



Certificate of Analysis

Product Name	Grazoprevir Hydrate		
Batch No.	20241101	Report No.	20241101
CAS No.	1350462-55-3	Quantity	20g
Manufacturing Date	2024.11.01	Retest Date	2026.11.05
Survey Date	2024.11.06	Issue Date	2024.11.06
Quality Standard	In-houseSpecification STP-QS-33-0070		
Items	Specifications	Results	
Appearance	White or almost white powder	White powder	
Differential	IR	Conforms	
	HPLC	Conforms	
	NMR	Conforms	
Solubility	Soluble in Dimethyl sulfoxide and almost insoluble in water.	Conforms	
Water	2.1%~3.0%	2.33%	
Loss on drying	≤ 1.0%	0.57%	
PSD	D90 Not more than 50μm	Conforms	
Residue on ignition	≤0.1%	0.04%	
Heavy metal	≤ 10ppm	ND	
Related substances	Max single impurity ≤0.1%	0.08%	
	Total impurities ≤1.0%	0.39%	
Purity（HPLC）	≥99.0%	99.61%	
Residue Solvents	Acetone: Not more than 5000ppm	1500ppm	
	Acetonitrile: Not more than 410ppm	100ppm	
	Methanol：Not more than 3000ppm	ND	

	Ethyl acetate: Not more than 5000ppm	ND
	Isopropanol: Not more than 5000ppm	ND
	Tetrahydrofuran: Not more than 720ppm	ND
	Dichloromethane: Not more than 600ppm	ND
Microbial limit	Total aerobic microbial count≤10 ³ cfu/g	Conforms
	Yeasts and molds ≤10 ² cfu/g	Conforms
	E.Coli : Negative	Conforms
Assay by HPLC(On anhydrous and solvent free basis)	Not less than 98.0% w/w and not more than 102.0% w/w	100.1%
Storage conditions	Vacuumed,sealed,keep out of the light,room temperature(below 25°C)	
Shipping conditions	Vacuumed,sealed,keep out of the light,below 25°C.	
Conclusion: The product meets in-house specification STP-QS-33-0070		
Prepared by :	Reviewed by:	Approved by :