

Certificate of Analysis

Item Number	Product Description	Lot Number
CP-B2050D	CHEMPURE D-Mannitol, 1Kg	00287CP1812023
Formula	Molecular Weight	Cas Number
$C_6H_{14}O_6$	182.2	69-65-8

QC TEST/RELEASE DATE: 07/11/2022

MANUFACTURING DATE: 07/11/2022

S.No	Test	Unit	Specifications	Test Value
1	Appearance		White crystalline powder	passed
2	Appearance of Solution		Clear and colorless solution	Clear and colorless solution
3	Melting Point	°C	165.0 - 170.0	166 - 168
4	Nickel (Ni)	ppm	≤ 1	< 1
5	Conductivity	μS/cm	≤ 20	<1.9
6	Total Yeast and Mold Count (TYMC)	cfu/g	≤ 100	< 10
7	Identification (IR)		Conforms	passed
8	Reducing Sugar	%	≤ 0.1	< 0.1
9	Loss on Drying	%	≤ 0.5	0.1%
10	Residual Solvents		Meet requirements	Conforms, not detected
11	Bacterial Endotoxins	IU/g	≤ 2.5	< 2.5
12	E.Coli		Negative	passed
13	Total Aerobic Microbial Count (TAMC)	cfu/g	≤ 100	< 10
14	Assay	%	96.0 - 101.5	99.9
15	Related Substance (Maltitol and Isomalt)	%	≤ 2.0	< 2.0
16	Related Substance (Sorbitol)	%	≤ 2.0	< 2.0
17	Related Substance (Total impurity)	%	≤ 2.0	< 2.0
18	Related Substance (Unspecified Impurities)	%	≤ 0.10	< 0.10

19	Specific Optical Rotation (USP)	°	+137 - +145	+141.1
20	Non Animal Origin		Conforms	passed
21	Grade		USP	passed

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