

Jinan Hongfangde Pharmatech Co., Ltd. Tel:18560059130 QQ: 2659530578 shfdchem@163.com www.hfdpharma.com

CERTIFICATE OF ANALYSIS

Product	Tianeptine sodium	
batch No.	18120101 Mfg. date	2018-12-01
Test Date	2018-12-20 质检专用章 Exp. date	2020-12
Tests	Specifications	Results
Description	White to yellowish 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 IR	Complies
	(2) It gives reaction of sodium	Complies
Impurities A	≤0.1%	Not detected
Related compounds	Any impurity ≤0.1%	0.026%
	Total impurities ≤0.4%	0.17%
Residual Solvents	Acetidin≤ 0.5%	Not detected
	Dichloromethane≤ 0.06%	Not detected
	Methanol≤ 0.3%	Not detected
	Acetone ≤ 0.5%	Not detected
	Acetonitrile≤0.041%	Not detected
	Ethanol≤0.5%	Not detected
	N, N-dimethylformamide N,N-≤0.088%	Not detected
Water	≤ 5.0%	2.02%
Assay	99.0%-101.0% (On anhydrous basis)	99.86%
Conclusion : Conform to EP9.0		

Analyst :lichao Checker: shilijuan Supervisor:maohongjun