MYLAN LABORATORIES LTD.
Specialty Formulation Facility
Bangalore - India

CERTIFICATE OF CONFORMANCE

Product Name :	Remdesivir for Injection – 100mg/Vial [DESREM][1's][MPPL, ROW]		
Strength/Potency	100 mg		
Dosage form:	Lyophilized Injectable		
Product Code:	3008013		
Pack size and type :	30ml/20 mm Tubular USP Type I Vial.		
Lot no.:	7605710		
Date of Manufacture:	Aug / 2020		
Expiration date :	Jul / 2022		
Importing Country:	ROW		
Total units released	29,599 Vials		
Manufacturing Doc.ID #	BOM No. BOM/00013860 BMR REF. No.2005320/520.0L/S2/V0		
Packing Doc.ID #	BPR REF. No: (PART A) 3008013/V1, PART B. Version No. (R12)		
Manufacturing, Packaging and Testing Site Name	Mylan Laboratories Ltd. Specialty Formulation Facility.		
Manufacturing, Packaging and Testing Site address:	284/B1, BJLR Industrial Area, Jigani Hobli, Anekal Taluk, Bangalore 560105, INDIA.		
Manufacturing, Packaging and Testing Authorization No.:	KR/DRUGS/KTK/28/384/2009		
Manufacturing, Packaging and Testing Site GMP Certificate No.	DCR/CR/1834/SPL-CL/15-16		
Validation Lot	Yes □ √	No□	
Comments: Nil			
LOT DEVIATION INVESTIGATIONS			
Deviation Number.	Resolved		
NIL	□Y	□N	√□NA
I hereby certify that the above tested finished drug Product manufactured by " Mylan laboratories Limited "was produced in accordance with all requirements listed in the product registration and in accordance with current Good manufacturing Practices for finished pharmaceuticals as specified in Drugs and cosmetics Act and Rules, Government of India.			
Authorized by	Chandra Mohan .D		
Title	Sr. Team Leader		
Signature	Cmohan		
Date	01/Sep/2020		

MYLAN LABORATORIES LIMITED
Plant: Mylan Laboratories Limited-SFF

PRODUCT RELEASE CERTIFICATE

PRC Serial Number : 6001122032

To : Finished Goods Stores

From : Quality Assurance Dept.

Name of the Product : Remdesivir for Injection [100mg/vial] [DESREM] [1's] [MPPL, ROW]

Product Code : 3008013

Batch No. : 7605710

No. of QP Samples (If Applicable): Not Applicable

Quantity Released (Including QP Samples) : 29,599.000 PAC (1'S)

1. Documents and records are correct and free of obvious errors.

2. Yield of the product at various stages are within the acceptable limits and any variation from the limits is investigated in accordance to the current approved standard operating procedures.

3. Accountability of pre-printed packing material used is correct and reconciliation is satisfactory.

4. Reference samples from the batch and completed records of manufacture and testing have been retained

5. All starting material, packaging material and finished product were analysed and complying with the specifications.

6. Product manufacturing and packing were supervised by trained qualified personnel in accordance with principles and guidelines of Good Manufacturing Practice.

Note: This product is certified free of BSE / TSE risk

Released by: Chandra Mohan Dokka
Date: 01-SEP-2020

*This is an electronically generated record, and hence does not require handwritten signature