Australian Government

Department of Health
Therapeutic Goods Administration

2014/032242

Mr Sreedhar Reddy
Adcock Ingram – a Medreich Company
No 49 (C&D) Bommasandra Industrial Area, Annejal Taluk, Bangalore Karnataka
Anekal Taluk
Bangalore 560 099
INDIA

Dear Mr Reddy,

Subject: Issue of GMP certificate MI-2015-CE-00655-1

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,

Robert Prestridge
Senior Inspector
Manufacturing Quality Branch

18 July 2016

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-2015-CE-00655-1

Issued to:

Adcock Ingram Limited - A Medreich Group Company

Manufacturing Site Address:

No 49 (C&D) Bommasandra Industrial Area Annejal Taluk Bangalore Karnataka
Anekal Taluk Bangalore 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 12 to 14 May 2016, 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: 14 May 2019

ISSUE DATE: 18 July 2016

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

Signed: .....

Robert Prestridge, 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-2015-CE-00655-1

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
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	Powders and Granules	Registered Therapeutic Good	Finished Product Manufacture

The following limitations are applicable to these manufacturing operations:

No further conditions are applicable

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

Signed: .....

Robert Prestridge, Senior Inspector
Manufacturing Quality Branch

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