

Kalchem International

Chemicals & Compounding Supplies

Certificate of Analysis

LETCO MEDICAL: Item/Lot Number(s)

Item: 685817	Item: 686385	Item: 686386	
Lot: 1508110054	Lot: 1508110055	Lot: 1508110056	

Description:	Pyridoxine HCl USP	Source Lot:	PH15065042	Expiration Date:	06/12/2019
Date of MFG:	06/13/2015	Country of Origin:	China	Irradiation/ ETO Treatment:	No

Test Criteria	Standard	Method	Result
Description	White to practically white crystals or crystalline powder	USP38	Practically white crystalline powder
Appearance	Colorless or white crystals or white crystalline powder	FCC IX	Practically white crystalline powder
Identification			
Infrared absorption	Consistent with the reference IR spectra	USP38	Consistent with the reference IR spectra
Chloride	A white curdy precipitate is formed with silver nitrate, the precipitate is insoluble in nitric acid but dissolves readily in ammonia	USP38, FCC IX	A white curdy precipitate is formed with silver nitrate, the precipitate is insoluble in nitric acid but dissolves readily in ammonia
Color reaction	A blue color appears in tube A, which fades rapidly and becomes red in a few minutes, but no blue color appears in tube B	FCC IX	A blue color appears in tube A, which fades rapidly and becomes red in a few minutes, but no blue color appears in tube B
Precipitation reaction	A white precipitate forms with phosphotungstic acid	FCC IX	A white precipitate forms with phosphotungstic acid
Loss on drying	NMT 0.5%	USP38, FCC IX	0.01%
Residue on ignition	NMT 0.1%	USP38, FCC IX	0.01%
Heavy Metals	NMT 0.003%	USP38	<0.001%
Residual solvent – Ethanol	NMT 0.5%	USP38	<0.01%
Chloride	16.9%~17.6%	USP38, FCC IX	17.2%
Lead	NMT 2 mg/kg	FCC IX	<0.1 mg/kg
Assay (on dry basis)	98.0% ~ 102.0%	USP38	99.8%
	98.0% ~ 100.5%	FCC IX	99.8%
Heavy Metals			
Lead	<0.5 mg/kg	AAS, in-house	<0.1mg/kg
Cadmium	<1.0 mg/kg	AAS, in-house	<1.0mg/kg
Arsenic	<1.0 mg/kg	AAS, in-house	<1.0mg/kg
Mercury	<0.1 mg/kg	AAS, in-house	<0.1mg/kg
Microbials			
Total Plate Count	NMT 100 cfu/g	Ch. P. 2010	<100 cfu/g
Yeast and Mold	NMT 10 cfu/g	Ch. P. 2010	<10 cfu/g
E. Coli	Negative	Ch. P. 2010	Negative
Salmonella	Negative	Ch. P. 2010	Negative
S. Aureus	Negative	Ch. P. 2010	Negative

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