Australian Government
Department of Health
Therapeutic Goods Administration

Mr Rajesh Sen
DGM Quality Assurance
Rusan Pharma Ltd
Unit-II, Shed No. 383, AS-I, Sector IV
Kandla Special Economic Zone (KASEZ)
Gandhidham District Kutch Gujarat 370230
India

TGA Reference: E20-365576

Subject: Issue of GMP certificate MI-2020-CE-10376-1

Dear Mr Sen,

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

Maurice Makdessi
Senior GMP Inspector
Manufacturing Quality Branch

9 August 2022

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

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2020-CE-10376-1

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.

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10 to 17 January 2022, 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 July 2018.

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: 17 October 2023

ISSUE DATE: 9 August 2022

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

Certificate Number:

MI-2020-CE-10376-1

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	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.

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.

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TGA Health Safety Regulation