



华中药业
HUAZHONG PHARMA

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

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CERTIFICATE OF ANALYSIS

Product Name: PYRIDOXINE HYDROCHLORIDE

Batch No.: Y62202401048

Manufacturing Date: JAN.09,2024

Reporting Date: JAN.12,2024

Expiry Date: JAN.08,2028

Quantity: 500KGS

Specification: BP2023/USP2022/IP2022

Test Item	Specification	Result
Appearance	A white or almost white crystalline powder	almost White crystalline powder
Identification	(A) Consistent with the reference IR spectra (B) The principal peak corresponds to that with the reference in the test for related substances (C) should be positive reaction	Consistent with the reference IR spectra The principal peak corresponds to that with the reference in the test for related substances Positive reaction
PH	2.4~3.0	2.7
Appearance of solution	clear, not more intense than Y7	clear, not more intense than Y7
Heavy metals	NMT20ppm	<20ppm
Loss on drying	NMT0.5%	0.1%
Sulfated ash	NMT0.1%	0.04%
Chloride content	16.9~17.6%	17.2 %
Related substances		
—Total impurities	NMT0.20%	0.035%
—Unspecified impurities	NMT0.10%	0.017%
—B impurity	NMT0.15%	ND
Residual solvent		
—Ethanol	NMT0.3%	<0.3%
Assay	99.0~101.0%	99.6%

Conclusion: This batch complies with the specification of BP2023/USP2022/IP2022

Report by: LI JINGYI
ISSUED BY MANUFACTURER: HUAZHONG PHARMACEUTICAL CO., LTD.
ISSUED DATE: MAR.18,2024

Approved by:

