

Lot: 0140513

Shandong Keyuan Pharmaceutical CO., LTD, China

中国 山东科源制药有限公司

CERTIFICATE OF ANALYSIS

检验报告书



CERTIFICATE NO.: 10-120487

PRODUCT NAME: XANTHINOL NICOTINATE

产品名称: 烟酸占替诺

BATCH NO.:

ANALYSIS DATE:

MFG. DATE:

批号: M1208004

分析日期: SEP. 01, 2012

生产日期: AUG. 11, 2012

QUANTITY:

TEST BASIS: CP2010

RETEST. DATE:

数量: 3kg

检验依据: 《中国药典》2010 年版

复验日期: AUG. 10, 2014

Results:

ITEMS	STANDARD	RESULTS
Characteristics	White crystals or crystalline powder, no smell, soluble in water or glacial acetic acid, slightly soluble in chloroform or anhydrous ethanol.	White crystalline powder, no smell, soluble in water or glacial acetic acid, slightly soluble in chloroform or anhydrous ethanol.
Melting Point	180-184°C	181-183.5°C
Identification	1) Positive reaction	1) Positive reaction
	2) Positive reaction	2) Positive reaction
	3) HPLC	Meets the requirements
	4) IR	Meets the requirements
Acidity (PH)	5.5-6.5	6.05
Loss on drying	≤0.5%	0.29%
Residue on ignition	≤0.1%	0.07%
Clarity and Color of solution	Meets the requirements	Meets the requirements
Heavy metal	≤10ppm	<10ppm
Related substances	Theophylline ≤0.3%	0.12%
	Total other impurity ≤0.3%	Non-detected
Residual Solvents	Ethanol NMT 5000ppm	300ppm
Assay	Calculating according to dry substance $C_{19}H_{26}N_6O_6$ should be not less than 98.0%.	99.7%
Conclusion	The test results conform with CP2010.	

Q.C.DIRECTOR 刘兴荣

CORRECTOR 周月月

ANALYST 胡胜旭