

Gree Industry Co.,Ltd

Linhai Economic Development Zone 250100 Shandong China

Tel:+86-531-88755607 Fax:+86-531-88755607

磺丁基倍他环糊精钠检验报告单

Certificate of Analysis for Betadex Sulfobutyl Ether Sodium

报告单编号: 25108016

批号 Lot No.	SB250102	包装规格 Package Specification	20 kg/桶 Drum
生产日期 Manu Date	2025.01.09 09.Jan.2025	有效期至 Expiry Date	2028.01.08 08.Jan.2028
批量 Lot Quantity	258.43kg	报告日期 Report Date	2025.01.18 18.Jan.2025
标准依据 Standard	企业标准和 USP-NF2024 Enterprise Standard and USP-NF2024	记录编号 Record Code	25108016-25108030
项目 Item		指标 Specification	检验结果 Result
外观 Appearance		白色无定形粉末 (CDE 登记标准) 白色或几乎白色无定形粉末 (USP) White to off-white, amorphous powder (USP)	白色无定形粉末 White amorphous powder
鉴别 Identification	红外光谱 IR	样品的红外吸收图谱应与对照品的红外图谱一致 The infrared absorption spectrum is consistent with that of the Standard	符合规定 Conform
	HPLC	样品液主峰的保留时间应与标准液的保留时间一致 The retention time of the major peak of the Sample solution corresponds to that of the Standard solution	符合规定 Conform
	平均取代度 Average Degree of Substitution	应符合平均取代度的规定 Meets the requirements of the test for Average Degree of Substitution	符合规定 Conform
	钠 Sodium	呈钠盐反应 Gives the reactions of Sodium	符合规定 Conform
溶液的澄清度 Clarity of Solution		应澄清 The solution is clear and essentially free from particles of foreign matter	符合规定 Conform
含量 (按照无水物计, %) Assay (Calculated on the anhydrous basis)		95.0~105.0	99.5
重金属 Heavy Metals (ppm)		≤5	<5
倍他环糊精 Beta Cyclodextrin (Betadex) (%)		≤0.1	0.011
1,4-丁烷磺内酯 1,4-Butane Sultone (ppm)		≤0.5	0.022
氯化钠 Sodium Chloride (%)		≤0.2	0.0069
4-羟基丁烷-1-磺酸 4-Hydroxybutane-1-sulfonic Acid (%)		≤0.09	未检出 Absent
双(4-磺丁基)醚二钠 Bis(4-sulfobutyl) ether Disodium (%)		≤0.05	未检出 Absent
细菌内毒素 Bacterial Endotoxins (EU/mg)		<0.02	<0.01
需氧菌总数 The Total Aerobic Microbial Count (cfu/g)		≤100	10



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项目Item	指标Specification	检验结果Result	
霉菌和酵母菌 The Total Combined Molds and Yeasts Count (cfu/g)	≤50	<10	
大肠埃希菌Escherichia Coli	不得检出Absent	未检出Absent	
取代度Average Degree of Substitution	6.2~6.9	6.5	
峰Peaks I-X (% 峰面积 Peak Area)	I	0.0~0.3	0.00
	II	0.0~0.9	0.49
	III	0.5~5.0	2.25
	IV	2.0~10.0	6.68
	V	10.0~20.0	13.26
	VI	15.0~25.0	21.52
	VII	20.0~30.0	24.38
	VIII	10.0~25.0	19.38
	IX	2.0~12.0	9.27
	X	0.0~4.0	2.77
pH	4.0~6.8	6.5	
水分Water Determination(%)	≤10	4	
结论: Conclusion:	本品按企业标准和USP-NF2024检验, 上述项目符合规定 Complies with Enterprise Standard and USP-NF2024 (For Injection)		<合格>

报告者By: 王新林
2025.01.18

复核者 Recheck: 张昊
2025.01.18

批准者 Director: 王新林
2025.01.18