



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

Certificate of Analysis

Product Name	Pibrentasvir		
CAS No	1353900-92-1	MFG.DATE	2024-11-08
Batch number	20241108	TEST DATE	2024-11-09
Quantity	1000g	Expiry Date	2026-11-07
Specification	1000g/bag	Standard	Enterprise standard

Item	Specification	Results
Appearance	Off-white to white powder	Off-white powder
Identification	IR	Conforms
	NMR	Conforms
Solubility	Soluble in methanol	Conforms
Loss on drying	$\leq 1.0\%$	0.35%
Residue on ignition	$\leq 0.1\%$	0.06%
Heavy Metal	$\leq 10\text{ppm}$	Conforms
Related substances	Max single impurity $\leq 0.1\%$	0.04%
	Total impurities $\leq 1.0\%$	0.13%
Purity (HPLC)	$\geq 99.0\%$	99.87%
Assay	98% ~ 102%	99.78%
Residue Solvents	Acetonitrile $\leq 410\text{ppm}$	N.D.
	Methanol $\leq 1500\text{ppm}$	220ppm
Microbiological Purity	Total aerobic bacteria NMT 1000cfu/g	150cfu/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	Qualified	

Tested by: Meng Xiao

Checked by: Shen Junli

Approved by: He Youguang

