

Certificate of Analysis

Product name:	Sofosbuvir		
Batch No.:	RY-170301	CAS No.:	1190307-88-0
Manufacturing date:	20170301	Expiry of Date	20190301
Quantity	52.5KG	Package	Drum

Items	Specification	Analysis Result
Appearance	White to off-white powder	Confirm
Identification	A:IR spectrum:Similar to reference substance B:Retention Time:Similar to reference substance	Confirm
Solubility	Slightly soluble in water, freely soluble in ethanol and acetone, soluble in 2-propanol and insoluble in heptane	Confirm
Polymorphic Identity	Form6	
Particle size distribution	D(0.9)<45um	43.60um
Melting point	120°C-130°C	122.0°C-124.0°C
Residue on ignition	≤0.20%	0.18%
Water (Volumetric Karl Fisher)	≤0.50%(w/w)	0.06%
Loss on drying	≤0.50%(w/w)	0.02%
Heavy metals	≤ 0.002%	Confirm
Impurity by HPLC	SFBA-1 ≤0.15% Any other impurity≤0.10% Total impurities≤0.50%	0.01% 0.02% 0.09%
Isomers	≤0.15%	0.006%
Residual Solvents	Acetone≤5000ppm Ethyl acetate≤5000ppm Toluene≤890ppm n-Heptane≤5000ppm Isopropyl acetate≤5000ppm	ND ND ND ND ND

	Isopropanol≤5000ppm Dichloromethane≤600ppm Chlorobenzene≤360ppm Acetic acid≤5000ppm Methanol≤3000ppm Tetrahydrofuran ≤720ppm Tert-Butylmethylether ≤5000ppm	ND ND ND ND ND ND ND
Assay	98.5%-101.5%	99.59%
Conclusion:	Complied with the specification.	