



D-Mannitolo

Synonyms:

Mannite

CH₂OH(CHOH)₄CH₂OH

Classification

Danger

Molecular weight

182.17 ONU

CAS

69-65-8 Transport hazard class:

EEC-N:

200-711-8 Packing

D-Mannitolo

> ERBApharm - Secondo farmacopea:
Ph.Eur.-USP-FU-JP

Grado Farmaceutico

Description	White crystalline powder	-
Appearance of solution	Conform*	Ph.Eur.
Acidity	Conform*	-
Melting point	165 - 167*	°C
Ni	<= 1*	ppm
Assay (HPLC)	97.0 - 102.0	% anhydrous



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Reducing sugars	$\leq 0.1^*$	% (Ph.Eur.)
Conductivity	$\leq 20^*$	$^{\circ}\text{S/cm}$
Microbial tests	-	-
Total aerobic microbial count (TAMC)	≤ 1000	UFC/g
Total yeasts/mould count (TYMC)	≤ 100	UFC/g
Escherichia coli	Absent	Ph.Eur.
Salmonella	Absent	Ph.Eur.
Residue on ignition	$\leq 100^*$	ppm
Identification (I.R.)	Positive	-
Identification D	Positive*	-
Related substances	-*	-
Impurity A (HPLC)	$\leq 2.0^*$	%
Impurities B+C (HPLC)	$\leq 2.0^*$	%
Other impurities (HPLC)	$\leq 0.10^*$	%
Total impurities (HPLC)	$\leq 2.0^*$	%
Loss on drying 105°C	≤ 0.3	%
Specific optical rotation at 20°C (anh.)	+23 to +25	$^{\circ}$



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ID	Size	Packaging
000000000000352051	1 kg	Bottiglia di plastica
000000000000352052	5 kg	Vaso di plastica
000000000000352053	25 kg	Secchio di plastica



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