Australian Government

Department of Health
Therapeutic Goods Administration

Mr Edward Yau
PuraPharm (Nanning) Pharmaceuticals Co Ltd
46 Keyuan Road, Industrial Park, New & Hi-Tech Industrial Development Zone
Nanning Guangxi – P.R.China

Our Reference: 2014/026566

Dear Edward Yau

Subject: Issue of GMP certificate MI-2016-CE-01706-1

Please find enclosed the GMP certificate for your manufacturing premises.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Signed and authorised by

David Rowbury
Senior Inspector
Manufacturing Quality Branch

17 August 2017

Contact: gmp@tga.gov.au, phone +61 2 6221 6881 or fax +61 2 6232 8426

Australian Government

Department of Health

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-CE-01706-1

Issued to:

PuraPharm (Nanning) Pharmaceuticals Co Ltd

Primary Manufacturing Site Address:

46 Keyuan Road, Industrial Park, New & Hi-Tech Industrial Development Zone
Nanning Guangxi China

Secondary Manufacturing Site Addresses:

Nanxing Herbs Warehouse, 4th & 5th floors, No. 5 Zhenhua Road, New & Hi-Tech Industrial Development Zone, Nanning Guangxi- P.R. China

3rd & 4th Floor, Plant 3, Phase Two, China-Asean Corporate Headquarters Base, No 3 Zongbu Road, High- Tech Industrial Development Zone, Nanning, Guangxi- P.R. China.

1st to 4th floor, Haige Logistics Warehouse, Building 8, Phase Two, China-ASEAN Corporate Headquarters Base, No 3 Zongbu Road, High- Tech Industrial Development Zone, Nanning, Guangxi- P.R. 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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20 to 23 February 2017, 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 – 15 January 2009.

This certificate reflects the status of the manufacturing sites 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: 23 February 2020

ISSUE DATE: 17 August 2017

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

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Certificate Number:

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MANUFACTURING OPERATIONS

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

Primary Site: 46 Keyuan Road, Industrial Park, New & Hi-Tech Industrial Development Zone Nanning Guangxi China

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Granules	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Powder, oral	Listed Therapeutic Good	Finished Product Manufacture

Secondary Site: Nanxing Herbs Warehouse, 4th & 5th floors, No. 5 Zhenhua Road, New & Hi-Tech Industrial Development Zone, Nanning Guangxi- P.R. China

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Not Applicable	Listed Therapeutic Good	Storage

Secondary Site: 3rd & 4th Floor, Plant 3, Phase Two, China-Asean Corporate Headquarters Base, No 3 Zongbu Road, High- Tech Industrial Development Zone, Nanning, Guangxi- P.R. China.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Not Applicable	Listed Therapeutic Good	Storage

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
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Secondary Site: 1st to 4th floor, Haige Logistics Warehouse, Building 8, Phase Two, China-ASEAN Corporate Headquarters Base, No 3 Zongbu Road, High- Tech Industrial Development Zone, Nanning, Guangxi- P.R. China

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Not Applicable	Listed Therapeutic Good	Storage

The following limitations are applicable to these manufacturing operations:

Manufacture is restricted to non-sterile herbal therapeutic goods only

This certificate does not authorise the manufacture of any product to which a Schedule of the Poisons Standard applies.

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
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