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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.	H362403057		批量, kg Quantity	11500	
包装规格 Packing Size	25kg/桶 (drum)		生产日期 Production Date	2024-03-30	
检验日期 Test Date	2024-04-03		有效期至 Valid Date	2027-03-29	
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.	USP	qualified
	鉴别 (Identification)	Be consistent with the refer	Be consistent with the refer	USP	qualified
	澄清度与颜色 (Clarity & Colour)	Clear and Colorless	Clear and Colorless	USP	qualified
	干燥失重 (Loss On Drying) %	≤0.5	0.05	USP	qualified
	镍 (Nickel) ppm	≤1.0	Negative (LOD=0.037)	USP	qualified
	山梨糖醇 (Sorbitol) %	≤2.0	0.019	USP	qualified
	麦芽糖醇和异麦芽糖醇 (Maltitol and Isomalt) %	≤2.0	0.015	USP	qualified
	不确定杂质 (Unspecified impurities) %	≤0.10	0.078	USP	qualified
	总杂质 (Total impurities) %	≤2.0	0.11	USP	qualified
	含量 (Assay) %	97.0-102.0	99.9	USP	qualified
	熔点 (Melting Point) °C	165-170	166.5-167.5	USP	qualified
	还原糖 (Reducing Sugar) %	≤0.1	<0.1	USP	qualified
	电导率 (Conductivity) μS/cm	≤20	1.3	USP	qualified
	需氧菌总数 (Total aerobic bacteria) CFU/g	≤10 ³	<10	USP	qualified
	霉菌和酵母菌 (Moulds And Yeasts) CFU/g	≤10 ²	<10	USP	qualified
	大肠杆菌 (Escherichia coli)	Negative	Not detected	USP	qualified
日期 Date	检验报告出具日期 (issuing date): 2024-04-08 签发日期 (issue date): 2024-04-08				
备注 Remarks					

批准 (Approved by):

王月红

审核 (Checked by):

刘志晓

编制 (Edited by):

王月红

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Recode NO: 09SM02027-R06 (03)



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.	H362403058		批量, kg Quantity	11500		
包装规格 Packing Size	25kg/桶 (drum)		生产日期 Production Date	2024-03-31		
检验日期 Test Date	2024-04-04		有效期至 Valid Date	2027-03-30		
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	USP	qualified	
	鉴别 (Identification)	Be consistent with the refer	Be consistent with the refer	USP	qualified	
	澄清度与颜色 (Clarity&Colour)	Clear and Colorless	Clear and Colorless	USP	qualified	
	干燥失重 (Loss On Drying) %	≤0.5	0.04	USP	qualified	
	镍 (Nickel) ppm	≤1.0	Negative (LOD=0.037)	USP	qualified	
	山梨糖醇 (Sorbitol) %	≤2.0	0.020	USP	qualified	
	麦芽糖醇和异麦芽糖醇 (Maltitol and Isomalt) %	≤2.0	0.015	USP	qualified	
	不确定杂质 (Unspecified impurities) %	≤0.10	0.071	USP	qualified	
	总杂质 (Total impurities) %	≤2.0	0.11	USP	qualified	
	含量 (Assay) %	97.0-102.0	99.9	USP	qualified	
	熔点 (Melting Point) °C	165-170	166.5-167.5	USP	qualified	
	还原糖 (Reducing Sugar) %	≤0.1	<0.1	USP	qualified	
	电导率 (Conductivity) μS/cm	≤20	1.5	USP	qualified	
	需氧菌总数 (Total aerobic bacteria) CFU/g	≤10 ³	<10	USP	qualified	
	霉菌和酵母菌 (Moulds And Yeasts) CFU/g	≤10 ²	<10	USP	qualified	
	大肠杆菌 (Escherichia coli)	Negative	Not detected	USP	qualified	
	日期 Date	检验报告出具日期 (issuing date) : 2024-04-09 签发日期 (issue date) : 2024-04-09				
	备注 Remarks					

批准 (Approved by) :

王月红

审核 (Checked by) :

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