Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Mr Syam Sundar Koneti
AGM - Quality & Regulatory
Glochem Industries Private Ltd
Survey No 174 to 176, IDA Bollaram Jinnaram Mandal
Sangareddy District Telangana State 502325
India

TGA Reference: 2014/025947

Subject: Issue of GMP certificate MI-2021-CE-09148-1

Dear Mr Koneti,

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

Jenny Hantzinikolas
Senior GMP Inspector
Manufacturing Quality Branch

29 September 2023

Contact: GMP@health.gov.au, Phone: 1800 020 653

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2021-CE-09148-1

Issued to:

Glochem Industries Private Ltd

Manufacturing Site Address:

Survey No 174 to 176, IDA Bollaram Jinnaram Mandal
Sangareddy District Telangana State 502325
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) of the *Therapeutic Goods Act 1989* in connection with marketing authorisations listing API manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20 to 22 June 2023, 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 May 2021.

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.

Issue Date: **29 September 2023** **Expiry Date:** **22 December 2026**

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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

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Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2021-CE-09148-1

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	API - Not Defined	Not Applicable	Active material manufacture

The following limitations are applicable to these manufacturing operations:

This certificate is limited to the manufacture of APIs by chemical synthesis.

ACTIVE SUBSTANCES MANUFACTURED

Amlodipine besylate

Amlodipine maleate

S(-)amlodipine besilate

Levocetrizine dihydrochloride

Cetirizine dihydrochloride

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