

neoFroxx GmbH

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www.neofroxx.com

Specification

Product	D(-)-Mannitol pure EP, USP (pharma grade)
Product number	LC-6225
Synonyms	D-Mannite
Formula	C ₆ H ₁₄ O ₆
Molecular weight	182.17 g/mol
CAS number	69-65-8
Storage	below 25°C
Retest period (months)	60

We herewith confirm that this product meets the requirements of the European Pharmacopoeia (EP) and the US Pharmacopoeia (USP).

Parameter	Specification
Assay (USP, EP)	97 - 102 %
Appearance (EP)	white or almost white crystals or powder (revised)
Solubility (EP)	passes test
Identity (USP, EP)	passes test
Specific rotation (EP)	+ 23° - + 25°
Melting point (USP, EP)	165 °C - 170 °C
Appearance of solution (USP, EP)	clear and colourless (revised)
Conductivity (USP, EP)	<= 20 µS/cm
Loss on drying (105°C, 4 h) (USP, EP)	<= 0.5 %

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Product	D(-)-Mannitol pure EP, USP (pharma grade)
Parameter	Specification
Related substances (USP, EP)	
Sorbitol	<= 2 %
Sum of isomalt and maltitol	<= 2 %
unspecified impurities (each impurity)	<= 0.1 %
total impurities	<= 2 %
Reducing sugars (as Glucose) (USP, EP)	<= 0.1 %
TAMC (USP, EP)	<= 1000 cfu/g
TYMC (USP, EP)	<= 100 cfu/g
Salmonella sp. (USP, EP)	not detectable in 10 g
E. coli (USP, EP)	not detectable in 1 g
Nickel (USP)	<= 0.0001 %

Einhausen, 28.04.2025