

L.Dis.No. 8958/STORES/2021

Dated: 30-01-2021

To,
M/s. SPAL Private Limited,
Plot No.12, Biotech Park,
Phase-II, Lalgadi Malakpet
Shameerpet, Medchal-Malkajgiri Dist,
Hyderabad, Telangana State - 500101.

Sir,
Sub: Drugs and Cosmetics Act, 1940 and Rules made there under - Issue of
World Health Organisation G.M.P. Certificate - Regarding.

Ref: 1. Your letter dated: 06.01.2021
2. Joint Inspection report Dated: 13.01.2021 & 14.01.2021.

-X-X-X-X-

With reference to your application cited, I forward here with **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Telangana State and CDSCO, Zonal Office, Hyderabad vide reference 2nd cited.

This Certificate is valid Up to for a period of Three years from the date of issue.

Yours faithfully,



B. Venkateswarlu
30/01/21

Dr. B. VENKATESHWARLU
Joint Director & Licensing Authority (FAC)

Dr. B. VENKATESHWARLU
Joint Director (ENF)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad - 500 038, T.S.

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**LIST OF PRODUCTS APPROVED UNDER WHO-GMP
CERTIFICATION SCHEME FOR EXPORT PURPOSE**

1. REMDESIVIR FOR INJECTION 100mg

SPREM 100

Each vial contains

Remdesivir 100 mg

Excipients q.s

Manufacturer : M/s. SPAL Private Limited
Plot No-12, Biotech Park,
Phase-II, Lalgadi Malakpet,
Shameerpet, Medchal-Malkajgiri Dist
Hyderabad, Telangana State.

When applicable : Placing the product on the market
detailed as above.

It is certified that the above products had been authorized to be placed on the market for use in the country and exporting countries.

Drug License No. : 3/RR/TS/2016/F/G, dated: 21.01.2021
under Form-28 valid up to 20.01.2026

It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals.

The unit M/s. SPAL Private Limited, Plot No-12, Biotech Park, Phase-II, Lalgadi Malakpet, Shameerpet, Medchal-Malkajgiri Dist, Hyderabad, and Telangana State was inspected jointly by Mr. Raghuvaran, Drugs Inspector, CDSCO, Hyderabad and Mr. Prasad, Drugs Inspector, Drugs Control Administration, Hyderabad, Telangana State on 13.01.2021 & 14.01.2021.

(b) The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacturer and Quality Control (As recommended by the World Health Organization) in respect of 01 (One) product to be sold or distributed within the Country or origin (or to be exported).

This Certificate is valid for Three years from the date of issue.

Yours faithfully,



B Venkateswarlu
30/01/21

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