

肌醇规格书（美国药典）

Inositol Specifications (USP/NF)

项目 Item		质量标准 Quality Standard	检测方法 Test Method
感官 Description		白色结晶性粉末，无臭、味甜，空气中稳定 White crystalline powder form, odorless with sweet taste; air-stable.	USP/NF
溶解性 Solubility		微溶于乙醇；不溶于乙醚及三氯甲烷 Sparingly soluble in ethanol; insoluble in ether and chloroform.	USP/NF
理化要求 Physical and Chemical Requirements	肌醇含量(以 $C_6H_{12}O_6$ 计) Inositol ($C_6H_{12}O_6$) content	按无水物计算，含量为 97.0%~102.0% 97.0%-102.0% on the anhydrous basis	USP/NF
	鉴别 (A,B) Identification (A,B)	A.光谱鉴定：符合红外吸收特征 A.Spectroscopic Identification: Complies with infrared absorption characteristics. B.色谱纯度：供试品溶液主峰保留时间与对照品溶液一致 B.Chromatographic Purity: Sample solution major peak retention time matches the Standard solution	USP/NF
	钡 Barium	通过试验 pass	USP/NF
	铅限量 Limit of lead	≤ 0.5 mg/kg	USP/NF
	干燥失量 Loss on drying	$\leq 0.5\%$	USP/NF
	有机杂质 Organic impurities	单个杂质 $\leq 0.3\%$ ，总杂质 $\leq 1.0\%$ （忽略 $<0.05\%$ 的杂质峰） Individual impurities $\leq 0.3\%$, Total impurities $\leq 1.0\%$ (Ignore peaks $<0.05\%$)	USP/NF
	澄清度 Clarity of solution	供试品溶液澄清度应与水一致 Sample solution clarity equivalent to water.	USP/NF
	溶液颜色 Color of solution	供试品溶液颜色：不得深于标准液 A - C 或水。 Sample solution color: No darker than Standard solutions A-C or water.	USP/NF
微生物限度 Microbial Limits	电导率 Conductivity	$\leq 20\mu S/cm$	USP/NF
	总需氧细菌 Total Aerobic Bacteria	$\leq 10^3$ CFU/g	USP/NF
	霉菌和酵母菌 Mold and yeast	$\leq 10^2$ CFU /g	USP/NF
	大肠杆菌 Escherichia coli	未检出 Not detectable	USP/NF

包装形式：净重 25 公斤/纸桶

保存期限：48 个月

保存条件：存放于通风、干燥、清洁无异味的库房中

Packaging: Net Weight 25 kg/Paper Drum

Shelf Life: 48 months

Storage Conditions: Store in a ventilated, dry, clean, and odor-free warehouse.