

Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

Product Name: Sorbitol TSG5

Quantity: 42.75MT

Batch No.: 452307026

Date of Certificate: 2023.08.05

Date of Manufacture: 2023.07.30

Date of Expiry: 2025.07.29

项目 Items	标准 Specification	检测结果 Test Result	
外观 Appearance	white or almost white, crystalline powder 白色或类白色结晶性粉末	Conforms符合	
气味 Odor	Odorless 无嗅	Conforms符合	
味道 Taste	Sweet and cool 味甜, 清凉	Conforms符合	
鉴别 Identification	A: the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a). 用供试溶液获得的色谱图中的主峰在保留时间和大小上与用参比溶液 (a) 获得的色谱图中的主峰值相似。	Conforms符合	
溶解性 Solubility	Very soluble in water, practically insoluble in ethanol (96%) 极易溶于水, 几乎不溶于96%乙醇	Conforms符合	
溶液颜色 Appearance of Solution	The solution is clear and colourless 溶液透明无色	Conforms符合	
比旋度 Specific Optical Rotation	+4.0~+7.0	+4.7	
电导率 Conductivity	≤20μs/cm	6.36	
还原糖 Reducing Sugars	≤0.2%	0.028	
水分 Water Content	≤1.5%	0.34	
微生物 Microbiological	菌落总数 TAMC	≤100cfu/g	<10
	总酵母菌和霉菌 TYMC	≤100cfu/g	<10
	大肠杆菌 Escherchia Coli	Negative未检出	Negative未检出
	沙门氏菌 Salmonella	Negative未检出	Negative未检出
含量 Assay	97.0%~102.0%	98.9	
<p>No organic solvents are used in the manufacturing of Sorbitol. Therefore, this batch of Sorbitol meets all requirements as set forth in the EP. 制造山梨糖醇时不使用有机溶剂。因此, 这批山梨醇符合EP中规定的所有要求。</p>			
检验结论 Conclusion	符合EP Comforms to EP		

