



Bahagian Regulatori Farmasi Negara National Pharmaceutical Regulatory Agency KEMENTERIAN KESIHATAN MALAYSIA

MINISTRY OF HEALTH MALAYSIA
36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia

Tel: +603-78835400 Fax: +603-79562924 / 79567075 http://npra.moh.gov.my

GMP Certificate No. 2174/21

Our Ref.

: KKM/NPRA.PKP/600-2/5 (37) \$1d.19

Date

: 30 June 2021

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia hereby certifies that:

The Manufacturer

: Orient Laboratories Sdn. Bhd.

Site Address

: No. 37, Jalan PS 3,

Taman Industri Prima Selayang,

68100 Batu Caves,

Selangor, Malaysia.

Has been inspected in accordance with Malaysian Control of Drugs and Cosmetics Regulations 1984 and Malaysian Drug Registration Guidance Document (DRGD).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on <u>30 September 2019 – 1 October 2019</u>, it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guides and Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements, 1st Edition, 2008.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts I and II.

The authenticity of this certificate may be verified with the issuing authority.

(DR. NORAIDA MOHAMAD ZAINOOR) RPh. 2289

Head of Good Manufacturing Practice Section Centre for Compliance & Quality Control National Pharmaceutical Regulatory Agency

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Part II

√ Human Medicinal Products

1.2	Non-sterile Products		
	1.2.1	Non-sterile products (processing operations for the following dosage forms) 1.2.1.2 Capsules, soft shell	
	1.2.2	Batch certification	
1.4	Other Products or Processing Activity		
	1.4.1	Manufacture of:	
		1.4.1.3 Others – Health Supplements (capsules, hard shell; capsules, soft shell; tablets), Traditional Medicines (capsules, hard shell; tablets;	
		powders; liquids for internal use)	
1.5	Packa	ging	
	1.5.1	Primary packing	
		1.5.1.1 Capsules, hard shell	
		1.5.1.2 Capsules, soft shell	
		1.5.1.6 Liquids for internal use	
		1.5.1.8 Other solid dosage forms - powders	
		1.5.1.13 Tablets	
	1.5.2	Secondary packing	
1.6	Qualit	ty Control Testing	
	The second second		
	1.6.2	Microbiological: non-sterility	

Any restrictions or clarifying remarks related to the scope of this certificate: -None-

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