

Certificate of Analysis
Product: Mannitol, Powder
Item Number: MANPU
Grade: USP
Lot Number: 5001512/1.1
Manufacture Date: 08/30/2024
Expiration Date: 08/29/2027
Country of Origin: China

Tested Property	Specification	Analysis
Appearance	White or almost white powder or crystal	White Crystal
Identification by IR	Conforms to spectra	Conforms
Assay	97.0 - 102.0%	99.7%
Sorbitol	Max 2.0%	0.3%
Sum of Maltitol & Isomalt	Max 2.0%	Not detected
Total Impurities	Max 2.0%	0.3%
Reducing sugars	Max 0.1%	<0.1%
Nickel	<0.1µg/g	<1µg/g
Melting point	165 - 170°C	166 - 168°C
Appearance of solution	Clear and Colorless	Pass
Loss on drying	Max 0.5%	0.1%
Conductivity	Max 20 µS/cm	2.0 µS/cm
Microbial Contamination, TAMC	Max 1000 CFU/g	<20 CFU/g
Microbial Contamination, TYMC	Max 100 CFU/g	<20 CFU
Absence of Escherichia Coli	Negative	Negative
Absence of Salmonella	Negative	Negative
Residual Solvents, USP <467>	None	Conforms
Unspecified Impurities	Max 0.10%	Not Detected
SOR	+23~+25	+23.9
TLC	Conformity	Conformity

[Phone: 512-668-9918](tel:512-668-9918), [Fax: 512-886-4008](tel:512-886-4008),
[E-mail: customercare@laballey.com](mailto:customercare@laballey.com),
www.laballey.com,

12501 Pauls Valley Road, Suite A, Austin, Texas 78737,
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