GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

No. DCD/MFG/CR-328/2020-21

Office of the Drug Controller
for the State of Karnataka,
Palace Road, Bengaluru -01,
Date: 02 JUL 2020

To,
M/s. Mylan Laboratories Ltd.,
[Specialty Formulation Facility],
No. 19A, Plot No. 284-B/1,
Bommasandra - Jigani Link Road,
Industrial Area, Anekal Taluk,
Bengaluru - 560 105.

Sir,

Sub: Drugs & Cosmetics Act 1940 and Rules 1945-Application for grant of additional product.

Ref: 1) Your application dated 02.07.2020 for additional product - **"Remdesivir for Injection 100 mg/Vial".**
2) DCG(I), New Delhi letter Ref. No. F. No. ND/MA/20/000084, dated 02.07.2020 with Form CT-23 Number of the permission and date of issue MF-ND-116/2020, dated 02.07.2020.

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You are hereby permitted to manufacture the following product under your manufacturing licence in Form 28 bearing No. KTK/28/384/2009.

Sl. No.	Name of the Product	Composition
1	Remdesivir for Injection 100 mg/Vial	Each Lyophilised Vial Contains: Remdesivir 100mg

The above permission is granted subject to the following conditions:

1. You are required to intimate the date of commencement of manufacture of the said product and to send the test reports of the first six batches of the product duly analysed at an approved laboratory.

2. You are directed to comply with the conditions specified in the DCG(I), New Delhi letter cited at above reference No. 2.

3. You should comply with Drugs (Price Control) Order 2013 as applicable to your unit and also to the price fixed by the NPPA for the product permitted under this letter, if any.

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DRUGS CONTROLLER FOR THE STATE OF KARNATAKA
OFFICE OF THE

4. The packing of the product shall be in conformity with the provisions of Schedule P-1 as applicable.

You are requested to submit the printed specimen labels/cartons of the above product in triplicate complying with labeling provisions to this office for records.

Yours faithfully,

(Amaresh Tumbagi)
Additional Drugs Controller &
Licensing Authority

OFFICE OF THE DRUGS CONTROLLER FOR THE STATE OF KARNATAKA