



Specification for Pyridoxine Hydrochloride Food Grade

Test Item	Specification	Method
Appearance	A white or almost white crystalline powder	Visual
Identification		
Infrared absorption	Consistent with the reference IR spectra	USP
Reaction of chlorides	A white curdy precipitate is formed with silver nitrate, the precipitate is insoluble in nitric acid but dissolves readily in ammonia	USP
Appearance of solution	Clear, not more intense than Y ₇	EP
pH	2.4 ~ 3.0	EP
Loss on drying	NMT 0.5%	USP
Residue on ignition	NMT 0.1%	USP
Chloride	16.9% ~ 17.6%	USP
Residual solvent - Ethanol	NMT 0.5%	USP
Related substances (Disregard limit: 0.05%)		
- Impurity B	NMT 0.15%	EP
- Unspecified Impurity	NMT 0.10%	
- Total Impurities	NMT 0.2%	
Assay (on dry basis)	98.0% ~ 102.0%	USP
Heavy metals		
Lead	≤0.5 mg/kg	AAS,in-house
Cadmium	≤0.5 mg/kg	AAS, in-house
Arsenic	≤0.5 mg/kg	AAS, in-house
Mercury	≤0.1 mg/kg	AAS, in-house
Microbials		
Total Aerobic Microbial Count	NMT 100 cfu/g	ChP
Total Yeasts and Moulds Count	NMT 10 cfu/g	ChP
E. Coli	Negative	ChP
Salmonella	Negative	ChP
S. Aureus	Negative	ChP



江西天新药业股份有限公司
JIANGXI TIANXIN PHARMACEUTICAL CO.,LTD.

Remark: The material meets all requirements of the valid compendia of BP, EP, USP and FCC when tested accordingly.

Additional information:

Country of origin: China

Retest period: 48 months (4 years)

Standard packaging: 25 kg net per fiber drum or carton with 2-layer PE inner bag

Storage: Preserve in tight, non-metallic containers, protected from light.

Last update: Jan 2, 2020

Approved by: Zhang Ping

Designation: QA Manager

Signature:

