EVAPHARMA
Securing Your Health

Certificate of analysis for finished products

Name of product: Remdesivir 5 mg / ml Concentrate for IV	
Active ingredients: Each vial contains Remdesivir 100 mg	**Code of method of analysis:** MOA-VA-353.03
Batch number: 2101265	
Batch type: Export	**Batch size:** FP 9708 BOXES (Frontier Market)
Mfg. date: 01/2021	**Exp. date:** 01/2022
Analysis date: 15/02/2021	**Printing date:** 23/03/2021

Item		Specifications	Result	Conformity
1-Physical tests:				
1-Description		Clear Colorless to slightly yellow solution , free from visible particles	Clear Colorless to slightly yellow solution , free from visible particles	Conform
2-Extractable volume		NLT 20 ml	21 ml	Conform
3-PH at 25°C		3.0-4.0	3.65	Conform
2-Chemical tests:				
1-HPLC Identification of Remdesivir		In the Assay, the retention time of the principal peak in the chromatogram obtained with standard solution is the same as that of the principal peak in the chromatogram obtained with test solution.	Conform	Conform
2- HPLC Assay of Remdesivir		90-110% w/w of label claim	95.56 %	Conform
3-Particulate Matters:		Average number of particles presents in the unit tested does not exceed 6000 per container equal to or greater than 10µm and does not exceed 600 per container equal to or greater than 25µm	Conform	Conform
4-Impurity profile	-Any unspecified individual impurity	NMT 0.2%	Max Imp 0.08 %	Conform
	-Total Impurities	NMT 2.0%	0.21 %	Conform
	GS-711463	NMT 1.0%	ND	conform
	GS-411524	NMT 1.0%	ND	conform
	Phenol	NMT 0.12%	ND	Conform
3-Microbiology tests:				
1-Sterility Test		Sterile (No turbidity)	Sterile	Conform
2-Bacterial Endotoxin Test (Quantitative method)		N.M.T. 0.98 endotoxin units per mg of Remdesivir	Pass	Conform
Conclusion		This product complies with the above specifications.		

Result : **Approved:** ☒ **Rejected:** ☐

Prepared by : Maggie 23/3/2021 **QA :** Lydia 23/03/21

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Digitally signed by Sîli Oleg
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