

CERTIFICATE OF ANALYSIS

Product Name: PYRIDOXINE HYDROCHLORIDE Batch No.: Y03202502205

Manufacturing Date: Feb.23,2025 Reporting Date: Mar.02,2025

Expiry Date: Feb.22,2028 Quantity: 500KGS

Specification:BP2023/USP2022/EP10.0/FCC11

Test Item	Specification	Result	Methods
Appearance	A white or almost white crystalline powder	almost White crystalline powder	Visual Perception
Identification	(1) should be positive reaction	(1) positive reaction	USP2022
	(2) Consistent with the reference IR spectra	(2) Consistent with the reference IR spectra	USP2022
Melting point	About205.0°C	205.2 °C	BP2023
PH	2.4-3.0	2.7	BP2023
Appearance of solution	clear,not more intense than Y7	clear,not more intense than Y7	BP2023
Heavy metals	NMT10ppm	< 10 ppm	USP2022
Pb	NMT0.5ppm	< 0.5 ppm	ICPMS
As	NMT1ppm	< 1 ppm	ICPMS
Hg	NMT0.1ppm	< 0.1 ppm	ICPMS
Cd	NMT1ppm	< 1 ppm	ICPMS
Loss on drying	NMT0.5%	0.1 %	USP2022
Sulfated ash	NMT0.10%	0.08 %	BP2023
Chloride content	16.9 - 17.6%	17.2 %	USP2022
Related substances (Disregard limit 0.05%)			
—Total impurities	NMT0.20%	0.062 %	BP2023
—Unspecified impurities	NMT0.10%	0.009 %	BP2023
—B impurity	NMT0.15%	0.029%	BP2023
Assay	99.0 - 101.0%	99.6 %	BP2023
Microbials			
—S. Aureus	Negative	Negative	CH.P.2020
—Salmonella	Negative/10g	Negative	CH.P.2020
—E.Coli	Negative	Negative	CH.P.2020
—Total Plate Count	NMT1000cfu/g	< 1000cfu/g	CH.P.2020
—Yeast and Mold	NMT100cfu/g	< 100cfu/g	CH.P.2020

Conclusion:This batch complies with the specification of BP2023/USP2022/EP10.0/FCC11

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