

倍他环糊精检验报告

Certificate for BETA CYCLODEXTRIN

CAS No.: 7585-39-9

批号 Batch No.		PD-1220260311	包装规格 Packing	25kg/袋 Bag
生产日期 Manufacturing Date		2026.03.11	数量 Quantity	5000kg
取样日期 Sampling Date		2026.03.18	报告日期 Report Date	2026.03.18
取样地点 Place of samping		洁净车间 Cleaning workshop	有效期至 Expiry Date	2028.03.10
检验标准 Test Standard		中国药典 CP2025		
检验项目 ITEMS		标准规定 CRITERIA		检验结果 RESULTS
性状 Appearance		白色结晶或结晶性粉末，在水中略溶，在甲醇、乙醇或丙酮中几乎不溶。 White, crystalline or crystalline powder, slightly soluble in water, almost insoluble in methanol, ethanol or acetone.		符合 Conform
含量（以干基计） Assay(on a dry basis)		98.0%~102.0%		99.8%
比旋光度[α] ₂₀ ^D Specific Rotation [α] ₂₀ ^D		+160° ~+164°		+161.8°
鉴别 Identification	化学 Chemical	本品的碘溶液水浴加热产生黄褐色沉淀 Generate a yellow-brown precipitate		符合 Conform
	色谱实验 Chromatography Experiment	供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time of the main peak of the test solution should be consistent with that of the main peak of the reference solution.		符合 Conform
	红外 Infrared Spectrometry	本品的红外光吸收图谱应与对照品的图谱一致 The infrared absorption spectrum of this product should be consistent with that of the reference substance.		符合 Conform
酸碱度 pH value		5.0~8.0		6.2
溶液的澄清度与颜色 The Clarity and Color of the Solution		应澄清无色; 如显浑浊, 与2号浊度标准液比较，不得更浓 It should be clear and colorless; if it appears turbid, it should be compared with the No. 2 turbidity standard solution and must not be more concentrated.		符合 Conform
杂质吸光度 Absorbance of Impurities		220-350 nm: ≤0.10 350-750 nm: ≤0.05		符合 Conform
氯化物 Chloride		≤0.018%		<0.018%
还原糖 Reducing Sugar		≤0.5%		<0.5%
残留溶剂 Residual Solvent	环己烷 Cyclohexane	≤0.388%		<0.388%
	三氯乙烯 Trichloroethylene	≤0.001%		<0.001%
	甲苯Toluene	≤0.001%		<0.001%
有关物质 Related Substance	阿尔法环糊精 Alpha Cyclodextrin	≤0.25%		<0.25%
	伽马环糊精 Gamma Cyclodextrin	≤0.25%		<0.25%
	各杂质 Various Impurities	≤0.5%		<0.5%
干燥失重 Loss on Drying		≤14.0%		9.6%
炽灼残渣 Residue on Ignition		≤0.1%		0.02%
重金属 Heavy Metal		≤5ppm		<0.0005%
砷盐 Arsenic Salt		≤0.0002%		<0.0002%
微生物限度 Microbial Limit	需氧菌总数 Total Aerobic Bacteria Count	≤1000 cfu/g		<10 cfu/g
	霉菌和酵母总数 Total Count of Molds and Yeasts	≤100 cfu/g		<10 cfu/g
	大肠埃希菌 Escherichia coli	不得检出 Absent		未检出 ND
贮藏 Storage		密闭，在干燥处保存。Keep in a sealed container and store in a dry place		
结论 Conclusion		本品符合中国药典CP2025标准。Compliant to the CP 2025		
报告人 Reporter:		审核人 Verifier:		批准人 Approver:

