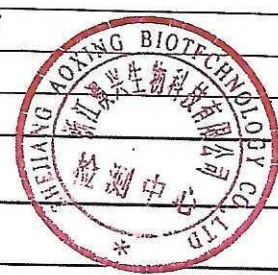




N- Acetyl- D- Glucosamine – 100mesh

Batch No.	Quantity	Packaging	Test Date	Manufacture Date	Exp. Date
0420200301	1000kg	25kg/drum	2020.03.17	2020.03.16	2023.03.15
ITEM	SPECIFICATION		TEST METHOD	RESULTS	
Properties (physical):					
Appearance	White Crystalline, Free Flowing Powder		USP37 -- <695>	Complies	
Bulk Density	NLT0.45g/ml		USP37 -- <616>	0.46g/ml	
As Tapped Density	Meets the requirements of USP37		USP37 -- <616>	Complies	
Particle Size	NLT 90% through 100 Mesh		USP37 -- <811>	Complies	
Analytical Properties:					
Assay (HPLC)	98.0~102.0% (on the dried basis)		USP37 -- <621>	99.47%	
Absorb	<0.25a.u. (10.0% Water Solut.-280nm)		USP37 -- <851>	0.12a.u.	
Specific Rotation (α : D^{20})	+39.0°~+43.0°		USP37 -- <781S>	+41.46°	
PH (20mg/ml.aq.sol.)	6.0~8.0		USP37 -- <791>	7.47	
Loss on Drying	NMT0.5%		USP37 -- <731>	0.16%	
Residue on Ignition	NMT 0.1%		USP37 -- <281>	0.02%	
Chloride (Cl)	NMT0.2%		USP37 -- <541>	0.007%	
Melting Range	196°C~205°C		USP37 -- <741>	202.6°C~203.7°C	
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	
Cadmium	NMT 0.5 ppm		GB/T 5009.15—2003	Complies	
Arsenic (As)	NMT 1.0 ppm		USP37 -- <211> II	Complies	
Mercury	NMT 0.1 ppm		USP37 -- <261>	0.05ppm	
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 -- <61>	Negative	
Salmonella	Negative in 1g		USP37 -- <61>	Negative	
Staphylococcus Aureus	Negative in 10g		USP37 -- <61>	Negative	
Enterobacteria & other gram neg	NMT 100 cfu/g		USP37 -- <61>	NMT 30 cfu/g	
Conclusion:	Meets USP 37 standards				
Packaging and Storage:	Store in tight, light-resistant containers under 25°C				
Reason for Change:	Updating Specification Format to USP 37				
Effective Date:5th,Oct,2014	Code & Version: N-Acetyl-G100/6				
Part No.:	NA DG 02				
Prepared by:	张 文 英				
Approved by QC Dept. Manager:	张 招 明				



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