

Technical Specification

PRODUCT : D-Mannitol ERBApharm According to pharmacopoeia : Ph.Eur.-USP-FU-JP

CODE : 352050

MOLECULAR WEIGHT :182,17

CAS N° : 69-65-8

FORMULA : CH₂OH(CHOH)₄CH₂OH

TEST	U.M.	SPECIFICATION
Description	-	White crystalline powder
Appearance of solution	Ph.Eur.	Conform*
Acidity	-	Conform*
Melting point	°C	165 - 167*
Conductivity	µS/cm	<= 20*
Residue on ignition	ppm	<= 100*
Reducing sugars	% (Ph.Eur.)	<= 0.1*
Ni	ppm	<= 1*
Assay (HPLC)	% anhydrous	97.0 - 102.0
Microbial tests	-	-
Total aerobic microbial count (TAMC)	UFC/g	<= 1000
Total yeasts/mould count (TYMC)	UFC/g	<= 100
Escherichia coli	Ph.Eur.	Absent
Salmonella	Ph.Eur.	Absent
Identification (I.R.)	-	Positive
Identification D	-	Positive*
Related substances	-	-*
Impurity A (HPLC)	%	<= 2.0*
Impurities B+C (HPLC)	%	<= 2.0*
Other impurities (HPLC)	%	<= 0.10*
Total impurities (HPLC)	%	<= 2.0*
Loss on drying 105°C	%	<= 0.3
Specific optical rotation at 20°C (anh.)	°	+23 to +25

CHARACTERS

Appearance: white or almost white crystals or powder.

Solubility: freely soluble in water, practically insoluble in ethanol (96 per cent).

It shows polymorphism.

This batch has been released by authorized personnel

* Parameters marked with * are tested periodically

It is under the customer responsibility to make sure the purchased product is suitable for his use and/or application.
 CARLO ERBA Reagents would not be guilty of any misuse or mishandling of any of its products, occurring potential damages or user hurts in case of in