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青岛明月海藻集团有限公司 甘露醇检验报告

QINGDAO BRIGHT MOON SEAWEED GROUP CO.,LTD MANNITOL INSPECTION REPORT

产品名称 Product Name	甘露醇 (MANNITOL)		产品类别 Product Category	药用辅料 Pharmaceutical Excipients		
生产批号 Batch NO.	H362312005		批量, kg Quantity	10825		
包装规格 Packing Size	25kg/桶 (drum)		生产日期 Production Date	2023-12-03		
检验日期 Test Date	2023-12-07		有效期至 Valid Date	2026-12-02		
检验结果 Test Result	项目 (Item)	标准值 (Standard)	检验结果 (Test Result)	检验依据 (According)	单项判定 (Individual decision)	
	性状 (Characters)	White crystalline powder or free-flowing granules is odorless and has a sweet taste Freely soluble in water soluble in alkaline solutions slightly soluble in pyridine very slightly soluble in alcohol practically insoluble in ether	White crystalline powder or free-flowing granules is odorless and has a sweet taste Freely soluble in water soluble in alkaline solutions slightly soluble in pyridine very slightly soluble in alcohol practically insoluble in ether	USP46	qualified	
	鉴别 (Identification)	Be consistent with the refer	Be consistent with the refer	USP46	qualified	
	澄清度与颜色 (Clarity&Colour)	Clear and Colorless	Clear and Colorless	USP46	qualified	
	干燥失重 (Loss On Drying) %	≤0.5	0.05	USP46	qualified	
	镍 (Nickel) ppm	≤1.0	Negative (LOD=0.036)	USP46	qualified	
	山梨糖醇 (Sorbitol) %	≤2.0	0.021	USP46	qualified	
	麦芽糖醇和异麦芽糖醇 (Maltitol and Isomalt) %	≤2.0	0.015	USP46	qualified	
	不确定杂质 (Unspecified impurities) %	≤0.10	0.071	USP46	qualified	
	总杂质 (Total impurities) %	≤2.0	0.10	USP46	qualified	
	含量 (Assay) %	97.0-102.0	99.9	USP46	qualified	
	熔点 (Melting Point) °C	165-170	166.5-167.5	USP46	qualified	
	还原糖 (Reducing Sugar) %	≤0.1	<0.1	USP46	qualified	
	电导率 (Conductivity) μS/cm	≤20	1.4	USP46	qualified	
	需氧菌总数 (Total aerobic bacteria) CFU/g	≤10 ³	<10	USP46	qualified	
	霉菌和酵母菌 (Moulds And Yeasts) CFU/g	≤10 ²	<10	USP46	qualified	
	大肠杆菌 (Escherichia coli)	Negative	Not detected	USP46	qualified	
	内毒素 (Endotoxins) EU/g	<2.5	<2.5		qualified	
	日期 Date	检验报告出具日期 (issuing date) : 2023-12-12 签发日期 (issue date) : 2023-12-12				
	备注 Remarks					

批准 (Approved by):

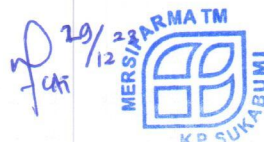
明月

审核 (Checked by):

李花蕊

编制 (Edited by):

王增顺





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青岛明月海藻集团有限公司 甘露醇检验报告

QINGDAO BRIGHT MOON SEAWEED GROUP CO., LTD MANNITOL INSPECTION REPORT

产品名称 Product Name	甘露醇 (MANNITOL)	产品类别 Product Category	药用辅料 Pharmaceutical Excipients		
生产批号 Batch NO.	H362310018	批量, kg Quantity	10400		
包装规格 Packing Size	25kg/袋 (bag) / 桶 (drum)	生产日期 Production Date	2023-10-09		
检验日期 Test Date	2023-10-14	有效期至 Valid Date	2026-10-08		
检验结果 Test Result	项目 (Item)	标准值 (Standard)	检验结果 (Test Result)	检验依据 (According)	单项判定 (Individual decision)
	性状 (Characters)	White crystalline powder or free-flowing granules.Is odorless and has a sweet taste.Freely soluble in water;soluble in alkaline solutions; slightly soluble in pyridine;very slightly soluble in alcohol;practically insoluble in ether.	White crystalline powder or free-flowing granules.Is odorless and has a sweet taste.Freely soluble in water;soluble in alkaline solutions; slightly soluble in pyridine;very slightly soluble in alcohol;practically insoluble in ether.	USP46	qualified
	鉴别 (Identification)	Be consistent with the refer	Be consistent with the refer	USP46	qualified
	澄清度与颜色 (Clarity&Colour)	Clear and Colorless	Clear and Colorless	USP46	qualified
	干燥失重 (Loss On Drying) %	≤0.5	0.04	USP46	qualified
	镍 (Nickel) ppm	≤1.0	Negative (LOD=0.036)	USP46	qualified
	山梨糖醇 (Sorbitol) %	≤2.0	0.028	USP46	qualified
	麦芽糖醇和异麦芽糖醇 (Maltitol and Isomalt) %	≤2.0	0.019	USP46	qualified
	不确定杂质 (Unspecified impurities) %	≤0.1	0.063	USP46	qualified
	总杂质 (Total impurities) %	≤2.0	0.11	USP46	qualified
	含量 (Assay) %	96.00-101.5	99.9	USP46	qualified
	熔点 (Melting Point) °C	165-170	166.5-167.5	USP46	qualified
	还原糖 (Reducing Sugar) %	≤0.1	<0.1	USP46	qualified
	电导率 (Conductivity) μS/cm	≤20	1.3	USP46	qualified
	需氧菌总数 (Total aerobic bacteria) CFU/g	≤10³	<10	USP46	qualified
	霉菌和酵母菌 (Moulds And Yeasts) CFU/g	≤10²	<10	USP46	qualified
	大肠杆菌 (Escherichia coli)	Negative	Not detected	USP46	qualified
	内毒素 (Endotoxins) EU/g	<2.5	<2.5		qualified
日期 Date	检验报告出具日期 (issuing date) : 2023-10-19 签发日期 (issue date) : 2023-10-19				
备注 Remarks					

批准 (Approved by):

王增顺

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