

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

CERTIFICATE NO.: 10-180717-1

PRODUCT NAME: XANTINOL NICOTINATE

BATCH NO.: P071-1806004 ANALYSIS DATE: Jul.13, 2018

MFG. DATE: Jun.02, 2018

QUANTITY: 3KG

TEST BASIS: CP2015

RETEST. DATE: Jun.01, 2023

Results: 分析结果

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 or crystalline powder, no smell, soluble in water or glacial acetic acid, slightly soluble in chloroform or anhydrous ethanol.
Melting Point	180-184°C	180-182°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	6.20
Clarity and Color of solution	Meeting the requirement	Meets the requirements
Related substances	Theophylline $\leq 0.3\%$	Non-detected
	Total other impurity $\leq 0.3\%$	Non-detected
Residual solvent	Ethanol ≤ 5000 ppm	588ppm
	Methyl alcohol ≤ 3000 ppm	Non-detected
	Methylbenzene ≤ 890 ppm	Non-detected
Heavy Metals	≤ 10 ppm	< 10 ppm
Loss on Drying	$\leq 0.5\%$	0.07%
Residue on ignition	$\leq 0.1\%$	0.04%
Microbiological screening	Total aerobic microbial count NMT 1000CFU/g	< 10 CFU/g
	Total yeast and moulds count NMT 100CFU/g	< 10 CFU/g
	E.coli absence per g	Non-detected
Assay	Calculating according to dry substance C ₁₉ H ₂₆ N ₆ O ₆ should be not less than 98.0%.	99.9%
Conclusion	The test results conform with CP2015.	

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ANALYST 王 2018.10.13 CORRECTOR 王 2018.10.13

Q.C.DIRECTOR 王 2018.10.13



由 扫描全能王 扫描创建