Australian Government

Department of Health
Therapeutic Goods Administration

Dr V. Satyanarayana
Sipra Labs Limited
7-2-1813/5/A, Adjacent to Post Office, Industrial Estate, Sanathnagar
Hyderabad
Telangana
India

Our Reference: 2015/028444

Dear Dr V. Satyanarayana

Subject: Issue of GMP certificate MI-2017-CE-01201-1

Please find enclosed the GMP certificate for your manufacturing premises.

You may note its changed layout with new security provisions: blue and grey curved dotted lines at the bottom half of each page. These provisions are intended to prevent unauthorised copying as part of a process to introduce issuing certificates electronically in the near future. This will also include using electronic signatures only.

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,

Noel Fraser
Senior Inspector
Manufacturing Quality Branch

16 February 2017

Contact: gmp@tga.gov.au, phone 1800 446 443 or fax 02 6232 8426

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2017-CE-01201-1

Issued to:

Sipra Labs Limited

Manufacturing Site Address:

7-2-1813/5/A, Adjacent to Post Office, Industrial Estate, Sanathnagar,
Hyderabad, Telangana, India

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 09 November 2015 to 13 November 2015, 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: 13 May 2018

ISSUE DATE: 16 February 2017

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

Signed: 16/02/17

Noel Fraser, Senior Inspector
Manufacturing Quality Branch

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

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2017-CE-01201-1

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
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Product Microbiological Contamination Testing
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing Physical
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Potency assays
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Endotoxin Testing
Testing Laboratory	Sterile	All Dosage Forms	Registered Therapeutic Good	Testing sterility
Testing Laboratory	Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing biological
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing chemical and physical
Testing Laboratory	Non Sterile	API - Not Defined	Not Applicable	Microbiological Contamination Testing
Testing Laboratory	Non Sterile	API - Not Defined	Not Applicable	Testing chemical and physical

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

Signed: 16/02/17

Noel Fraser, Senior Inspector
Manufacturing Quality Branch

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Certificate Number:

MI-2017-CE-01201-1

The following limitations are applicable to these manufacturing operations:

Nil applicable.

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

Signed: 16/02/17

Noel Fraser, Senior Inspector
Manufacturing Quality Branch

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