

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

PURCHASE ORDER NO.: 4502640637

Product name: Vitamin B₆ (Pyridoxine Hydrochloride) Food Grade

Batch No.: PH16033034

Manufacturing date: Mar 11, 2016

Reporting date: Mar 19, 2016

Retest date: Mar 10, 2020

Quantity: 1,000 kg

Package: 25 kg per carton

Package size: 390 × 290 × 320 (mm)

Article No.: 03102

Irradiation / ETO treatment: No

Test Item	Specification	Method	Result
Appearance	A white or almost white crystalline powder	Visual	Conforms
Identification			
Infrared absorption	Consistent with the reference IR spectra	USP	Consistent with the reference IR spectra
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	A white curdy precipitate is formed with silver nitrate, the precipitate is insoluble in nitric acid but dissolves readily in ammonia
Appearance of solution	Clear, not more intense than Y ₂	EP	Clear, not more intense than Y ₂
pH	2.4 - 3.0	EP	2.7
Loss on drying	NMT 0.5%	USP	0.01%
Residue on ignition	NMT 0.1%	USP	0.02%
Chloride	16.9% ~ 17.6%	USP	17.2%
Residual solvent - Ethanol	NMT 0.5%	USP	< 0.01%
Related substances (Disregard limit: 0.05%)			
- Impurity B	NMT 0.15%	EP	Not detected
Unspecified Impurity	NMT 0.10%		< 0.05%
- Total Impurities	NMT 0.2%		< 0.05%
Assay (on dry basis)	98.0% ~ 102.0%	USP	99.8%
Heavy metals			
Lead	0.5 mg/kg	AAS, FCC	< 0.1 mg/kg
Cadmium	1.0 mg/kg	AAS, in-house	< 1.0 mg/kg
Arsenic	1.0 mg/kg	AAS, in-house	< 1.0 mg/kg
Mercury	0.1 mg/kg	AAS, in-house	< 0.1 mg/kg
Microbials			
Total Aerobic Microbial Count	NMT 10 ⁶ cfu/g	ChP	< 10 ⁶ cfu/g
Total Yeasts and Moulds Count	NMT 10 ⁴ cfu/g	ChP	< 10 ⁴ cfu/g
E. Coli	Negative	ChP	Negative
Salmonella	Negative	ChP	Negative
S. Aureus	Negative	ChP	Negative
Conclusion: This batch was analyzed and found to meet the specifications as given above.			
Compendial compliance guarantee This material meets all requirements of the following valid compendia when tested accordingly BP, EP, USP, FCC			
Remark: Preserve in a tightly closed container, protected from light.			

Reported by: *[Signature]*

Approved by: *[Signature]*

Kalchem International, Inc
224 South Main Street - Lindsay, OK 73052
Toll Free 888-298-9905 | FAX: 405-756-2373