



Certificate of Analysis

Product name	Tianeptine sodium	Mfg. Date	2021-08-16
Batch No.	KL210816	Shelf life	24Months
Item	Specification	Test result	
Description	White to Off-white powder,very hygroscopic	Off-white powder,very hygroscopic.	
Solubility	Freetly soluble In water and methanol and dichloromethane	Complies	
Identification	(1) By IR, To match with working standard	Complies	
	(2) It gives reaction of sodium	Complies	
Impurities A	≤0.1%	Not detected	
Related compounds	Any impurity ≤0.1%	0.04%	
	Total impurities ≤0.4%	0.19%	
Residual Solvents	Acetidin ≤ 0.5%	0.01%	
	Dichloromethane ≤ 0.06%	0.003%	
	Methanol ≤ 0.3%	0.01%	
	Acetone ≤ 0.5%	Not detected	
	Acetonitrile ≤0.041%	0.003%	
	Ethanol ≤0.5%	0.02%	
	N, N-dimethylformamide ≤0.088%	Not detected	
Water	≤ 5.0%	2.60%	
Assay	99.0%-101.0% (On anhydrous basis)	99.92%	
Conclusion	Conform to EP8.0		
Package	25kg/drum, packed with double PE bags inside.		
Storage	Room temperature, keep in cool dry place		
Report Date: Aug 16,2021		QC: Zhang yan	

