Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2022-CE-09110-1

Issued to:

Rusan Pharma Ltd

Manufacturing Site Address:

Unit-II Shed No 383 AS-I Sector IV Kandla Special Economic Zone (KASEZ)
Gandhidham District Kutch Gujarat 370230
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 15-April-2024 to 17-April-2024, 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: **05-August-2024** **Expiry Date:** **17-April-2027**

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 therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Patch, dermal	Registered Therapeutic Good	Finished Product Manufacture

The following limitations are applicable to these manufacturing operations:

This certificate does not authorise the manufacture of preparations containing biological medicines, penicillins, cephalosporins, hormones, steroids or antineoplastic drugs.

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