



Australian Government

Department of Health
Therapeutic Goods Administration

Vinod Shukla
DGM-QA
Rusan Pharma Ltd
Khasra No 122 MI Central Hopetown
SELAQUI DISTRICT: DEHRADUN UTTARAKHAND 248197
INDIA

TGA Reference: E20-365612

Subject: Issue of GMP certificate MI-2020-CE-09609-1

Dear Vinod Shukla,

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

1 February 2022

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



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Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2020-CE-09609-1

Issued to:

Rusan Pharma Limited

Manufacturing Site Address:

Khasra No. 122 MI Central Hope Town,
SELAQUI DISTRICT: DEHRADUN UTTARAKHAND 248197
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 COVID19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 15 to 18 November 2021, 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: 18 November 2024

ISSUE DATE: 1 February 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.



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Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2020-CE-09609-1

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	Solid Unit Dosage Forms - Tablets	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Oral Liquid, syrup	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.