Shandong Keyuan Pharmaceutical CO. ,LTD, China

中国山东科源制药股份有限公司

CERTIFICATE OF ANALYSIS

检验报告书

QA放行章

QC 检验专用章

CERTIFICATE NO.: 10-220659-1

PRODUCT NAME: XANTINOL NICOTINATE

BATCH NO.: P071-2204001　　Date of Report:May19,2022　　MFG. DATE：MAR.05,2022

QUANTITY: 2KG　　TEST BASIS：CP2015　　RETEST. DATE：MAR.04,2027

Results:

Item	The acceptance criteria	Results of analysis
Characteristics	White crystals or crystalline powder, no smell soluble in water or glacial acetic acid,slightly soluble in chloroform or anhydrous ethanol.	White crystals powder, no smell soluble in water and glacial acetic acid，slightly soluble in chloroform and anhydrous ethanol.
Melting Point	180-184℃	181-183.5℃
Identification	1)The solution shows a white deposition when adding tannic acid test solution sitive reaction	Positive reaction
	2)The solution shows a light blue deposition when adding cupric sulfate test solution.	Positive reaction
	3)HPLC	Meets the requirements
	4)IR	Meets the requirements
Acidity(pH)	5.5-6.5	6.3
Clarity and Color of solution	Meeting the requirement	Meets the requirements
Related substances	Theophylline≤0.3%	0.03%
	Total other impurity（other than Nicotinic acid and Theophylline）≤0.3%	Non-detected
Residual solvent	Ethanol≤0.5%	0.03%
	Methyl alcohol≤0.3%	Non-detected
	Methylbenzene≤0.089%	Non-detected
Heavy Metals	≤10ppm	＜10ppm
Loss on Drying	≤0.5%	0.2%
Residue on ignition	≤0.1%	0.04%
Microbiological screening	Total aerobic microbial count NMT 1000CFU/g	＜10CFU/g
	Total yeast and moulds count NMT 100CFU/g	＜10CFU/g
	E.coli absence per g	Non-detected
Assay	Calculating according to dry substance $C_{19}H_{26}N_6O_6$ should be 98.5-101.0%.	100.1%
Conclusion	The test results conform with CP2015.	

ANALYST　　CORRECTOR　　Q.C.DIRECTOR

Address: Keyuan Street, Shandong Shanghe Economic Development Zone, Jinan, Shandong, China