

SPECIFICATION

Product name: D-Mannitol USP

Lot#: SAMPLE

Manufacture Date: XXXXX

Retest Date: XXXX

CAS#: 69-65-8

Analytical	Specification as per USP
Identification	
Appearance	White crystalline powder
Solubility	soluble in water, freely soluble in alcohol, not soluble in Ether
ID Test A	Complies with test
ID Test B	Complies with test
Melting point	166 -170 °C
Specific optical rotation	+137 - + 145
Acidity	Complies with USP
Total impurities	Max. 2.0%
Loss on drying	Max. 0.5 %
Residue on Ignition	Max. 0.1%
Assay (% dried basis)	98.0% to 102.0%
Reducing sugars	Complies with USP
Chlorides	30 mg/kg max
Sulfates	100 mg/kg max
Oxalate	0.02 mg/kg max
Heavy metals	10 mg/kg max
Arsenic	2 mg/kg max
Total aerobic microbial count	1000 cfu/g max
Total yeasts and moulds	100 cfu/g max
Escherichia coli	Not detected
Salmonella	Not detected