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Certificate of analysis

品名	磺丁基倍他环糊精钠 Betadex sulfobutyl ether sodium	CAS	182410-00-0
货号	D15972	批次	OK202411090
生产日期	2024-11-09	复测日期	2026-11-08
执行标准:企业标准			
分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS	
外观 Appearance	本品为白色无定形粉末，易溶于水，略溶于甲醇，几乎不溶于乙醇、1-丁醇、乙腈、2-丙醇、乙酸乙酯、无水乙醇、二氯甲烷。 This product is a white amorphous powder that is easily soluble in water, slightly soluble in methanol, and almost insoluble in ethanol, 1-butanol, acetonitrile, 2-propanol, ethyl acetate, anhydrous ethanol, and dichloromethane.	符合 Conform	
鉴别 identify			
A. 红外光谱检查 A. Infrared spectroscopy inspection	红外光吸收图谱应与对照品的图谱一致 The infrared absorption spectrum should be consistent with the spectrum of the reference substance	在 276nm 的波长处有最大吸收 Has maximum absorption at a wavelength of 276nm	
B、含量测定 B. Content determination	样品溶液主峰的保留时间应与标准品溶液主峰的保留时间一致 The retention time of the main peak in the sample solution should be consistent with that of the main peak in the standard solution	符合 Conform	

C. 取代度 C. Degree of substitution	符合平均取代度项下要求 Meets the requirements under the average degree of substitution	符合 Conform
D. 鉴定测试 D. Appraisal testing	钠盐鉴别 Sodium salt identification	呈正反应 positive reaction
含量 Content	95.0%--105.0%	98.76%
重金属 Heavy metals	<5ppm	<5ppm
倍他环糊精 Beta cyclodextrin	<0.1%	未检出 Not detected
1,4-丁烷磺内酯 1,4-Butanosulfolactone	<0.5ppm	<0.5ppm
氯化钠 Sodium chloride	<0.2%	0.013%
4-羟基丁烷-1-磺酸 4-hydroxybutane-1-sulfonic acid	<0.09%	未检出 Not detected
双(4-磺丁基)醚二钠 Bis(4-sulfobutyl) ether disodium	<0.05%	未检出 Not detected
细菌内毒素 Bacterial endotoxins	应符合相关要求 Should meet relevant requirements	<10IU/g
微生物限度 Microbial limit	好氧微生物总数<100cfu/g Total number of aerobic microorganisms<100cfu/g	<10cfu/g
	霉菌和酵母菌总数<50cfu/g The total number of mold and yeast is less than 50cfu/g	<10cfu/g
	大肠杆菌不得检出 Escherichia coli cannot be detected	未检出 Not detected
溶液的澄清度 Clarity of solution	见 USP40-NF35 Refer to USP40-NF35	符合 Conform
平均取代度 Average degree of substitution	6.2-6.9	6.4
磺丁基倍他环糊精钠峰IX的限度范围、检测结果 Limit range and detection results of peak IX of sodium sulfobutyl betacyclodextrin		
磺丁基倍他环糊精钠峰 I-X Sodium peak of sulfobutyl betacyclodextrin I - X	限度范围 (% 峰面积) Limit range (% peak area)	检测结果 (% 峰面积) Test results (% peak area)

I	0-0.3	0.01
II	0-0.9	0.59.
III	0.5-5.0	1.73
IV	2.0-10.0	6.55
V	10.0-20.0	19.26
VI	15.0-25.0	18.66
VII	20.0-30.0	21.76
VIII	10.0-25.0	19.11
IX	2.0-12.0	10.13
X	0-4.0	2.21
PH	4.0-6.8	6.34.
水分 moisture content	< 10%	5.70%

注：此产品仅限用于科研，禁止直接用于临床，如有失误，后果自负。

QA：杜冰冰

QC：谢辉

