

### BAHAGIAN REGULATORI FARMASI NEGARA

National Pharmaceutical Regulatory Agency

# KEMENTERIAN KESIHATAN MALAYSIA

Ministry of Health Malaysia

Lot 36, Jalan Prof. Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor, Malaysia

Tel: +603-78835400 https://www.npra.gov.my

GMP Certificate No. 3143/23

Our Ref.

: KKM/NPRA.PKP/600-2/5 ( 76 ) Ind 32

Date

: **25** July 2023

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

### Part I

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

The Manufacturer

: B-Crobes Laboratory Sdn. Bhd.

Site Address

: 18 & 20, Lintasan Perajurit 17G,

Taman Teknologi Industri & Perusahaan Ipoh,

31400 Ipoh,

Perak, 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>18 May 2023</u>, 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. NORAIDA MOHAMAD ZAINOOR) RPh. 2289

*Head* of 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)
	1.2.1.8 Other solid dosage forms – granules
	1.2.2 Batch certification
1.4	Other products or processing activity
	1.4.4 Manufacture of:
	1.4.1.3 Others – health supplements (granules)
1.5	Packaging
	1.5.1 Primary packing
	1.5.1.8 Other solid dosage forms - granules
	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------ End of pages ------

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