

品名 Product		氨基葡萄糖硫酸钠盐 Glucosamine Sulfate Sodium Chloride			
批号 Batch No	数量 Quantity	分析日期 Analysis Date	包装 Package	生产日期 Manufacture Date	重测日期 Retest Date
WA202305001	1000Kg	May 17, 2023	25Kg/Drum	May 11, 2023	May 10, 2026
项目 Items	欧洲/美国药典标准 EP c.e./USP c.e. Standards		测试方法 EP/USP Test Method	测试结果 Results	
外观 & 溶解性 Appearance & Solubility	白色结晶性粉末, 易溶于水, 略溶于甲醇, 不溶于丙酮 White crystalline powder, Freely soluble in water, Sparingly soluble in methanol, Practically insoluble in acetone.		EP c.e.	Complied	
溶液外观 Appearance of solution 浊度 & 色度 Clarity & Colour	Clear: ≤ 3.0 NTU		EP c.e.—<2.2.1>	Complied	
	Colourless: Not more intensely coloured than reference standard B9		EP c.e.—<2.2.2>	Complied	
鉴别 Identification	A: Infrared absorption spectrophotometry B/C/D: It gives reaction of Chloride(AgNO ₃ TS) /Sodium(K ₂ H ₂ Sb ₂ O ₇ TS)/Sulfate(BaCl ₂ TS). E: Specific optical rotation(See tests)		A: EP c.e./USP c.e.—<197K>. B / C / D: EP c.e./USP c.e. E: EP c.e.	Complied	
含量 Assay	98.0%~102.0% (dried substance)		EP c.e.	99.97 %	
比旋度 Specific Rotation $[\alpha]_D^{20}$	+50.0°~+55.0°(dried substance, 2.5g/25ml, 3 h)		EP c.e.	+52.6 °	
透光率 Transm.	$>90.0\%$ (10.0% Water Solut. -450nm)		EP c.e./USP c.e.—<851>	96.1 %	
干燥失重 Loss of Drying	$\leq 0.5\%$ (105°C, 2 h)		EP c.e./USP c.e.—<731>	0.13 %	
炽灼残渣 Residue of Ignition	23.5%~26.0%		EP c.e.	24.19 %	
酸碱度 PH	3.0~5.0 (2.5g/25ml)		EP c.e.	4.1	
硫酸根 Sulfate	16.3%~17.3%		EP c.e./USP c.e.	16.73 %	
氯化物 Chloride	11.7%~13.0%		EP c.e./USP c.e.—<541>	12.43 %	
钠盐 Sodium	7.0%~8.3%		USP c.e.—<621>	8.09 %	
钾盐 Potassium	符合药典测试 USP Test: No Precipitate is formed		USP c.e.	Complied	
残留溶剂 & 有机挥发性杂质 Residual Solvents & Organic Volatile Impurities	USP Test: Meets the Requirements (Ethanol < 5000ppm)		EP c.e./USP c.e.—<467> I GC	Complied	
堆积密度 Bulk Density	$\geq 0.80\text{g/ml}$ (20 Mesh); $\geq 0.60\text{g/ml}$ (100 Mesh) or Other		EP c.e./USP c.e.—<616> Loose	0.84 g/ml	
	As Tapped Density:		EP c.e./USP c.e.—<616> Tapped	1.16 g/ml	
相关物质 & 杂质 Related Substances & Impurities	单一杂质 Unspecified impurities $\leq 0.05\%$		EP c.e. HPLC	Complied	
	总杂质 Total impurities $\leq 0.2\%$		EP c.e. HPLC	Complied	
	忽略限度 Disregard limit $\leq 0.03\%$		EP c.e. HPLC	Complied	
铁盐 Iron	$\leq 10.0\text{ppm}$		EP c.e./USP c.e.—<241>/<851>/GB	$<10.0\text{ppm}$	
重金属 Heavy Metals	$\leq 10\text{ppm}$		EP c.e.	$<10\text{ppm}$	
铅盐 Lead	$\leq 5.0\text{ppm}$		EP c.e./USP c.e.—<251>/<851>	$<5.0\text{ppm}$	
砷盐 Arsenic	$\leq 0.5\text{ppm}$		EP c.e./USP c.e.—<211> II /<851>	$<0.5\text{ppm}$	
微生物 Microbiological(TAMC)	总数 Total Plate Count $\leq 1,000\text{CFU/g}$		EP c.e./USP c.e.—<61>	15 CFU/g	
酵母菌和霉菌 Yeast & Moulds(TYMC)	$\leq 100\text{CFU/g}$		EP c.e./USP c.e.—<61>	10 CFU/g	
大肠杆菌 Escherichia Coli	阴性 Negative/g		EP c.e./USP c.e.—<62>	Negative	
沙门氏菌 Salmonella	阴性 Negative/10g		EP c.e./USP c.e.—<62>	Negative	
金黄色葡萄球菌 Staphylococcus Aureus	阴性 Negative/g		EP c.e./USP c.e.—<62>	Negative	
粒度 Particle Size	20~40Mesh: 5%~20%; 40~60 Mesh: 15%~55% 60~120Mesh: 25%~56% <120 Mesh: 5%~10%		EP c.e./USP c.e.—<786>	Complied	
结论 Conclusion	Pass				
(C ₆ H ₁₄ NO ₅) ₂ SO ₄ ·2NaCl 573.31 [1296149-13-7] Packaging and storage: Preserved in tight, light-resistant containers					



THIS PRODUCT FULFILLS EP & USP