DRUGS CONTROL ADMINISTRATION
Government of Telangana

L. Dis. No.:3638/E1/2020

Dated: 16 -02-2021

To
Mylan laboratories Limited
(Specialty Formulation facility)
No. 19A, Plot No.284-B/1,
Bommasandra-Jigani Link Road,
Industrial Area, Anekal Taluk,
Bangalore- 560105
ON
Gland Pharma Limited (Unit-II)
Plot No. 42 to 52, Sy, No. 166,171,172 & 177,
TSIIC Phase-III, IDA Pashamylaram (V),
Patancheru (M), Sangareddy District – 502307,
Telangana State, India.

Digitally signed by Dicusar Vladimir
Date: 2021.12.21 10:30:16 EET
Reason: MoldSign Signature
Location: Moldova

Sirs,

Sub:- Drugs and Cosmetics Act, 1940 and Rules made thereunder-Issue of **World Health Organization Good Manufacturing Practice**Certificate– Regarding.

Ref:- 1. Your application dt. 01-10-2021
2. CDSCO Ref.No.5-6(030)2020/3838 dated 09-02-2021
3. Joint Inspection dated: 02/09/2020&03/09/2020

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With reference to your application cited, I forward herewith the **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drug Control Administration, Hyderabad, and CDSCO, Zonal Office, Hyderabad, Telangana vide reference 3rd cited.

This certificate is valid for a period of **Three years** from the date of issue.

Date:

Deputy Director Drugs Control Administration Government Of Telangana HYDERABAD

Yours faithfully,

16/02/2021

G. Ramdhan, M.Pharm
Deputy Director-I (FAC) &
Licensing Authority

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L. Dis. No.:3638/E1/2021 – **Issue of WHO GMP Certificate** to **Mylan laboratories Limited (Specialty Formulation facility), ON M/s.Gland Pharma Limited (Unit-II),** Plot No. 42 to 52, Sy, No. 166,171,172 & 177,TSIIC Phase-III, IDA Pashamylaram (V), Patancheru(M), Sangareddy District – 502307,Telangana State, India.

LIST OF PRODUCTS APPROVED UNDER WHO GMPCERTIFICATION SCHEME FOR EXPORT PURPOSE

S.No	Generic Name	Brand Name	Composition	Pack Size	Market
1	Remdesivir for Injection 100mg/vial (DCGI NOC No. SND/MA/20/000224 Dated: 28/09/2020	DESREM	Each Lyophilized vial contains: Remdesivir 100mg	30 mL Vial	Export
(Shelf life assigned:12 months as per F.No.ND/MA/20/000084, dt:15.01.2021)					

Manufacturer : **Mylan laboratories Limited (Specialty Formulation facility)**
On
M/s.Gland Pharma Limited (Unit-II)
Plot No. 42 to 52, Sy, No. 166,171,172 & 177,
TSIIC Phase-III, IDA Pashamylaram (V)
Patancheru (M), Sangareddy District – 502307,
Telangana State, India.

When applicable :Placing the products on the market 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. :TS/SGY/2020-65910 dated 15-09-2020
Under Form- 28Valid till 14-09-2025

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

The Unit M/s.**Mylan laboratories Limited (Specialty Formulation facility), On M/s.Gland Pharma Limited (Unit-II),** Plot No. 42 to 52, Sy, No. 166,171,172 & 177, TSIIC Phase-III, IDA Pashamylaram, Patancheru, Sangareddy District – 502307, Telangana State, India was Jointly inspected by Mrs.L. Suganthi, Dr. Jay Jyothi Roy, Drugs Inspector, CDSCO, Hyderabad and Sri. Ch.Karthik Siva Chaitanya, Drugs Inspector, R.C.Puram(Mfg.), Drugs Control Administration, Hyderabad on 02/09/2020 & 03/09/2020

The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality control (As recommended by the World Health Organization) in respect of products mentioned above 01 Product (One Product) to be sold or distributed with in the country of origin (or to be exported).

This certificate is valid for a period of **Three years** from the date of issue.

Yours faithfully,

16/09/2021

Date:

G. Ramdhan, M.Pharm
Deputy Director-I (FAC) &
Licensing Authority