



南京源森泰生物科技有限公司  
NANJING YANST BIO-TECH CO.,LTD

质检单  
CERTIFICATE OF ANALYSIS

产品名称 Product Name	Ritonavir 利托那韦	CAS Number	155213-67-5
批号 Batch Number	F120020001	数量 Quantity	1kg
生产日期 Manufacturing Date	2020.02.09	有效期至 Expiry Date	2022.02.08
ANALYTICAL ITEMS	USP Specifications	RESULTS	
Appearance	White to off-white powder	White powder	
Solubility	Freely soluble in methanol and in ethanol,soluble in 2-propanol	Conform	
Identification	HPLC:The retention time of the test sample corresponds to that of the reference standard	Conform	
	IR:The infrared absorption spectrum of the test sample is concordant with the spectrum of reference standard	Conform	
Water content by KF	Not more than 0.5%	0.10%	
Specific optical rotation	Between +7.0 and 10.5°(C=2 in MeOH)	+9.25°	
Loss on drying	Not more than 0.2%	0.12%	
Residue on ignition	Not more than 0.2%	0.09%	
Heavy metals	Not more than 20ppm	Conform	
Sulphated ash	Not more than 0.10%	0.06%	
Organic volatile impurities	Ethylacetate:Not more than 0.5%	0.12%	
	Heptane:Not more than 0.5%	0.11%	
	Tetrahydrofuran:Not more than 0.072%	ND	
Related substance (by HPLC,Area%)	Impurity E(RRT=0.36) : Not more than 0.3%	0.09%	
	Impurity O(RRT=1.11):Not more than 0.3%	ND	
	Impurity T(RRT=2.87):Not more than 0.2%	ND	
	Any other individual impurity:Not more than 0.1%	0.05%	
	Total impurities:Not more than 1.0%	0.14%	
Assay by HPLC	Between 98.0% and 102.0%	99.29%	
Conclusion	Qualified		

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