

MYLAN LABORATORIES LIMITED-SPECIALTY FORMULATION FACILITY

CERTIFICATE OF ANALYSIS - FINISHED PRODUCT (LIMS)

Page 1 of 4

Product name : DESREM	
Generic Name : Remdesivir for Injection 100mg/vial	
Batch No. : 7605648	A.R. No. / Date : 40000100298 / 29-Jul-2020
Batch Size : 30952 Nos	Sample no. : 535560
Mfg. Date : 07-2020	Product code : 3008013
Exp. Date : 06-2022	Specification No. : 2005320/PRS/R1
Customer : Mylan Pharmaceuticals Pvt. Ltd.	

Tests	Specifications	Results
Description	White to off-white to yellow lyophilized powder or lumps or solid in vial plugged with stopper and aluminium seal.	White lyophilized solid in vial plugged with stopper and aluminium seal.
Identification A	By HPLC: The retention time of the Remdesivir peak in sample solution chromatogram should correspond to that of standard solution chromatogram as obtained from Assay by HPLC test.	The retention time of the Remdesivir peak in sample solution chromatogram corresponds to that of standard solution chromatogram as obtained from Assay by HPLC test.
Identification B	By HPLC: The UV spectrum of Remdesivir peak of the sample solution should correspond to that of standard solution as obtained in the Assay by HPLC test.	The UV spectrum of Remdesivir peak of the sample solution corresponds to that of standard solution as obtained in the Assay by HPLC test.
pH	Between 3.0 and 4.0	3.46
Color of solution	Sample solution should not be more intense than BY5.	Sample solution is not more intense than BY5.
Constituted Solution		
A. Reconstitution time	Not more than 5.0 minutes	0.80 minutes
B. Completeness and clarity of solution		
i)	Solid should dissolve completely leaving no visible residue as undissolved matter.	Solid dissolves completely leaving no visible residue as undissolved matter.

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CIN: U24231TG1984PLC005146

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ii)	The constituted solution should not be significantly less clear than an equal volume of the diluent contained in similar vessel and examined similarly.	The constituted solution is not significantly less clear than an equal volume of the diluent contained in similar vessel and examined similarly.
C. Particulate matter	The solution should be essentially free from particles of foreign matter that can be observed on visual inspection.	The solution is essentially free from particles of foreign matter that can be observed on visual inspection.
Container Content [Extractable volume]	After reconstitution: Not less than 20mL	21mL
Water by KF	Not more than 3.0 %	0.57 %
Particulate Matter by Light Obscuration		
Particle size greater than or equal to 10 µm	Not more than 6000 particles per vial	260.4 per vial
Particle size greater than or equal to 25 µm	Not more than 600 particles per vial	15.4 per vial
Uniformity of dosage units by weight variation	The Acceptance value of 10 dosage units should be less than or equal to L1 % [L1 is 15.0]	L1: 0.4
Assay by HPLC	Each vial contains Remdesivir Label claim - Limits	
Assay in %	100 mg: Between 95.0% and 105.0% of Label claim	98.9 %
Assay in mg	100 mg: Between 95.0 mg and 105.0 mg	98.9 mg

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Related substances by HPLC		
Trihydroxy Cyano Triazine	Not more than 1.0%	BQL[LOQ=0.07%]
Phenol impurity	Not more than 1.0%	BDL[LOD=0.02%]
Remdesivir Amide analog	Not more than 1.0%	BQL[LOQ=0.07%]
Remdesivir Rp isomer	Not more than 1.0%	BQL[LOQ=0.07%]
Remdesivir Acetonide	Not more than 1.0%	BQL[LOQ=0.07%]
Any unspecified impurity	Not more than 0.5%	BQL[LOQ=0.07%]
Total impurities	Not more than 2.5%	BQL
Sterility	Must be sterile	Sterile
Bacterial Endotoxins by LAL test	Not more than 0.9 EU/mg	Less than 0.6750 EU/mg

Conclusion: .The sample complies with above standards as per IH Specifications

Remarks : Not Applicable

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Checked by	: R. Bosu Babu	Approved by	: Govindaraju. S
Designation	: Sr. Team Leader QC	Designation	: Sr. Group Leader QC
Date	: 30-Jul-2020	Date	: 30-Jul-2020

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