

Specification of D- Glucosamine Hydrochloride

ITEM	SPECIFICATION	TEST METHOD
Properties (physical):		
Appearance	White Crystalline, Free Flowing Powder	USP32 -- <695>
Odour	Odourless	Complies
Bulk Density	NLT0.60g/ml	USP32 -- <616>
As Tapped Density	Meets the requirements of USP32	USP32 -- <616>
Particle Size	NLT 90% through 80 Mesh	USP32 -- <811>
Analytical Properties:		
Assay (HPLC)	98.0—102.0% (on the dried basis)	USP32 -- P2100(A)--<621>
Identification		
A: Infrared Absorption	Meets the requirement	A: USP32 -- P2100--<197K>
B: Tests for Chloride	Meets the requirement	B: USP32 -- <191>
C: Retention time in the Assay	Corresponds to the reference standard	C: USP32 -- P2100--<621>
Transm	>90.0% (10.0%Water Solut.-450nm)	USP32 -- <197>
Absorb	<0.25a.u. (10.0% Water Solut.-280nm)	USP32 -- <197>
Specific Rotation (α) _D ²⁰	+70.00°-- +73.00°	USP32 -- <781S>
pH (20mg/ml.aq.sol.)	3.0—5.0	USP32 -- <791>
Loss on Drying	NMT0.5%	USP32 -- <731>
Residue on Ignition	NMT 0.1%	USP32 -- <281>
Chloride (Cl)	16.2% -- 16.7%	USP32 -- <221>
Sulfate	NMT 0.24%	USP32 -- <221>
Heavy Metals	NMT 10 ppm	USP32 -- <231> II
Iron (fe)	NMT 10 ppm	USP32 -- <241>
Lead	NMT 0.5 ppm	USP32 -- <251>
Arsenic (As)	NMT 3.0 ppm	USP32--<211> II
Mercury	NMT 0.5 ppm	USP32 -- <261>
Organic volatile impurities	Meets the Requirements	USP32 -- <467> I
Microbial:		
Total Aerobic	NMT 1,000 cfu/g	USP32 -- <61>
Yeast and Mold	NMT 100 cfu/g	USP32 -- <61>
E. Coli	Negative in 1g	USP32 -- <61>
Salmonella	Negative in 1g	USP32 -- <61>
Staphylococcus Aureus	Negative in 10g	USP32 -- <61>
Enterobacteria & other gram neg	NMT 100 cfu/g	USP32 -- <61>