

**WEIFANG SHENGTAI MEDICINE CO., LTD.**

NO.1202, FANGSHAN ROAD, CHANGLE COUNTY, WEIFANG, SHANDONG, CHINA

**CERTIFICATE OF ANALYSIS 检验报告单**

Product Name 产品名称	Dextrose Anhydrous 无水葡萄糖	Grade 级别	Injection Grade 注射级
Batch No. 批号	202307042	Batch Quantity 批数量	150000kg
Manufacture Date 生产日期	July 30, 2023 2023年7月30日	Expiry Date 有效期	Two years 两年
Packing 包装形式	25kg/per bag 袋		
Standard 检验依据	USP 43 and CHP 2020 requirements USP 43 标准及中国药典 2020 标准		

Items 指标	Standard 标准	Results 结果
Identification 鉴别	A. Meets the requirement/满足要求	Confirm
	B. The principal peak from the Sample solution is similar in retention time and size to the principal peak from Standard solution A 供试品溶液色谱图主峰在保留时间、大小上与标准溶液 A 色谱图主峰相似。	The principal peak from the Sample solution is similar in retention time and size to the principal peak from Standard solution A
	C. Water 水分 ≤1.0%	0.06%
Assay 含量	97.5%-102.0%	99.6%
Related Substances 相关物质	Maltose and Isomaltose 麦芽糖和异麦芽糖杂质总和≤0.4%	0.02%
	Maltotriose 麦芽三糖杂质≤0.2%	0%
	Fructose 果糖杂质≤0.15%	0%
	Unspecified 未知杂质≤0.10%	0%
	Total Impurities 总杂质≤0.5%	0.02%
Color and Clarity of Solution 溶液颜色和澄清度	The sample solution is clear and not more intensely colored than the reference solution 溶液澄清且颜色浅于参考溶液	The sample solution is clear and not more intensely colored than the reference solution
Conductivity 电导率	≤20 μS/cm	2.9μS/cm
Dextrin 糊精	The sample dissolves completely 样品完全溶解	The sample dissolves completely
Soluble Starch, Sulfites 可溶性淀粉, 亚硫酸盐	≤15ppm	<15ppm
Aerobic Plate Count 需氧菌落数	≤1000cfu/g	<10cfu/g
Moulds and Yeasts 霉菌和酵母菌总数	≤100cfu/g	<10cfu/g
Escherichia Coli 大肠埃希菌	Negative	Not detected
Bacterial Endotoxin 细菌内毒素限值	<1.25EU/g	<0.3EU/g

**Conclusion:** The products meet the requirements of USP 43 and CHP2020 requirements.

结论: 产品符合 USP 43 标准及中国药典 2020 标准。

Analyst 检验人:

Reviewer 复核人:

Approver 审批人: