

Bioequivalence Requirements for Generic Products Containing Scheduled Poison in Dosage Forms of Effervescent, Dispersible, Orodispersible, Sublingual, Lozenges, Buccal and Chewable Tablets/ Capsules

The Drug Control Authority (DCA) in their 284th meeting, has decided to enforce the bioequivalence (BE) requirements on generic products containing scheduled poison in dosage forms of effervescent, dispersible, orodispersible, sublingual, buccal and chewable tablets/ capsules effective from 1st January 2018 for all new product application/submission. This requirement is also applicable for registered products with renewal due date from 1st January 2019 onwards.

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
1	ACYCLOVIR 800MG	ZOVIRAX TABLET 800MG (DISPERSIBLE) MAL19950570ARZ	GLAXO WELLCOME S.A., SPAIN
	ACYCLOVIR 400MG	ZOVIRAX DISPERSIBLE TABLETS 400MG MAL19962830A	THE WELLCOME FOUNDATION LTD, UNITED KINGDOM
	ACYCLOVIR 200MG	ZOVIRAX DISPERSIBLE TABLET 200MG MAL19962829ARZ	GLAXO WELLCOME S.A., SPAIN
2	ARIPIPIRAZOLE	ARISA 10MG ORODISPERSIBLE TABLET MAL23056005AZ	PHARMATHEN INTERNATIONAL S.A. (GREECE)
		ARISA 15MG ORODISPERSIBLE TABLET MAL23056006AZ	PHARMATHEN INTERNATIONAL S.A. (GREECE)
3	ASENAPINE MALEATE (EQ 5MG BASE)	SAPHRIS SUBLINGUAL TABLET 5MG MAL20112129ACRZ	CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM
	ASENAPINE MALEATE (EQ 10MG BASE)	SAPHRIS SUBLINGUAL TABLET 10MG MAL20112130ACRZ	CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM

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4	BETAHISTINE DIHYDROCHLORIDE	VERTICLEAR ORODISPERSIBLE FILM 24MG MAL26086137AZ	SHILPA MEDICARE LIMITED (INDIA)
5	BILASTINE 10MG	BILAXTEN 10MG ORODISPERSIBLE TABLETS MAL21046009AZ	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S.R.L., ITALY
		BILADRIVE-20 BILASTINE ORALLY DISINTEGRATING TABLET 20 MG MAL26086136ACZ	ATHENA DRUG DELIVERY SOLUTIONS PVT LTD. (INDIA)
6	BUPRENORPHINE HYDROCHLORIDE (EQ 0.2MG BASE)	TEMGESIC SUBLINGUAL TABLET 0.2MG MAL19860975AZ	RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE)	SUBUTEX SUBLINGUAL TABLET 8MG MAL20013547A	RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE)	SUBUTEX SUBLINGUAL TABLET 2MG MAL20013546A	RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 0.4MG BASE)	SUBUTEX SUBLINGUAL TABLET 0.4MG MAL20013545A	RECKITT BENCKISER HEALTHCARE (UK) LTD, UNITED KINGDOM
7	BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE)	SUBOXONE 8 MG SUBLINGUAL TABLETS MAL20061582ACRZ	RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE)	SUBOXONE 2MG SUBLINGUAL TABLETS MAL20061581ACRZ	RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND	SUBOXONE SUBLINGUAL FILM 8MG/2MG	MONOSOL RX, UNITED STATES

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

	NALOXONE HYDROCHLORIDE (EQ 2MG BASE)	MAL13075058ACZ	
	BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE)	SUBOXONE SUBLINGUAL FILM 2MG/0.5MG MAL13075057ACZ	MONOSOL RX, UNITED STATES
8	BUPROPION HYDROCHLORIDE 150MG	WELLBUTRIN SR TABLETS MAL20081803ARZ	GLAXOSMITHKLINE LLC, UNITED STATES
9	DEFERASIROX 125MG	EXJADE 125MG DISPERSIBLE TABLETS MAL20061603ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
	DEFERASIROX 250MG	EXJADE 250MG DISPERSIBLE TABLETS MAL20061604A	NOVARTIS PHARMA STEIN AG SWITZERLAND
	DEFERASIROX 500MG	EXJADE 500MG DISPERSIBLE TABLETS MAL20061605ARZ	NOVARTIS PHARMA STEIN AG, SWITZERLAND
		Exjade Dispersible Tablets manufactured by Novartis Pharma Stein AG, Switzerland can be obtained from United Arab Emirates, Bahrain, Brazil, Canada, Switzerland, Chile, China, Ecuador, Indonesia, Jordan, Kuwait, Kazakhstan, Morocco, Macedonia, New Zealand, Oman, Panama, Philippines, Palestine, Paraguay, Qatar, Serbia, Thailand, Turkey, Taiwan, Ukraine, United States and South Africa. <i>(Source of information: Novartis Corporation (Malaysia) Sdn Bhd, 2022)</i>	
10	DESLORATADINE 2.5MG	AJALORIN 2.5MG ORODISPERSIBLE TABLET MAL19016047ACZ	GENEPHARM S.A., GREECE
	DESLORATADINE 5MG	AJALORIN 2.5MG ORODISPERSIBLE TABLET MAL19016044ACZ	GENEPHARM S.A., GREECE

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

11	DOLUTEGRAVIR SODIUM 5MG	TIVICAY 5MG DISPERSIBLE TABLET MAL26086134ACRZ	GLAXO OPERATIONS UK LTD (UNITED KINGDOM)
12	DONEPEZIL HYDROCHLORIDE 10MG	ARICEPT EVESS ORODISPERSIBLE TABLET 10MG MAL09042405ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN
	DONEPEZIL HYDROCHLORIDE 5MG	ARICEPT EVESS ORODISPERSIBLE TABLET 5MG MAL09042397ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN
13	ERDOSTEINE 300MG	ERDOMED® 300MG DISPERSIBLE TABLETS MAL20076015ARZMA	EDMOND PHARMA S.R.L, ITALY
14	ESCITALOPRAM OXALATE (EQ 20MG BASE)	AJALOPRAM 20 MG ORODISPERSIBLE TABLET MAL18086103ACZ	GENEPHARM S.A., GREECE
	ESCITALOPRAM OXALATE (EQ 15MG BASE)	AJALOPRAM 15MG ORODISPERSIBLE TABLET MAL18086104ACZ	GENEPHARM S.A., GREECE
	ESCITALOPRAM OXALATE (EQ 10MG BASE)	AJALOPRAM 10MG ORDISPERSIBLE TABLET MAL18086106ACZ	GENEPHARM S.A., GREECE
	ESCITALOPRAM OXALATE (EQ 5MG BASE)	AJALOPRAM 5MG ORODISPERSIBLE TABLET MAL18086105ACZ	GENEPHARM S.A., GREECE
15	FENTANYL CITRATE (EQ 400MCG BASE)	ABSTRAL 400 MICROGRAM SUBLINGUAL TABLETS MAL17085057ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM
	FENTANYL CITRATE (EQ 200MCG BASE)	ABSTRAL 200 MICROGRAM SUBLINGUAL TABLETS MAL17085056ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

		ABSTRAL 200 MICROGRAM SUBLINGUAL TABLETS MAL14025004ACZ	RECIPHARM STOCKHOLM AB, SWEDEN
	FENTANYL CITRATE (EQ 100MCG BASE)	ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS MAL17085055ACZ	AESICA QUEENBOROUGH LIMITED, UNITED KINGDOM
		ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS MAL14025003ACZ	RECIPHARM STOCKHOLM AB, SWEDEN
16	FLURBIPROFEN 8.75MG	STREPSILS MAX PRO HONEY & LEMON 8.75MG LOZENGE MAL13045049AZ	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, UNITED KINGDOM
		STREPSILS MAX PRO HONEY & LEMON 8.75MG LOZENGE MAL18016023ASZ	RECKITT BENCKISER HEALTHCARE MANUFACTURING (THAILAND) LIMITED
17	GIMERACIL 7.28MG, OTERACIL POTASSIUM 24.5MG AND TEGAFUR 25MG	TS-ONE OD TABLET 25 MAL19071005ARZ	TAIHO PHARMACEUTICAL CO.,LTD, JAPAN
	GIMERACIL 5.8MG, OTERACIL POTASSIUM 19.6MG AND TEGAFUR 20MG	TS-ONE OD TABLET 20 MAL19071004ARZ	TAIHO PHARMACEUTICAL CO.,LTD, JAPAN
18	GLYCERYL TRINITRATE 0.5MG	GTN ACTAVIS TABLET 500 MCG MAL19871706ACZ	ACCORD-UK LTD, UNITED KINGDOM ACTAVIS UK LIMITED, UNITED KINGDOM
19	LAMOTRIGINE 50MG	LAMICTAL DISPERSIBLE TABLET 50MG MAL19930433ACRZ	DELPHARM POZNAN SPOLKA AKCYJNA(POLAND)
	LAMOTRIGINE 25MG	LAMICTAL DISPERSIBLE TABLET 25MG MAL19970262ACRZ	GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

			DELPHARM POZNAN SPOLKA AKCYJNA(POLAND)
	LAMOTRIGINE 5MG	LAMICTAL DISPERSIBLE TABLET 5MG MAL19970261ACRZ	GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND DELPHARM POZNAN SPOLKA AKCYJNA(POLAND)
	LAMOTRIGINE 2MG	LAMICTAL CHEWABLE DISPERSABLE 2MG TABLETS MAL20061515ARZ	GLAXO WELLCOME INC, UNITED STATES DELPHARM POZNAN SPOLKA AKCYJNA(POLAND)
20	LANSOPRAZOLE 15MG	PREVACID FDT 15 MG TABLET MAL08042459ARZ	KOKANDO CO. LTD (JAPAN)
	LANSOPRAZOLE 30MG	PREVACID FDT 30MG TABLET MAL08042460ARZ	KOKANDO CO. LTD (JAPAN)
21	LORATADINE 10MG	CLARITYNE RAPID TABLET 10MG MAL20014313ACZ	SCHERER DDS LTD, UNITED KINGDOM
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2019” – 19 November 2019, Clarityne Rapid Tablet and Claritin Reditabs manufactured by Catalent U.K. Swindon Zydis Limited, United Kingdom is allowed to be used as a comparator.	
22	MIRTAZAPINE 45MG	REMERON SOLTAB 45MG MAL05023179ACR	CIMA LABS INC , UNITED STATES
	MIRTAZAPINE 30MG	REMERON SOLTAB 30MG MAL14015019ACRZ	ANESTA LLC, UNITED STATES CEPHALON, INC (UNITED STATES)
	MIRTAZAPINE 15MG	REMERON SOLTAB 15MG	ANESTA LLC, UNITED STATES

LIST OF COMPARATOR PRODUCTS IN DOSAGE FORMS OF EFFERVESCENT, DISPERSIBLE, ORODISPERSIBLE, SUBLINGUAL, LOZENGES, BUCCAL AND CHEWABLE TABLETS/ CAPSULES

		MAL14015018ACRZ	CEPHALON, INC (UNITED STATES)
23	MONTELUKAST SODIUM (EQ 5MG BASE)	SINGULAIR CHEWABLE TABLET 5MG MAL19990956ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
24	MONTELUKAST SODIUM (EQ 4MG BASE)	SINGULAIR 4MG CHEWABLE TABLET MAL20020121ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
25	NICOTINE 4MG	NICOTINELL FRUIT 4MG, CHEWING-GUM MAL06011709ACRZ	FERTIN PHARMA A/S , DENMARK
		This product can be obtained from Denmark, Iceland, Israel, New Zealand, Switzerland and United Kingdom. (Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)	
	NICOTINE 2MG	NICOTINELL FRUIT 2MG, CHEWING-GUM MAL06011708ACRZ	FERTIN PHARMA A/S, DENMARK
		This product can be obtained from Austria, Belgium, Denmark, Finland, France, Iceland, Ireland, Israel, Republic of Korea, Luxembourg, Netherland, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom. (Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)	
	NICOTINE 4MG	NICOTINELL MINT 4MG, CHEWING-GUM MAL06011711ACRZ	FERTIN PHARMA A/S, DENMARK
		This product can be obtained from Denmark, Finland, Iceland, Israel, New Zealand, Norway, Sweden and United Kingdom. (Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)	
	NICOTINE 2MG	NICOTINELL MINT 2MG, CHEWING-GUM MAL06011710ACRZ	FERTIN PHARMA A/S , DENMARK
		This product can be obtained from Denmark, Finland, Hong Kong, Iceland, Israel, Japan, Republic of Korea, New Zealand, Norway, Sweden, Thailand & United Kingdom. Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)	

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NICOTINE RESINATE (EQ 4MG BASE)	NICORETTE ICY MINT 4 MG GUM MAL15045059ARZ	MCNEIL AB, SWEDEN
NICOTINE RESINATE (EQ 2MG BASE)	NICORETTE ICY MINT 2 MG GUM MAL15045076ARZ	MCNEIL AB, SWEDEN
NICOTINE POLACRILEX (EQ 4MG BASE)	NIQUITIN 4MG LOZENGES MAL06100577ARZ	GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES
NICOTINE POLACRILEX (EQ 2MG BASE)	NIQUITIN 2MG LOZENGES MAL06100578ARZ	GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES
NICOTINE POLACRILEX (EQ 4MG BASE)	NIQUITIN 4MG MINT LOZENGES MAL09051546AZ	GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES
NICOTINE POLACRILEX (EQ 2MG BASE)	NIQUITIN 2MG MINT LOZENGES MAL09051545AZ	GLAXO SMITH KLINE CONSUMER HEALTHCARE, UNITED STATES
NICOTINE BITARTRATE DIHYDRATE (EQ 1MG BASE)	NICOTINELL MINT 1MG LOZENGE MAL06011707ACRZ	SANICO N.V., BELGIUM
NICOTINE POLACRILEX 10MG (EQ 2MG NICOTINE)	SKIIP NICOTINE MINI LOZENGE 2MG (CHERRY FLAVOUR) MAL25026002AZ	RUBICON RESEARCH PRIVATE LIMITED, INDIA
NICOTINE POLACRILEX 10MG (EQ 2MG NICOTINE)	SKIIP NICOTINE MINI LOZENGE 2MG (CINNAMON FLAVOUR) MAL25026003AZ	RUBICON RESEARCH PRIVATE LIMITED, INDIA
NICOTINE POLACRILEX 10MG (EQ 2MG NICOTINE)	SKIIP NICOTINE MINI LOZENGE 2MG (MINT FLAVOUR) MAL25026001AZ	RUBICON RESEARCH PRIVATE LIMITED, INDIA
NICOTINE POLACRILEX 20MG (EQ 4MG NICOTINE)	SKIIP NICOTINE MINI LOZENGE 4MG (CHERRY FLAVOUR) MAL25026005AZ	RUBICON RESEARCH PRIVATE LIMITED, INDIA

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	NICOTINE POLACRILEX 20MG (EQ 4MG NICOTINE)	SKIIP NICOTINE MINI LOZENGE 4MG (CINNAMON FLAVOUR) MAL25026006AZ	RUBICON RESEARCH PRIVATE LIMITED, INDIA
	NICOTINE POLACRILEX 20MG (EQ 4MG NICOTINE)	SKIIP NICOTINE MINI LOZENGE 4MG (CINNAMON FLAVOUR) MAL25026004AZ	RUBICON RESEARCH PRIVATE LIMITED, INDIA
26	OLANZAPINE 10MG	ZYPREXA ZYDIS 10MG ORODISPERSIBLE TABLET MAL04125491ACRZ	CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM
	OLANZAPINE 5MG	ZYPREXA ZYDIS 5MG ORODISPERSIBLE TABLET MAL04125490ACRZ	CATALENT UK SWINDON ZYDIS LIMITED, UNITED KINGDOM
27	PERINDOPRIL ARGININE 10MG	COVERSYL OD 10MG, ORODISPERSIBLE TABLETS MAL13095087AZ	SERVIER (IRELAND) INDUSTRIES LTD, IRELAND
	PERINDOPRIL ARGININE 5MG	COVERSYL OD 5MG, ORODISPERSIBLE TABLETS MAL13095085AZ	SERVIER (IRELAND) INDUSTRIES LTD, IRELAND
	PERINDOPRIL ARGININE 2.5MG	COVERSYL OD 2.5MG, ORODISPERSIBLE TABLETS MAL13095086AZ	SERVIER (IRELAND) INDUSTRIES LTD, IRELAND
28	PIROXICAM 20MG	FELDENE DISPERSIBLE TABLET MAL19962549ACZ	FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE
29	RANITIDINE HYDROCHLORIDE (EQ 150MG BASE)	ZANTAC EFFERVESCENT TABLET 150MG MAL07011019AZ	GLAXOWELLCOME PRODUCTION , FRANCE
30	RIFAMPICIN 75 MG, ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG	RHZ KID DT (RIFAMPICIN 75 MG, ISONIAZID 50 MG AND PYRAZINAMIDE 150 MG DISPERSIBLE TABLETS)	OXALIS LABS (INDIA)

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		MAL25056006ACZ	
31	SILDENAFIL CITRATE (EQ 100MG BASE)	AJENAFIL 100MG CHEWABLE TABLET MAL18046144AZ	GENEPHARM S.A., GREECE
	SILDENAFIL CITRATE (EQ 50MG BASE)	AJENAFIL 50MG CHEWABLE TABLET MAL18046145AZ	GENEPHARM S.A., GREECE
	SILDENAFIL CITRATE (EQ 25MG BASE)	AJENAFIL 25MG CHEWABLE TABLET MAL18046146AZ	GENEPHARM S.A., GREECE
32	SILDENAFIL CITRATE	HOVID ERECOR ORODISPERSIBLE FILMS 50MG MAL23096012ACZ	ZIM LABORATORIES LIMITED (INDIA)
33	TADALAFIL 20MG	LEBIVA ODS-20 TADALAFIL ORALLY DISINTEGRATING STRIPS 20MG MAL2309611ACZ	ZIM LABORATORIES LIMITED (INDIA)
34	TADALAFIL 5MG	CALIBERI ORODISPERSIBLE FILM 5MG MAL21036001AZ	CTCBIO INC, SOUTH KOREA
35	TADALAFIL 10MG	HOVID ERETAF ORODISPERSIBLE FILMS 10MG	ZIM LABORATORIES LIMITED, INDIA
36	TADALAFIL 20MG	HOVID ERETAF ORODISPERSIBLE FILMS 20MG	ZIM LABORATORIES LIMITED, INDIA
37	VERDANAFIL HYDROCHLORIDE (EQ 10MG BASE)	LEVITRA 10 MG ORODISPERSIBLE TABLETS MAL12035080ARZ	BAYER AG (LEVERKUSEN), 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

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