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-09392-1

Issued to:

Macsen Drugs

Manufacturing Site Address:

F-261 262 263 RIICO Industrial Area
Gudli Tehsil Mavli Udaipur Rajasthan 313024
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 13 to 14 April 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: **4 October 2023** **Expiry Date:** **14 October 2025**

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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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:

Microbiological testing is conducted by third party testing laboratories under the control of Macsen Drugs.

ACTIVE SUBSTANCES MANUFACTURED

Methylene Blue USP, Methylthioninium Chloride Ph Eur / BP, Silver Sulfadiazine USP, Selenium Sulfide USP / Ph Eur, Indigotindisulfonate Sodium USP, Selenious Acid USP, Fluorescein Sodium USP / Ph Eur

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