MAL19940655AZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA
23.	FESOTERODINE FUMARATE 8MG	TOVIAZ 8 MG PROLONGED-RELEASE TABLETS MAL20102018ACRZ	AESICA PHARMACEUTICALS GMBH, GERMANY
	FESOTERODINE FUMARATE 4MG	TOVIAZ 4 MG PROLONGED-RELEASE TABLETS MAL20102017ACRZ	AESICA PHARMACEUTICALS GMBH, GERMANY
24.	FEXOFENADINE HYDROCHLORIDE 60MG AND PSEUDOEPHEDRINE HYDROCHLORIDE 120MG	TELFAS-T TABLET MAL20040553ARZ	SANOFI WINTHROP INDUSTRIE, FRANCE SANOFI-AVENTIS US LLC

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
25.	FLUVASTATIN SODIUM (EQ 80MG BASE)	LESCOL XL 80MG TABLETS MAL20032266ARZ	NOVARTIS FARMACEUTICA S.A., SPAIN
26.	GALANTAMINE HYDROBROMIDE (EQ 24MG BASE)	REMINYL PROLONGED RELEASE CAPSULES 24MG MAL20091917AZ	JANSSEN CILAG S.P.A., ITALY
	GALANTAMINE HYDROBROMIDE (EQ 16MG BASE)	REMINYL PROLONGED RELEASE CAPSULES 16MG MAL20091916AZ	JANSSEN CILAG S.P.A., ITALY
	GALANTAMINE HYDROBROMIDE (EQ 8MG BASE)	REMINYL PROLONGED RELEASE CAPSULES 8MG MAL20091915AZ	JANSSEN CILAG S.P.A., ITALY
27.	GLICLAZIDE 60MG	DIAMICRON MR TABLETS 60 MG MAL10080067AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		DIAMICRON MR 60MG, MODIFIED RELEASED TABLET MAL13055061ACSZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA
	GLICLAZIDE 30MG	DIAMICRON MR TABLET 30MG MAL20021130AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		DIAMICRON MR, MODIFIED RELEASE TABLET, 30MG MAL08010764ACSZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA
28.	GLIMEPIRIDE 2MG AND METFORMIN HYDROCHLORIDE 500MG	AMARYL M SR 2/500MG TABLET MAL11030017AZ	HANDOK INC., SOUTH KOREA
29.	INDAPAMIDE 1.5MG	NATRILIX SR, SUSTAINED-RELEASE COATED TABLET	LES LABS SERVIER INDUSTRIE, FRANCE

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		MAL19973570AZ	
30.	INDAPAMIDE 1.5MG AND AMLODIPINE BESILATE (EQ 5MG BASE)	NATRIXAM 1.5MG/5MG, MODIFIED RELEASE TABLETS MAL15125048AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE
	INDAPAMIDE 1.5MG AND AMLODIPINE BESILATE (EQ 10MG BASE)	NATRIXAM 1.5MG/10MG, MODIFIED-RELEASE TABLETS MAL15125049AZ	LES LABORATOIRES SERVIER INDUSTRIE, FRANCE
31.	ISOSORBIDE-5-MONONITRATE 60MG	IMDUR 60MG TABLET MAL19940090ACZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA
	ISOSORBIDE-5-MONONITRATE 30MG	IMDUR 30MG TABLET MAL19940091ACZ	ASTRAZENECA PHARMACEUTICAL CO. LTD., CHINA
32.	KETOPROFEN 100MG	ORUDIS E-100 TABLET (E/C) MAL19940625A	PT AVENTIS PHARMA, INDONESIA
33.	LEVETIRACETAM 500MG	MONAVRI XR 500MG EXTENDED RELEASE TABLET MAL16025028AZ	UCB PHARMA S.A. BELGIUM
		Product is available in Korea, Mexico , and United States under the brand name Keppra XR . (Source of information: Paraxel International, 2020)	
34.	LORATADINE 10MG AND PSEUDOEPHEDRINE SULPHATE 240MG	CLARINASE 24HR EXTENDED RELEASE TABLETS MAL20040896ACZ	SAG MANUFACTURING S.L.U., SPAIN
	LORATADINE 5MG AND PSEUDOEPHEDRINE SULPHATE 120MG	CLARINASE REPETABS MAL19930250ACZ	SCHERING-PLOUGH LABO N.V., BELGIUM

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
35.	MESALAZINE 1200MG	MEZAVANT XL 1200MG, GASTRO-RESISTANT, PROLONGED RELEASE TABLETS MAL17085067ACZ	COSMO SPA, ITALY
	MESALAZINE 1000MG	PENTASA PROLONGED RELEASE TABLET 1000MG MAL15045066AZ	FERRING INTERNATIONAL CENTER SA, SWITZERLAND
	MESALAZINE 500MG	SALOFALK 500MG GASTRO-RESISTANT TABLETS MAL19987336ACSZ PENTASA PROLONGED RELEASE TABLET 500MG MAL19940439AZ	LOSAN PHARMA GMBH, GERMANY FERRING INTERNATIONAL CENTER SA, SWITZERLAND
	MESALAZINE 250MG	SALOFALK 250MG GASTRO-RESISTANT TABLET MAL19987335ACSZ	LOSAN PHARMA GMBH, GERMANY
36.	METFORMIN HYDROCHLORIDE 1000MG	GLUCOPHAGE XR 1000MG EXTENDED RELEASE TABLET MAL15065037AZ	MERCK SANTE S.A.S., FRANCE
	METFORMIN HYDROCHLORIDE 750MG	GLUCOPHAGE XR 750MG TABLET MAL10033141AZ	MERCK SANTE S.A.S., FRANCE
	METFORMIN HYDROCHLORIDE 500MG	GLUCOPHAGE XR 500 MG TABLET MAL07050002AZ	MERCK SANTE S.A.S., FRANCE
37.	METHYLPHENIDATE HYDROCHLORIDE 40MG	RITALIN LA MODIFIED-RELEASE CAPSULES 40MG MAL05092210ACRZ	RECRO GAINESVILLE LLC, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	METHYLPHENIDATE HYDROCHLORIDE 30MG	RITALIN LA MODIFIED-RELEASED CAPSULE 30MG MAL05092208ACRZ	RECRO GAINESVILLE LLC, UNITED STATES
	METHYLPHENIDATE HYDROCHLORIDE 20MG	RITALIN LA MODIFIED-RELEASE CAPSULE 20MG MAL05092201ACRZ	RECRO GAINESVILLE LLC, UNITED STATES
	METHYLPHENIDATE HYDROCHLORIDE 40MG	MEDIKINET MR 40MG HARD CAPSULES MAL18106139AZ	MEDICE ARZNEIMITTEL PÛTTER GMBH, GERMANY
	METHYLPHENIDATE HYDROCHLORIDE 30MG	MEDIKINET MR 30MG HARD CAPSULES MAL18106137AZ	MEDICE ARZNEIMITTEL PÛTTER GMBH, GERMANY
	METHYLPHENIDATE HYDROCHLORIDE 20MG	MEDIKINET MR 20MG HARD CAPSULES MAL18106133AZ	MEDICE ARZNEIMITTEL PÛTTER GMBH, GERMANY
	METHYLPHENIDATE HYDROCHLORIDE 10MG	MEDIKINET MR 10MG HARD CAPSULES MAL18106134AZ	MEDICE ARZNEIMITTEL PÛTTER GMBH, GERMANY
	METHYLPHENIDATE HYDROCHLORIDE 5MG	MEDIKINET MR 5MG HARD CAPSULES MAL18106136AZ	MEDICE ARZNEIMITTEL PÛTTER GMBH, GERMANY
	METHYLPHENIDATE HYDROCHLORIDE 54MG	CONCERTA 54 MG EXTENDED-RELEASE TABLET MAL05072102ARZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES
	METHYLPHENIDATE HYDROCHLORIDE 36MG	CONCERTA 36 MG EXTENDED-RELEASE TABLET MAL05072101ARZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	METHYLPHENIDATE HYDROCHLORIDE 27MG	CONCERTA 27 MG EXTENDED-RELEASE TABLET MAL08061554ARZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES
	METHYLPHENIDATE HYDROCHLORIDE 18MG	CONCERTA 18 MG EXTENDED RELEASE TABLET MAL05072100ARZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES
38.	MIRABEGRON 50MG	BETMIGA PROLONGED-RELEASE TABLETS 50MG MAL15015107ACRZ	AVARA PHARMACEUTICAL TECHNOLOGIES, INC., UNITED STATES
	MIRABEGRON 25MG	BETMIGA PROLONGED-RELEASE TABLETS 25MG MAL15015106ACRZ	AVARA PHARMACEUTICAL TECHNOLOGIES, INC., UNITED STATES
39.	MORPHINE SULPHATE 100MG	MST CONTINUS TABLET 100MG MAL19920160AZ	BARD PHARM LTD, UNITED KINGDOM
	MORPHINE SULPHATE 60MG	MST CONTINUS TABLET 60MG MAL19920159AZ	BARD PHARM LTD, UNITED KINGDOM
	MORPHINE SULPHATE 30MG	MST CONTINUS TABLETS 30MG MAL19920157AZ	BARD PHARM LTD, UNITED KINGDOM
	MORPHINE SULPHATE 10MG	MST CONTINUS TABLET 10MG MAL19920158AZ	BARD PHARM LTD, UNITED KINGDOM
40.	MYCOPHENOLIC SODIUM (EQ 360MG BASE)	MYFORTIC 360MG GASTRO-RESISTANT TABLETS MAL20040812ARZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY NOVARTIS PHARMA STEIN AG, SWITZERLAND
	MYCOPHENOLIC SODIUM (EQ 180MG BASE)	MYFORTIC 180MG GASTRO-RESISTANT TABLETS MAL20040811ARZ	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
			NOVARTIS PHARMA STEIN AG, SWITZERLAND
41.	NAPROXEN 500MG AND ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (EQ 20MG BASE)	VIMOVO 500MG/20MG MODIFIED-RELEASE TABLETS MAL20112128ACRZ	PATHEON PHARMACEUTICALS INC., UNITED STATES
42.	NIFEDIPINE 60MG	ADALAT LA 60MG MAL20001247AZ	BAYER AG, GERMANY
	NIFEDIPINE 30MG	ADALAT LA 30MG MAL20001248AZ	BAYER AG, GERMANY
43.	OMEPRAZOLE 10MG (List 5)	LOSEC 10MG CAPSULE MAL19970657A	ASTRAZENECA AB, SWEDEN
	OMEPRAZOLE 20MG (List 5)	LOSEC 20 MG CAPSULE PBKD890139A	ASTRAZENECA AB, SWEDEN
	As agreed upon in <i>Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2008 – 4th December 2008</i> : label on generic immediate release products of Omeprazole tablets must include the statement ' not interchangeable with capsule form '. While label on generic immediate release products of Omeprazole capsule must include statement ' not interchangeable with tablet form '.		
	As agreed upon in <i>Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 3/2014 – 15 December 2014</i> : the following products are being added as additional comparator in Malaysia.		
		OMEZOLE 20MG CAPSULE MAL20000377AZ	HOVID BERHAD, MALAYSIA
		OMILOCK CAPSULE 20MG MAL19993078AZ	SM PHARMACEUTICAL SDN. BHD., MALAYSIA
		PROBITOR 20MG CAPSULE MAL09122031AZ	LEK PHARMACEUTICALS D. D., SLOVENIA

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		ROMESEC CAPSULE 20MG MAL19992760AZ	RANBAXY (M) SDN. BHD., MALAYSIA
44.	OMEPRAZOLE MAGNESIUM (EQ 20MG BASE)	LOSEC MUPS 20MG TABLET MAL19992065AZ	ASTRAZENECA AB, SWEDEN
	OMEPRAZOLE MAGNESIUM (EQ 10MG BASE)	LOSEC MUPS 10MG TABLET MAL19992064AZ	ASTRAZENECA AB, SWEDEN
45.	OXYCODONE HYDROCHLORIDE 80MG	OXYCONTIN CONTROLLED- RELEASE TABLETS 80MG MAL14125152ARZ	PURDUE PHARMACEUTICALS L.P., UNITED STATES
	OXYCODONE HYDROCHLORIDE 40MG	OXYCONTIN CONTROLLED- RELEASE TABLETS 40MG MAL14125147ARZ	PURDUE PHARMACEUTICALS L.P., UNITED STATES
	OXYCODONE HYDROCHLORIDE 20MG	OXYCONTIN CONTROLLED- RELEASE TABLETS 20MG MAL14125148ARZ	PURDUE PHARMACEUTICALS L.P., UNITED STATES
	OXYCODONE HYDROCHLORIDE 10MG	OXYCONTIN CONTROLLED- RELEASE TABLETS 10MG MAL14125150ARZ	PURDUE PHARMACEUTICALS L.P., UNITED STATES
46.	OXYCODONE HYDROCHLORIDE 40MG AND NALOXONE HYDROCHLORIDE 20MG	TARGIN PROLONGED RELEASE TABLETS 40MG/20MG MAL12055011ACRZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
	OXYCODONE HYDROCHLORIDE 20MG AND NALOXONE HYDROCHLORIDE 10MG	TARGIN PROLONGED RELEASE TABLETS 20MG/10MG MAL12055006ACRZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	OXYCODONE HYDROCHLORIDE 10MG AND NALOXONE HYDROCHLORIDE 5MG	TARGIN PROLONGED RELEASE TABLETS 10MG/5MG MAL12055001ACRZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
	OXYCODONE HYDROCHLORIDE 5MG AND NALOXONE HYDROCHLORIDE 2.5MG	TARGIN PROLONGED RELEASE TABLETS 5MG/2.5MG MAL12055007ACRZ	BARD PHARMACEUTICALS LIMITED, UNITED KINGDOM
47.	PALIPERIDONE 9MG	INVEGA 9 MG EXTENDED RELEASE TABLETS MAL20081768AZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES
	PALIPERIDONE 6MG	INVEGA 6 MG EXTENDED RELEASE TABLETS MAL20081767AZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES
	PALIPERIDONE 3MG	INVEGA 3 MG EXTENDED RELEASE TABLETS MAL20081766AZ	JANSSEN CILAG MANUFACTURING L.L.C, UNITED STATES
48.	PANTOPRAZOLE SODIUM SESQUIHYDRATE (EQ 40MG BASE)	CONTROLOC 40MG TABLET MAL19972093ARZ	TAKEDA GMBH, GERMANY NYCOMED GMBH, GERMANY
	PANTOPRAZOLE SODIUM SESQUIHYDRATE (EQ 20MG BASE)	CONTROLOC 20MG TABLET MAL20032151AZ	TAKEDA GMBH, GERMANY NYCOMED GMBH, GERMANY
49.	PAROXETINE HYDROCHLORIDE HEMIHYDRATE (EQ 25MG BASE)	SEROXAT CR TABLET 25MG MAL06051292ARZ	GLAXOSMITHKLINE INC., CANADA

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	PAROXETINE HYDROCHLORIDE HEMIHYDRATE (EQ 12.5MG)	SEROXAT CR TABLET 12.5MG MAL06051291ARZ	GLAXOSMITHKLINE INC., CANADA
50.	POSACONAZOLE 100MG	NOXAFIL 100MG MODIFIED RELEASE TABLET MAL16045045ARZ	N.V. ORGANON, NETHERLANDS
51.	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 1.5MG	SIFROL EXTENDED RELEASE TABLET 1.5 MG MAL20102064AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, GERMANY
	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE 0.375MG	SIFROL EXTENDED RELEASE TABLET 0.375 MG MAL20102062AZ	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG, GERMANY
52.	PREDNISOLONE 5MG	LODOTRA MODIFIED-RELEASE TABLETS 5MG MAL16065013ACRZ	AENOVA FRANCE S.A.S., FRANCE
	PREDNISOLONE 2MG	LODOTRA MODIFIED-RELEASE TABLETS 2MG MAL16065011ACRZ	AENOVA FRANCE S.A.S., FRANCE
	PREDNISOLONE 1MG	LODOTRA MODIFIED-RELEASE TABLETS 1MG MAL16065012ACRZ	AENOVA FRANCE S.A.S., FRANCE
53.	QUETIAPINE FUMARATE (EQ 400MG BASE)	SEROQUEL XR EXTENDED RELEASE TABLET 400MG MAL09011465ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
	QUETIAPINE FUMARATE (EQ 300MG BASE)	SEROQUEL XR EXTENDED RELEASE TABLET 300MG MAL09011464ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	QUETIAPINE FUMARATE (EQ 200MG BASE)	SEROQUEL XR EXTENDED RELEASE TABLET 200MG MAL09011463ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
	QUETIAPINE FUMARATE (EQ 50MG BASE)	SEROQUEL XR EXTENDED RELEASE TABLET 50MG MAL09011462ARZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
54.	RABEPRAZOLE SODIUM 20MG	PARIET TABLET 20MG MAL19992541ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN EISAI CO LTD, JAPAN
	RABEPRAZOLE SODIUM 10MG	PARIET TABLET 10MG MAL19992540ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN EISAI CO LTD, JAPAN
55.	RANOLAZINE 750MG	RANEXA 750MG PROLONGED-RELEASE TABLETS MAL16035015AZ	MENARINI - VON HEYDEN GMBH, GERMANY
	RANOLAZINE 500MG	RANEXA 500MG PROLONGED-RELEASE TABLETS MAL16035012AZ	MENARINI - VON HEYDEN GMBH, GERMANY
	RANOLAZINE 375MG	RANEXA 375MG PROLONGED-RELEASE TABLETS MAL16035014AZ	MENARINI - VON HEYDEN GMBH, GERMANY
56.	ROPINIROLE HYDROCHLORIDE (EQ 4MG BASE)	REQUIP PD 24 HOUR™ 4MG PROLONGED RELEASE TABLETS MAL10053656ARZ	GLAXO WELLCOME S.A., SPAIN
	ROPINIROLE HYDROCHLORIDE (EQ 2MG BASE)	REQUIP PD 24 HOUR™ 2MG PROLONGED RELEASE TABLETS MAL10053654ARZ	GLAXO WELLCOME S.A., SPAIN

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
57.	SALBUTAMOL SULPHATE (EQ 8MG BASE)	VOLMAX 8MG CR TABLET MAL19890619AR	GLAXOSMITHKLINE SPA, STRADA ASOLANA 68, SAN POLO DI TORRILE PARMA, 43056 ITALY
	SALBUTAMOL SULPHATE (EQ 4MG BASE)	VOLMAX 4MG CR TABLET MAL19890618AR	GLAXOSMITHKLINE SPA, STRADA ASOLANA 68, SAN POLO DI TORRILE PARMA, 43056 ITALY
		Product is available in Saudi Arabia and several African countries e.g. Rwanda and Burundi . <i>(Source of information: GlaxoSmithKline Pharmaceutical Sdn. Bhd, 2013)</i>	
58.	SAXAGLIPTIN HYDROCHLORIDE (EQ 5MG BASE) AND METFORMIN HYDROCHLORIDE 1000MG	KOMBIGLYZE XR TABLET 5/1000MG MAL11115004AZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
	SAXAGLIPTIN HYDROCHLORIDE (EQ 5MG BASE) AND METFORMIN HYDROCHLORIDE 500MG	KOMBIGLYZE XR TABLET 5/500MG MAL11115005AZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
	SAXAGLIPTIN HYDROCHLORIDE (EQ 2.5MG BASE) AND METFORMIN HYDROCHLORIDE 1000MG	KOMBIGLYZE XR TABLET 2.5/1000MG MAL11115003AZ	ASTRAZENECA PHARMACEUTICALS LP, UNITED STATES
59.	SITAGLIPTIN PHOSPHATE (EQ 100MG BASE) AND METFORMIN HYDROCHLORIDE 1000MG	JANUMET XR 100MG/1000MG (SITAGLIPTIN PHOSPHATE/ METFORMIN HCL EXTENDED-RELEASE) FILM-COATED TABLETS MAL14125081ARZ	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, PUERTO RICO
	SITAGLIPTIN PHOSPHATE (EQ 50MG BASE) AND METFORMIN	JANUMET XR 50MG/500MG (SITAGLIPTIN PHOSPHATE/ METFORMIN HCL EXTENDED-RELEASE) FILM-COATED TABLETS	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, PUERTO RICO

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	HYDROCHLORIDE 500MG	MAL14125082ARZ	
	SITAGLIPTIN PHOSPHATE (EQ 50MG BASE) AND METFORMIN HYDROCHLORIDE 1000MG	JANUMET XR 50MG/1000MG (SITAGLIPTIN PHOSPHATE/ METFORMIN HCL EXTENDED-RELEASE) FILM-COATED TABLETS MAL14125083ARZ	MSD INTERNATIONAL GMBH (PUERTO RICO BRANCH) LLC, PUERTO RICO
60.	SODIUM VALPROATE 500MG	EPILIM 500 ENTERIC COATED TABLET MAL19950223A	SANOFI SYNTHELABO LTD, UNITED KINGDOM
	SODIUM VALPROATE 200MG	EPILIM 200 ENTERIC COATED TABLET MAL19860953AZ	SANOFI-AVENTIS, SA, SPAIN SANOFI SYNTHELABO LTD, UNITED KINGDOM
61.	SODIUM VALPROATE 333MG AND VALPROIC ACID 145MG (EQ TO 500MG SODIUM VALPROATE)	EPILIM CHRONO 500 CONTROLLED RELEASE MAL19910049AZ	SANOFI WINTHROP INDUSTRIE, FRANCE
62.	SULPHASALAZINE 500MG	SALAZOPYRIN EN TABLET 500MG MAL19950470ACZ	RECIPHARM UPPSALA AB, SWEDEN KEMWELL AB, SWEDEN
63.	TACROLIMUS MONOHYDRATE (EQ 5MG BASE)	ADVAGRAF 5MG PROLONGED-RELEASE HARD CAPSULES MAL12115072AZ	ASTELLAS IRELAND CO. LTD., IRELAND
	TACROLIMUS MONOHYDRATE (EQ 1MG BASE)	ADVAGRAF 1MG PROLONGED-RELEASE HARD CAPSULES MAL12115073AZ	ASTELLAS IRELAND CO. LTD., IRELAND

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	TACROLIMUS MONOHYDRATE (EQ 0.5MG BASE)	ADVAGRAF 0.5MG PROLONGED-RELEASE HARD CAPSULES MAL12115074AZ	ASTELLAS IRELAND CO. LTD., IRELAND
64.	TAMSULOSIN HYDROCHLORIDE 400MCG	HARNAL OCAS 400MCG FILM-COATED TABLET MAL20091914AZ	ASTELLAS PHARMA EUROPE B.V., NETHERLANDS
65.	TAPENTADOL HYDROCHLORIDE (EQ 250MG BASE)	NUCYNTA ER TABLETS 250MG MAL15045081AZ	JANSSEN ORTHO LLC, PUERTO RICO
	TAPENTADOL HYDROCHLORIDE (EQ 200MG BASE)	NUCYNTA ER TABLETS 200MG MAL15045082AZ	JANSSEN ORTHO LLC, PUERTO RICO
	TAPENTADOL HYDROCHLORIDE (EQ 150MG BASE)	NUCYNTA ER TABLETS 150MG MAL15045079AZ	JANSSEN ORTHO LLC, PUERTO RICO
	TAPENTADOL HYDROCHLORIDE (EQ 100MG BASE)	NUCYNTA ER TABLETS 100MG MAL15045080AZ	JANSSEN ORTHO LLC, PUERTO RICO
	TAPENTADOL HYDROCHLORIDE (EQ 50MG BASE)	NUCYNTA ER TABLETS 50MG MAL15045083AZ	JANSSEN ORTHO LLC, PUERTO RICO
66.	THEOPHYLLINE 250MG	NUELIN SR 250 TABLET MAL13075064ACZ	ADCOCK INGRAM LIMITED - A MEDREICH GROUP COMPANY, INDIA
	THEOPHYLLINE 125MG	NUELIN SR 125 TABLET MAL13085050ACZ	ADCOCK INGRAM LIMITED - A MEDREICH GROUP COMPANY, INDIA
67.	TOLTERODINE TARTRATE 4MG	DETRUSITOL SR 4MG EXTENDED RELEASE CAPSULES MAL20021402ACRZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	TOLTERODINE TARTRATE 2MG	DETRUSITOL SR 2MG EXTENDED RELEASE CAPSULES MAL20021401ACRZ	CATALENT PHARMA SOLUTIONS, LLC, UNITED STATES
68.	TRAMADOL HYDROCHLORIDE 100MG	TRAMAL RETARD 100MG TABLET MAL19973635A	GRUNENTHAL GMBH, AACHEN GERMANY
		Product is available in Australia, Austria, Belgium, China, Denmark, Finland, France, Greece, Ireland, Italy, Korea, Luxembourg, Netherlands, New Zealand, Norway, Pakistan, Philippines, Portugal, Spain, Sweden, Switzerland, Taiwan, Thailand, United Kingdom. <i>(Source of information: Grunenthal Gmbh, Germany, 2021)</i>	
69.	TRIMETAZIDINE DIHYDROCHLORIDE 35MG	VASTAREL MR MAL20051401AZ	LES LABS SERVIER INDUSTRIE, FRANCE
		VASTAREL MR MAL09011457ACSZ	KOTRA PHARMA (M) SDN. BHD., MALAYSIA
70.	VENLAFAXINE HYDROCHLORIDE (EQ 150MG BASE)	EFEXOR XR 150MG CAPSULE MAL20002459ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
	VENLAFAXINE HYDROCHLORIDE (EQ 150MG BASE)	EFEXOR XR 75MG CAPSULE MAL20002460ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
	VENLAFAXINE HYDROCHLORIDE (EQ 150MG BASE)	EFEXOR XR 37.5MG CAPSULE MAL06030815ARZ	PFIZER IRELAND PHARMACEUTICALS, IRELAND
71.	VERAPAMIL HYDROCHLORIDE 240MG	ISOPTIN SR 240MG, PROLONGED-RELEASE TABLET MAL07010942AZ	ABBVIE DEUTSCHLAND GMBH & CO.KG, GERMANY

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 8/8/2023

LIST OF COMPARATOR PRODUCTS FOR MODIFIED RELEASE ORAL SOLID DOSAGE FORM