



XI'AN CORE PURE BIO&TECH CO., LTD.
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D- Glucosamine Sulfate Potassium Chloride – (Vegetarian)

Batch No.	Quantity	Packaging	Test Date	Manufacture Date	Exp. Date
0220190802	1000kg	25kg/drum	2019.08.26	2019.08.24	2019.08.23
ITEM		SPECIFICATION		TEST METHOD	RESULTS
Properties (physical):					
Appearance		White Crystalline, Free Flowing Powder		USP37 -- <695>	Complies
Odour		Odourless		Complies	Complies
Bulk Density		NLT0.80g/mL		USP37 -- <616>	0.86g/mL
As Tapped Density		Meets the requirements of USP37		USP37 -- <616>	Complies
Particle Size		NLT 98% through 40 Mesh		USP37 -- <811>	Complies
Analytical Properties:					
Assay (HPLC)		98.0%~102.0% (on the dried basis)		USP37 -- <621>	99.34%
Identification					
A: Infrared Absorption		Meets the requirement		A: USP37 -- <197K>	Complies
B: Tests for Chloride,Potassium,and Sulfate		Meets the requirement		B: USP37 -- <191>	Complies
C: Retention time in the Assay		Corresponds to the reference standard		C: USP37 -- <621>	Complies
Transm		>90.0% (10.0%Water Solut.-450nm)		USP37 -- <197>	98.9%
Specific Rotation (α) _D ²⁰		+47.0°~+53.0°		USP37 -- <781S>	+51.24°
pH (20mg/mL.aq.sol.)		3.0~5.0		USP37 -- <791>	4.54
Loss on Drying		NMT1.0%		USP37 -- <731>	0.01%
Residue on Ignition		26.5%~31.0%		USP37 -- <281>	28.92%
Chloride (Cl)		11.3% ~12.3%		USP37 -- <221>	11.80%
Content of Sulfate		15.5%~16.5%		USP37	15.91%
Potassium		11.7%~13.0%		GB/T 5009.91	12.35%
Sodium		Not impart a pronounced yellow color to a nonluminous flame		USP37	Complies
Heavy Metals		NMT 10 ppm		USP37 -- <231> II	Complies
Iron (fe)		NMT 10 ppm		USP37 -- <241>	Complies
Lead		NMT 0.5 ppm		USP37 -- <251>	0.06ppm
Arsenic (As)		NMT 1.0 ppm		USP37 -- <211> II	0.06ppm
Mercury		NMT 0.1 ppm		USP37 -- <261>	0.05ppm
Cd		NMT 0.5 ppm		GB/T 5009.15	0.03ppm
Organic volatile impurities		Meets the Requirements		USP37 -- <467> I	Complies
Microbial:					
Total Aerobic		NMT 1,000 cfu/g		USP37 -- <61>	NMT 100 cfu/g
Yeast & Mold		NMT 100 cfu/g		USP37 -- <61>	NMT 30 cfu/g
E. Coli		Negative in 1g		USP37 -- <62>	Negative
Salmonella		Negative in 1g		USP37 -- <62>	Negative
Staphylococcus Aureus		Negative in 10g		USP37 -- <62>	Negative
Enterobacteria & other gram neg		NMT 100 cfu/g		USP37 -- <62>	NMT 30cfu/g
Conclusion:		Meets USP37 standards			
Packaging and Storage:		Store in tight, light-resistant containers			
Reason for Change:		Updating Specification Format to USP37			
Effective Date: 5th,Oct,2014		Code & Version: DG2KCL V40/5			
Part No.:		DG KCL 03			