Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-CE-11258-1

Issued to:

Pharmtech (Hong Kong) Limited

Manufacturing Site Address:

5th & 6th Floor, Unit 7 17th Floor and Unit 10 18th Floor,
Cheung Fung Industrial Building 23-39 Pak Tin Par Street
TSUEN WAN HONG KONG - SAR OF CHINA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing manufacturers located outside Australia.

This certificate is issued based on a remote inspection of GMP compliance during COVID19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 27 to 29 July 2021, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 July 2021.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 29 January 2024

ISSUE DATE: 5 November 2021

This Certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

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MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Powders and granules	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Lotion	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Hard Capsules	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms – Tablets	Registered Therapeutic Good	Packaging and labelling
Medicine/Device manufacture	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Secondary packaging
Medicine manufacture	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing
Medicine manufacture	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Release for supply

The following limitations are applicable to these manufacturing operations:

The bulk formulation of medicines is limited to only those products that qualify as Traditional Chinese medicines, complementary medicines, and sunscreens.

The release for supply of registered therapeutic goods is limited to only those products that qualify as Traditional Chinese medicines, complementary medicines, and sunscreens.

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