

Certificate of Analysis

Product name:	Ledipasvir:Copovidone solid dispersion(1:1)		
Batch No.:	RY-160601	CAS No.:	/
Manufacturing date:	20160615	Expiry of Date	20180614
Quantity	16.0KG	Package	Aluminum oil bag

Items	Specification	Analysis Result
Appearance	off-white to pale-yellow powder	Pale-yellow powder
Identification	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
Water (Volumetric Karl Fisher)	≤0.50%(w/w)	2.11%
Impurity by HPLC	Any other impurity≤0.20% Total impurities≤0.50%	0.07% 0.25%
Residual Solvents	Acetone≤5000ppm Ethanol≤5000ppm	ND ND
Assay(Calculated by Ledipasvir)	45.0%~55.0%	50.40%
Conclusion:	Complied with the specification.	

