

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 Ingredient	Comparator Products	
		Trade Mark/ Registration 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 5mg	Saphris Sublingual Tablet 5mg MAL20112129ACRZ	Catalent UK Swindon Zydis Limited , United Kingdom
	Asenapine 10mg	Saphris Sublingual Tablet 10mg MAL20112130ACRZ	Catalent UK Swindon Zydis Limited , United Kingdom
3.	Buprenorphine Hcl 0.2mg	Temgesic Sublingual Tablet 0.2mg MAL19860975AZ	Reckitt Benckiser Healthcare (UK) Ltd , United Kingdom
4.	Deferasirox 125mg	Exjade 125mg Dispersible Tablets MAL20061603ARZ	Novartis Pharma Stein AG, Switzerland
	Deferasirox 500mg	Exjade 500mg Dispersible Tablets MAL20061605ARZ	Novartis Pharma Stein AG, Switzerland

No.	Active Ingredient	Comparator Products	
		Trade Mark/ Registration No.	Manufacturer
5.	Desloratadine 2.5mg	Ajalorin 2.5mg Orodispersible Tablet MAL19016047ACZ	Genepharm A.A., Greece
	Desloratadine 5mg	Ajalorin 2.5mg Orodispersible Tablet MAL19016044ACZ	Genepharm A.A., Greece
6.	Donepezil 5mg	Aricept Evess Orodispersible Tablet 5mg MAL09042397ACRZ	Bushu Pharmaceuticals Ltd. Misato factory, Japan
	Donepezil 10mg	Aricept Evess Orodispersible Tablet 10mg MAL09042405ACRZ	Bushu Pharmaceuticals Ltd. Misato factory, Japan
7.	Escitalopram oxalate 5mg	Ajalopram 5mg Orodispersible Tablet MAL18086105AZ	Genepharm S.A., Greece
	Escitalopram oxalate 10mg	Ajalopram 10mg Orodispersible Tablet MAL18086106AZ	Genepharm S.A., Greece
	Escitalopram oxalate 15mg	Ajalopram 15mg Orodispersible Tablet MAL18086104AZ	Genepharm S.A., Greece
	Escitalopram oxalate 20mg	Ajalopram 20 mg Orodispersible Tablet MAL18086103AZ	Genepharm S.A., Greece
8.	Fentanyl Citrate 100mcg	Abstral 100 microgram sublingual tablets MAL14025003ACZ	Recipharm Stockholm AB (Sweden)
	Fentanyl Citrate 200mcg	Abstral 200 microgram sublingual tablets MAL14025004ACZ	Recipharm Stockholm AB (Sweden)
9.	Lamotrigine 2mg	Lamictal Chewable Dispersable 2mg Tablets MAL20061515ARZ	Glaxo Wellcome Inc, United States
	Lamotrigine 5mg	Lamictal Dispersible Tablet 5mg MAL19970261ARZ	Glaxo Smith Kline Pharmaceuticals Sa , Poland

No.	Active Ingredient	Comparator Products	
		Trade Mark/ Registration No.	Manufacturer
	Lamotrigine 25mg	Lamictal Dispersible Tablet 25mg MAL19970262ARZ	Glaxo Smith Kline Pharmaceuticals Sa , Poland
10.	Loratadine 10mg	Clarityne Rapid Tablet 10mg MAL20014313ACZ	SCHERER DDS LTD, UK
		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 can also be used as a comparator.	
11.	Mirtazapine 15mg	Remeron Soltab 15mg MAL14015018ACRZ	Cephalon, Inc (United States)
	Mirtazapine 30mg	Remeron Soltab 30mg MAL14015019ACRZ	Cephalon, Inc (United States)
	Mirtazapine 45mg	Remeron Soltab 45mg MAL05023179ACR	CIMA Labs Inc , United States
12.	Montelukast 4mg	Singulair 4mg Chewable Tablet MAL20020121ARZ	Merck Sharp & Dohme Ltd , United Kingdom
	Montelukast 5mg	Singulair Chewable Tablet 5mg MAL19990956ARZ	Merck Sharp & Dohme Ltd , United Kingdom
13.	Naloxone + Buprenorphine Hcl 2mg	(i) Suboxone 2mg Sublingual Tablets MAL20061581ACZ	Reckitt Benckiser Healthcare (UK) Limited , United Kingdom
		(ii) Suboxone Sublingual Film 2mg/0.5mg MAL13075057ACZ	MonoSol Rx, United States
	Naloxone + Buprenorphine Hcl 8mg	(i) Suboxone 8 mg Sublingual Tablets MAL20061582ACZ	Reckitt Benckiser Healthcare (UK) Limited , United Kingdom
		(ii) Suboxone Sublingual Film 8mg/2mg MAL13075058ACZ	MonoSol Rx, United States
14.	Nicotine 1mg	Nicotinell Mint 1mg Lozenge MAL06011707ACRZ	Sanico N.V., Belgium

No.	Active Ingredient	Comparator Products	
		Trade Mark/ Registration No.	Manufacturer
	Nicotine 2mg	(i) 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 & United Kingdom. (Information received from GSK Malaysia on 24 October 2019).	
		(ii) 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. (Information received from GSK Malaysia on 24 October 2019).	
		(iii) NiQuitin 2mg Mint Lozenges MAL09051545AZ	Glaxo Smith Kline Consumer Healthcare, United States
		(iv) NiQuitin 2mg Lozenges MAL06100578ARZ	Glaxo Smith Kline Consumer Healthcare, United States
	Nicotine 4mg	(i) Nicotinell Fruit 4mg, Chewing-gum MAL06011709ACRZ	Fertin Pharma A/S , Denmark
		This product can be obtained from Denmark, Iceland, Israel, New Zealand, Switzerland & United Kingdom. (Information received from GSK Malaysia on 24 October 2019).	
		(ii) 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 & United Kingdom. (Information received from GSK Malaysia on 24 October 2019).	
		(iii) NiQuitin 4mg Mint Lozenges MAL09051546AZ	Glaxo Smith Kline Consumer Healthcare, United States
		(iv) NiQuitin 4mg Lozenges	Glaxo Smith Kline Consumer Healthcare, United States

No.	Active Ingredient	Comparator Products	
		Trade Mark/ Registration No.	Manufacturer
		MAL06100577ARZ	
15.	Nitroglycerin 0.5mg / Glyceryl Trinitrate 0.5mg	Glyceryl Trinitrate Tablet BP 500 mcg MAL19871706AZ	Actavis UK Limited
16.	Olanzapine 5mg	Zyprexa Zydis 5mg Orodispersible Tablet MAL04125490ACZ	Catalent UK Swindon Zydis Limited, United Kingdom
	Olanzapine 10mg	Zyprexa Zydis 10mg Orodispersible Tablet MAL04125491ACZ	Catalent UK Swindon Zydis Limited, United Kingdom
17.	Perindopril Arginine 2.5mg	Coversyl OD 2.5MG, orodispersible tablets MAL13095086AZ	Servier (Ireland) Industries Ltd, Ireland
	Perindopril Arginine 5mg	Coversyl OD 5MG, orodispersible tablets MAL13095085AZ	Servier (Ireland) Industries Ltd, Ireland
	Perindopril Arginine 10mg	Coversyl OD 10MG, orodispersible tablets MAL13095087AZ	Servier (Ireland) Industries Ltd, Ireland
18.	Piroxicam	Feldene Dispersible Tablet MAL19962549ACZ	Fareva Amboise, France Pfizer PGM, France
19.	Ranitidine 150mg	Zantac Effervescent Tablet 150mg MAL07011019AZ	GlaxoWellcome Production , France
20.	Sildenafil citrate 25mg	Ajenafil 25mg Chewable Tablet MAL18046146AZ	Genepharm S.A., Greece
	Sildenafil citrate 50mg	Ajenafil 50mg Chewable Tablet MAL18046145AZ	Genepharm S.A., Greece
	Sildenafil citrate 100mg	Ajenafil 100mg Chewable Tablet MAL18046144AZ	Genepharm S.A., Greece

No.	Active Ingredient	Comparator Products	
		Trade Mark/ Registration No.	Manufacturer
21.	Verdanafil	Levitra 10 mg orodispersible tablets MAL12035080ARZ	Bayer Schering Pharma Ag (Leverkusen) (Germany)

* This list is not meant to be exhaustive and will be updated from time to time. If you need further clarification, kindly email to **be_sug@npra.gov.my**

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