

Certificate of Analysis

Product Name: MANNITOL POWDER

Batch No: FG2311009

Manufacture date: Nov.13,2023

Expiry date: Nov.12,2025

Item		Specfication	Result
Appearance		White or almost white crystals or powder	Conforms
Solubility		Freely soluble in water, very slightly soluble in ethanol	Conforms
Identification	Specific Optical Rotation	+23°~+25°	+23.8°
	Melting Point	165.0°~170.0°	165.8°~168.9°
	Infrared Absorption	Conforms	Conforms
Apperance of Solution		Clear and Colorless	Conforms
Conductivity		≤20μs/cm	3.0μs/cm
Reducing Sugars		≤0.1%	<0.1%
Heavy Metals		≤5ppm	<5ppm
Nickel		≤1ppm	<1ppm
Loss on Drying		≤0.5%	0.21%
Related Substances	A (Sorbitol)	≤2.0%	0.50%
	B (Maltitol) +C(Isomalt)	≤2.0%	0
	Unspecified	≤0.1%	0
	Total	≤2.0%	0.50%
Microbiological	Total Aerobic Count	≤10 ³ cfu/g	<10 cfu/g
	Yeast and Mold	≤10 ² cfu/g	<10 cfu/g
	E.Coli	Negative	Negative
	Salmonella	Negative	Negative
Assay		97.0%~102.0%	99.1%
Bacterial Endotoxins		≤ 2.5EU/g	<2.5EU/g
Particle size		85% pass 100mesh	
Conclusion		Complies with the current USP/BP requirements	

Checker:

Inspector:



For and on behalf of
HYLEN CO., LTD.

 Authorized Signature(s)

HYLEN CO.,LTD.

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