Australian Government

Department of Health
Therapeutic Goods Administration

Mr Hemant Udawant
AGM - QA
Albany Molecular Research Hyderabad Research Centre Pvt Ltd
Plot No G-1/1 1/2 Near MIDC Water Tank,
MIDC Area Waluj
Aurangabad Maharashtra 431136
INDIA

Our Reference: 2014/024212

Dear Mr Udawant,

Subject: Issue of GMP certificate MI-2019-CE-01051-1

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

Stephen Hart
Senior Inspector
Manufacturing Quality Branch

01 February 2019

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

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2019-CE-01051-1

Issued to:

Albany Molecular Research Hyderabad Research Centre Pvt Ltd

Manufacturing Site Address:

Plot No G-1/1 1/2, Near MIDC Water Tank, MIDC Area
Waluj Aurangabad Maharashtra 431 136

INDIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of Active Pharmaceutical Ingredients (APIs) 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 API manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 28 May 2018 to 1 June 2018, 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 January 2017.

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: 0**1 December 2020**

ISSUE DATE: **01 February 2019**

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

Australian Government

Department of Health

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2019-CE-01051-1

MANUFACTURING OPERATIONS

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

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Non Sterile	Not Applicable	Registered Therapeutic Good	Active material manufacture

ACTIVE SUBSTANCES MANUFACTURED

This certificate is limited to the manufacture of APIs by chemical synthesis, namely Atenolol, Furosemide, Diatrizoate Sodium and Diatrizoate Meglumine.

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The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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TGA Health Safety Regulation