

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.	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
3.	BUPRENORPHINE HYDROCHLORIDE (EQ 0.2MG BASE)	TEMGESIC SUBLINGUAL TABLET 0.2MG MAL19860975AZ	RECKITT BENCKISER HEALTHCARE (UK) LTD, 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
	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
4.	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
5.	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
6.	DONEPEZIL HYDROCHLORIDE 10MG	ARICEPT EVESS ORODISPERSIBLE TABLET 10MG MAL09042405ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN

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NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
	DONEPEZIL HYDROCHLORIDE 5MG	ARICEPT ENESS ORODISPERSIBLE TABLET 5MG MAL09042397ACRZ	BUSHU PHARMACEUTICALS LTD. MISATO FACTORY, JAPAN
7.	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 ORODISPERSIBLE TABLET MAL18086106ACZ	GENEPHARM S.A., GREECE
	ESCITALOPRAM OXALATE (EQ 5MG BASE)	AJALOPRAM 5MG ORODISPERSIBLE TABLET MAL18086105ACZ	GENEPHARM S.A., GREECE
8.	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
		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

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NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		ABSTRAL 100 MICROGRAM SUBLINGUAL TABLETS MAL14025003ACZ	RECI PHARM STOCKHOLM AB, SWEDEN
9.	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
10.	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
11.	LAMOTRIGINE 25MG	LAMICTAL DISPERSIBLE TABLET 25MG MAL19970262ARZ	GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND
	LAMOTRIGINE 5MG	LAMICTAL DISPERSIBLE TABLET 5MG MAL19970261ARZ	GLAXO SMITH KLINE PHARMACEUTICALS SA, POLAND
	LAMOTRIGINE 2MG	LAMICTAL CHEWABLE DISPERSABLE 2MG TABLETS MAL20061515ARZ	GLAXO WELLCOME INC, UNITED STATES
12.	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	

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NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		manufactured by Catalent U.K. Swindon Zydys Limited, United Kingdom is allowed to be used as a comparator.	
13.	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 MAL14015018ACRZ	ANESTA LLC, UNITED STATES CEPHALON, INC (UNITED STATES)
14.	MONTELUKAST SODIUM (EQ 5MG BASE)	SINGULAIR CHEWABLE TABLET 5MG MAL19990956ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
15.	MONTELUKAST SODIUM (EQ 4MG BASE)	SINGULAIR 4MG CHEWABLE TABLET MAL20020121ARZ	MERCK SHARP & DOHME LTD, UNITED KINGDOM
16.	BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE)	SUBOXONE 8 MG SUBLINGUAL TABLETS MAL20061582ACZ	RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE)	SUBOXONE 2MG SUBLINGUAL TABLETS MAL20061581ACZ	RECKITT BENCKISER HEALTHCARE (UK) LIMITED , UNITED KINGDOM
	BUPRENORPHINE HYDROCHLORIDE (EQ 8MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 2MG BASE)	SUBOXONE SUBLINGUAL FILM 8MG/2MG MAL13075058ACZ	MONOSOL RX, UNITED STATES

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		PRODUCT NAME AND MAL NO.	MANUFACTURER
	BUPRENORPHINE HYDROCHLORIDE (EQ 2MG BASE) AND NALOXONE HYDROCHLORIDE (EQ 0.5MG BASE)	SUBOXONE SUBLINGUAL FILM 2MG/0.5MG MAL13075057ACZ	MONOSOL RX, UNITED STATES
17.	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. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i>	
	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. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i>	
	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. <i>(Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i>	
	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. <i>Source of information: Glaxosmithkline Pharmaceutical Sdn. Bhd, 2019)</i>	

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		PRODUCT NAME AND MAL NO.	MANUFACTURER
	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
18.	GLYCERYL TRINITRATE 0.5MG	GTN ACTAVIS TABLET 500 MCG MAL19871706ACZ	ACTAVIS UK LIMITED, UNITED KINGDOM
19.	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
20.	PERINDOPRIL ARGININE 10MG	COVERSYL OD 10MG, ORODISPERSIBLE TABLETS	SERVIER (IRELAND) INDUSTRIES LTD, IRELAND

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NO.	ACTIVE PHARMACEUTICAL INGREDIENT (API)	COMPARATOR PRODUCTS	
		PRODUCT NAME AND MAL NO.	MANUFACTURER
		MAL13095087AZ	
21.	PERINDOPRIL ARGININE 5MG	COVERSYL OD 5MG, ORODISPERSIBLE TABLETS MAL13095085AZ	SERVIER (IRELAND) INDUSTRIES LTD, IRELAND
22.	PERINDOPRIL ARGININE 2.5MG	COVERSYL OD 2.5MG, ORODISPERSIBLE TABLETS MAL13095086AZ	SERVIER (IRELAND) INDUSTRIES LTD, IRELAND
23.	PIROXICAM 20MG	FELDENE DISPERSIBLE TABLET MAL19962549ACZ	FAREVA AMBOISE, FRANCE PFIZER PGM, FRANCE
24.	RANITIDINE HYDROCHLORIDE (EQ 150MG BASE)	ZANTAC EFFERVESCENT TABLET 150MG MAL07011019AZ	GLAXOWELLCOME PRODUCTION , FRANCE
25.	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
26.	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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