



华中药业
HUAZHONG PHARMACEUTICAL CO., LTD

华中药业股份有限公司
HUAZHONG PHARMACEUTICAL CO., LTD

Add :No.118 XianShan Road,
Xiangyang, Hubei, China
Tel: +86-710-3150034
Fax: +86-710-3150684

CERTIFICATE OF ANALYSIS

Product Name: THIAMINE HYDROCHLORIDE Batch No. : Y01202112020

Manufacturing Date: Dec. 03, 2021 Reporting Date: Dec. 08, 2021

Expiry Date: Dec. 02, 2024 Quantity: 500KGS

Specification: BP2020/USP43

Test Item	Specification	Result
Appearance	white or almost white crystalline powder or colourless crystals	White crystalline powder
Identification	(1) should be positive reaction (2) Consistent with the reference IR spectra	(1) positive reaction (2) Consistent with the reference IR spectra
Appearance of solution	clear, not more intense than Y7	clear, not more intense than Y7
Heavy metals	NMT20ppm	<20ppm
PH	2.7~3.3	3.0
Sulphates	NMT300ppm	<300ppm
Limit of nitrate	No brown ring	No brown ring
Water	NMT 5.0%	2.3%
Residue on ignition	NMT0.1%	0.05%
Absorbance of solution	NMT0.025	0.011
Residual Solvents		
- - Methanol	NMT0.3%	<0.3%
- - Ethanol	NMT0.5%	<0.5%
Related substances (Disregard limit 0.05%)		
- - Impurity A	NMT0.15%	0.02%
- - Impurity B	NMT0.3%	0.01%
- - Impurity C	NMT0.15%	0.01%
- - Any impurity	NMT0.1%	0.01%
- - Total impurities	NMT0.5%	0.09%
Assay	98.5~101.0%	99.5%

Conclusion: This batch complies with the specification of BP2020/USP43

Report by: WANG YABIN

Approved by:

王雪迪