

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

PURCHASE ORDER NO.: 4502640637

Product name: Vitamin B₆ (Pyridoxine Hydrochloride) Food Grade Batch No.: PH16035032

Manufacturing date: Mar 12, 2016

Reporting date: Mar 19, 2016

Retest date: Mar 11, 2020

Quantity: 500 kg


Package: 25 kg per carton

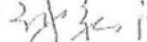
Package size: 390 × 290 × 320 (mm)

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 ₇	EP	Clear, not more intense than Y ₇
pH	2.4 ~ 3.0	EP	2.7
Loss on drying	NMT 0.5%	USP	0.01%
Residue on ignition	NMT 0.1%	USP	0.01%
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	99.7%
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 100 cfu/g	ChP	< 100 cfu/g
Total Yeasts and Moulds Count	NMT 10 cfu/g	ChP	< 10 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: 

Approved by: 

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