

CERTIFICATE OF ANALYSIS

Product Name	Remdesivir	Batch NO.	RY20200918
Production date	2020.09.18	Expired Date	2022.09.17
CAS NO.	1809249-37-3	Standard	Enterprise standard
Tests	Limits	Test results	
Appearance	White or off-white Powder	White powder	
Solubility	Insoluble in water and soluble in ethanol	Conforms	
Identification	HPLC: the retention time of main peak of test product is consistent with that of standard.	Conforms	
Specific rotation	-18° ~-25°	-20.32°	
Water	≤1.0%	0.07%	
Heavy metal	≤10ppm	Conforms	
Related substance	Rp-Isomer ≤0.1%	0.003%	
	Nitrophenol≤0.1%	N.D.	
	RD-3.1≤0.1%	N.D.	
	RD-C≤0.1%	N.D.	
	RD-D≤0.1%	N.D.	
	RD-E≤0.1%	N.D.	
	Any unknown single impurity≤0.1%	0.02%	
	The total impurities≤0.3%	0.07%	
Purity (HPLC)	≥99.7%	99.93%	
	Methylene dichloride≤0.06%	N.D.	
	n-Heptane ≤0.5%	N.D.	
	Acetonitrile ≤0.041%	N.D.	



Residue of solvents	Ethyl acetate $\leq 0.5\%$	N.D.
	Acetone $\leq 0.5\%$	N.D.
	Isopropyl ether $\leq 0.5\%$	N.D.
	Isopropyl acetate $\leq 0.5\%$	N.D.
	2,2-dimethoxypropane $\leq 0.1\%$	N.D.
	N,N-Diisopropylethylamine $\leq 0.1\%$	N.D.
	Isopropanol $\leq 0.5\%$	0.02%
	Tetrahydrofuran $\leq 0.072\%$	N.D.
Bacterial Endotoxin	$\leq 0.5\text{EU/mg}$	Conforms
Assay (HPLC)	98.0%~102.0%	99.8%
Storage: sealed preservation at room temperature.		
Conclusion: This batch meets enterprise standard.		



Tested by: Esther

Checked by: Alice

Approved by: Mich