杭州瑾岚医药技术开发有限公司

Hangzhou Jinlan Pharm-Drugs Technology CO., Ltd.

Certificate of Analysis

Name of Product	Molnupiravir CAS 2349386-89-4			
Batch No.	20210823	Manufacture date	2021/08/23	
Analysis date	2021/08/23	Retest date	2022/08/22	
Quantity	100Kg	Standard	In-House	
Structure	HO N O O O O O O O O O O O O O O O O O O			

Item		Specification	Results
Character	Appearance	White to off-white crystalline powder	Conforms
	Solubility	Free soluble in dimethyl sulfoxide or methanol, sparingly soluble in water, slightly soluble in ethyl acetate, practically insoluble in n-heptane	Conforms
Identificati on	IR	The IR absorption spectrum of sample must exhibit maxima at the same wavelength as the of reference standard.	Conforms
	HPLC	The retention time of major peak in test solution obtained in the test of Related substances by HPLC should correspond to that of the system suitability solution	Conforms
Water content (by KF)		≤ 0.5%	0.08%
Chloride		≤ 0.05%	Conforms
Sulfate		≤ 0.05%	Conforms

Residue on Ignition	≤ 0.1%	0.06%
	Impurity 9090-403≤0.3%	0.03%
Related substances	Impurity 9090-3≤0.3%	ND
Related Substances	Any individual unspecified impurity ≤0.10%	0.05%
	Total impurities≤1.0%	0.11%
	Methyl tert-butyl ether≤ 0.5%	0.04%
Residual Solvents	Isopropanol≤ 0.5%	ND
	2-Methyltetrahydrofuran≤ 0.5%	ND
Assay (HPLC) 98.0% ~ 102.0%(on anhydrous basis)		99.7%
Conclusion	Conform to In-house standard.	NGS TECHNOLOGY 海技术开发音网 Co

Tested by: Meng Xiao

Checked by: Shen Junli

Approved by: He Youguang