



黄冈市富驰制药有限责任公司

FUCHI PHARMACEUTICAL CO., LTD OF HUANGGANG CITY

CERTIFICATE OF ANALYSIS

PRODUCT:TAURINEJP15/USP35+0.5%Anti-cakingagent

QUANTITY:20000kg

BATCHNO.:C002-YB1603253

REPORTED DATE: 2016/03/07

MANU DATE: FEB 26, 2016

EXP DATE:FEB 25, 2019

Item	USP35 Standard	JP15 Standard	Results
Characteristics	White Crystals Or White Crystalline Powder,Odorless	White Crystals Or White Crystalline Powder,Odorless	White Crystalline Powder,Odorless
Identification	Infrared Absorption	Infrared absorption Spectrum should conform to requirement	Conforms
pH	/	4.1~5.6	5.0
Test			
Clarity And Color Of Solution	Clear And Colorless	Clear And Colorless	Clear And Colorless
Heavy Metals	0.0015% Max	10ppm Max	10ppm Max
Chloride	0.05% Max	0.011% Max	0.011% Max
Sulphate	0.03% Max	0.010% Max	0.010% Max
Iron	0.003% Max	10ppm Max	10ppm Max
Ammonium	/	0.02% Max	0.02% Max
Easily Carbonizable Substances	No Color Develops	/	Colorless
Related Substances	/	Should conform to requirement	Conforms
Loss On Drying	0.3% Max	0.20% Max	0.15%
Residue On Ignition	0.3% Max	0.1% Max	0.1%
Chromatographic Purity	0.5% Max	/	0.2% Max
Total Plate Count	NMT 1000cfu/g	NMT 1000cfu/g	20cfu/g
Yeast And Mould	NMT 100cfu/g	NMT 100cfu/g	<10cfu/g
Salmonella	Negative/25g	Negative/25g	Conforms
E. Coli	Negative/10g	Negative/10g	Conforms
Coliform	3mpn/g	3mpn/g	Conforms
Staphylococcus	Negative/10g	Negative/10g	Conforms
Enterobacteriaceae	Negative/g	Negative/g	Conforms
Assay	98.5-101.5%	99.0-101.0%	99.0%
Cadmium	1 ppm Max	1 ppm Max	Conform
Mercury	0.1 ppm Max	0.1 ppm Max	Conform
Arsenic	1ppm Max	1ppm Max	Conform
Lead	1 ppm Max	1 ppm Max	Conform
Particle size	80% Passing 100 Mesh	80% Passing 100 Mesh	Conform
Bulk Density	0.7-0.9g/MI	0.7-0.9g/MI	Conforms
Tap Density	0.8-1.1g/MI	0.8-1.1g/MI	Conforms
Total Impurity	2.0% Max	2.0% Max	Conforms
Conclusion	The Product Conforming To JP15/USP35		

Head Of Dept: Cai weijian

Reviewer: Li dan

Reporter: Xiong yan