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
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GMP Certificate No. 1696/20

Our Ref. : KKM/NPRA.PKP/600-2/5 (63) jld 13
Date : 16 June 2020

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia confirms the following:

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 **30 September - 01 October 2019**, it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guides.

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. ROSHAYATI MOHAMAD SANI) RPh. 1449
Head of Centre of Compliance & Quality Control
National Pharmaceutical Regulatory Agency

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Part II

√ Human Medicinal Products

1. MANUFACTURING OPERATIONS – 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) and traditional (Tablets, Capsules, hard shell; powders, liquids for internal use)
1.5	**Packaging**
	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 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal product – Powders
	1.5.2 Secondary packing
1.6	**Quality Control Testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

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

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