



瑾 岚 医 药 技 术 开 发 有 限 公 司
Hangzhou Jinlan Pharm-Drugs Technology CO., Ltd.

Certificate of Analysis

Product Name	Glecaprevir		
CAS No	1365970-03-1	MFG.DATE	2024-09-27
Batch number	20240927	TEST DATE	2024-09-28
Quantity	2500g	Expiry Date	2026-09-26
Specification	100g/Drum	Standard	Enterprise standard

Item	Specification	Results
Appearance	White to light brown powder	White powder
Identification	IR	Conforms
	NMR	Conforms
Solubility	Soluble in methanol	Conforms
Loss on drying	≤ 1.0%	0.47%
Residue on ignition	≤0.1%	0.07%
Heavy metal	≤ 10ppm	Conform
Related substances	Max single impurity ≤0.1%	0.07%
	Total impurities ≤1.0%	0.23%
Purity (HPLC)	≥99.0%	99.77%
Assay	98% ~ 102%	99.46%
Residue Solvents	Acetonitrile ≤410ppm	N.D.
	Methanol ≤1500ppm	N.D.
Microbiological Purity	Total aerobic bacteria NMT 1000cfu/g	138cfu/g
	Total number of moulds and yeast NMT 100cfu/g	N.D.
	Escherichia Coli should be absent.	N.D.
Storage	Room temperature, light-protect.	
Conclusion	The tested results are qualified.	

Tested by: Meng Xiao

Checked by: Shen Junli

Approved by: He Youguang

