Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2013-CE-04456-1

Issued to:

Tianda Pharmaceuticals (Zhuhai) Ltd

Manufacturing Site Address:

82 Anlian Road

Qianshan Zhuhai 519070 Peoples Republic 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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 24 – 27 March 2014, 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 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: 27 March 2017

ISSUE DATE: 20 June 2014

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Hongixa Jin
Senior GMP Inspector
Office of Manufacturing Quality

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
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 8444 Fax: 02 6232 8605 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	Solid Unit Dosage Forms - Tablets	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	Granules	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Oral Liquid	Registered Therapeutic Good	Finished Product Manufacture
Active Pharmaceutical Ingredient manufacture	Non Sterile	Not Applicable	Not Applicable	API - Plant Extraction

The following conditions are applicable to these manufacturing operations:

The certificate does not authorise the manufacture of preparations containing penicillins, cephalosporins, hormones, steroids or antineoplastic drugs.

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Hongxia Jin
Senior GMP Inspector
Office of Manufacturing Quality

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