

Bioequivalence Requirements for Anti-Retrovirals

The Drug Control Authority (DCA) decided to impose bioequivalence requirements on generic anti retroviral (ARV) drugs in accordance with the World Health Organisation (WHO) recommendations. The requirement announced and highlighted in the Newsletter of The Drug Control Authority Volume 20 dated April 2003

The following is the list of anti retroviral drugs registered with DCA.

LIST OF ANTI RETROVIRAL (ARV) DRUGS REGISTERED WITH DCA

No.	Active Ingredient	Comparator Products	
		Trade Mark / Registration No.	Manufacturer
1.	Abacavir	i) Ziagen Tablet (MAL20001015ARZ)	Glaxo Smith Kline Pharmaceutical SA, Poland Glaxo Wellcome Operations UK Ltd, United Kingdom
2.	Lamivudine	i) Zeffix Tablet 100mg (MAL19992323ARZ) ii) 3TC Tablets 150mg (MAL19963153ARZ)	Glaxo Smith Kline Pharmaceuticals SA, Poland Glaxo Wellcome Operations UK Ltd, United Kingdom Glaxo Smith Kline Pharmaceuticals SA, Poland Glaxo Wellcome Operations UK Ltd, United Kingdom
3.	Zidovudine	i) Retrovir Capsule 100mg (MAL19880248AZ)	1. S.C. Europharm S.A, Romania 2. Smithkline Beecham Pharm, Manor Royal, Crawley, West Sussex, RH10 9QJ, United Kingdom
This product can be obtained from Singapore, Taiwan & Indonesia (Information updated from GSK dated 27th January 2013)			
		ii) Zidovudine Capsules USP 100mg (MAL10053660AZ) iii) Zidovudine Tablets USP 300mg (MAL08051751AZ) iv) Zidovudine Tablets 300mg (MAL12070004AZ)	M/S Aurobindo Pharma Ltd, India M/S Aurobindo Pharma Ltd, India Mylan Laboratories Limited, India Matrix Laboratories Ltd, India

No.	Active Ingredient	Comparator Products	
		Trade Mark / Registration No.	Manufacturer
		As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 2/2013 – 2 September 2013	
4.	Efavirenz	i) Stocrin Tablet 50mg (MAL07050913A) ii) Stocrin Tablet 200mg (MAL07050912A) iii) Stocrin Tablets 600mg (MAL20032164A) iv) Stocrin Capsule 200mg (MAL19992039AR) V) Stocrin Capsule 100mg (MAL19992038AR) vi) Stocrin Capsule 50mg (MAL19992037AR) vii) Stocrin Tablet 50mg (MAL14055019ACRZ) viii) Stocrin Tablet 200mg (MAL14055020ACRZ) ix) Stocrin Tablets 600mg (MAL14035016ACRZ)	Merck Sharp & Dohme (Australia) Pty Ltd, Australia Merck Sharp & Dohme (Australia) Pty Ltd, Australia Merck Sharp & Dohme (Australia) Pty Ltd, Australia Bristol-Myers Squibb Holding Pharma Ltd, United States Bristol-Myers Squibb Holding Pharma Ltd, United States Bristol-Myers Squibb Holding Pharma Ltd, United States Zhejiang Huahai Pharmaceutical Co., Ltd (China) Zhejiang Huahai Pharmaceutical Co., Ltd (China) Zhejiang Huahai Pharmaceutical Co., Ltd (China)
5.	Indinavir	i) Crixivan Capsule 400mg (MAL19970276AR)	Merck & Co Inc, United States
6.	Nelfinavir	i) Viracept Film-Coated Tablet 250mg (MAL05032533A) ii) Viracept Tablets 250mg (MAL20020815AS)	Roche Farma S.A, Spain F.Hoffmann-LA Roche Ltd, Switzerland
7.	Saquinavir	i) Invirase Hard-Gelatin Capsule 200mg (MAL19970498ARZ) ii) Invirase Film-Coated Tablet 500mg (MAL07081488ARZ)	Roche Farma S.A, Spain F.Hoffmann-LA Roche Ltd, Switzerland Roche Farma S.A, Spain

No.	Active Ingredient	Comparator Products	
		Trade Mark / Registration No.	Manufacturer
8.	Atazanavir	i) Reyataz Capsule 200mg (MAL20061580AR)	Bristol-Myers Squibb Company, United States
		ii) Reyataz Capsule 100mg (MAL20061578AR)	Bristol-Myers Squibb Company, United States
		iii) Reyataz Capsule 150mg (MAL20061579AR)	Bristol-Myers Squibb Company, United States
		<p>The product is available in Singapore and Thailand. It can be purchased by contacting Idis Managed Access as below: (Information obtained via an email from BMS, Thailand dated 5 January 2017)</p> <p>Idis Managed Access Email: MAPPProgramAssociate@clinigengroup.com Website: www.clinigengroup.com</p> <p>As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2018' – 25 May 2018: Reyataz Capsule manufactured by AstraZeneca Pharmaceuticals LP, United States can also be used as a comparator.</p>	
9.	Darunavir	i) Prezista 300 mg Film-Coated Tablets (MAL20081771AZ)	Janssen Cilag SPA, Italy
10.	Raltegravir	i) Isentress 400mg Tablet (MAL20081777ARZ)	MSD International GmbH (Singapore Branch), Singapore Merck & Co Inc., United States
11.	Maraviroc	i) Celsentri Film-Coated Tablets 150mg (MAL20081833AZ)	Pfizer Manufacturing Deutschland GmbH, Germany Godecke GmbH, Germany
		ii) Celsentri Film-Coated Tablets 300mg (MAL20081834AZ)	Pfizer Manufacturing Deutschland GmbH, Germany Godecke GmbH, Germany
12	Etravirine	i) Intelence 100mg Tablets (MAL20091947AZ)	Janssen-Cilag S.P.A, Italy

No.	Active Ingredient	Comparator Products	
		Trade Mark / Registration No.	Manufacturer
13	Darunavir	i) Prezista 300mg Film-Coated Tablets (MAL20081771AZ)	Janssen Cilag S.P.A, Italy
14.	Tenofovir	Tenvir Film-Coated Tablet MAL20091933AZ	Cipla Ltd, India
15.	Tenofovir + Emtricitabine	Tenvir EM Tablets, MAL20091962AZ	Cipla Ltd, India
16.	Lopinavir + Ritonavir	Kaletra 100mg/25mg Film-Coated Tablet MAL10063000AZ	AbbVie Deutschland Gmbh & Co. KG, Germany
		Kaletra Film-Coated Tablet MAL08031363ARZ	AbbVie Deutschland GmbH & Co. KG, Germany
		Kaletra Capsules MAL20020995ACZ	Cardinal Health 409 Inc, United States
17	Tenofovir Disoproxil Fumarate + Emtricitabine+ Efavirenz	Viraday Tablets (Tenofovir Disoproxil Fumarate 300mg + Emtricitabine 200mg + Efavirenz 600 mg) MAL13065053AZ	Cipla Ltd, India

* This list is not meant to be exhaustive and will be updated from time to time according to the registration of new antiretroviral drugs in Malaysia.

Updated on 21/08/2018