

Material	25311.297
Material description	D(-)-Mannitol
Grade	Ph.Eur./USP
CAS Number	69-65-8
Molecular formula	C ₆ H ₁₄ O ₆
Molecular mass	182.17

Additional information

Characteristics	Specifications
Appearance	Conforms (see CoA/CoS)
Heavy metals (as Pb)	≤ 5 ppm
Residual solvents	Unlikely by manuf.process
Metal catalysts	Unlikely by manuf.process
Residual metal catalysts (skip lot):	.
As (Arsenic)	≤ 2 ppm
Cd (Cadmium)	≤ 1 ppm
Co (Cobalt)	≤ 1 ppm
Hg (Mercury)	≤ 2 ppm
Pb (Lead)	≤ 3 ppm
V (Vanadium)	≤ 1 ppm
Conforms to Ph.Eur./USP	Passes test
Ph.Eur. specifications:	.
Assay (dried substance) [Ph.Eur.]	97.0 - 102.0 %
Identification C	Passes test Ph.Eur.
Appearance of solution	Passes test Ph.Eur.
Conductivity (20°C; 20 %) [Ph.Eur.]	≤ 20 µS/cm
Melting point [Ph.Eur.]	165 - 170 °C
Reducing sugars (as C ₆ H ₁₂ O ₆) [Ph.Eur.]	≤ 0.1 %
D-Sorbitol [Ph.Eur.]	≤ 2.0 %
D-Maltitol and isomalt [Ph.Eur.]	≤ 2.0 %
Unspecified impur. (for each) [Ph.Eur.]	≤ 0.10 %
Total impurities [Ph.Eur.]	≤ 2.0 %
Disregard limit [Ph.Eur.]	≤ 0.05 %
Loss on drying (105°C; 4 h) [Ph.Eur.]	≤ 0.5 %
TAMC [Ph.Eur.]	≤ 1000 CFU/g
TYMC [Ph.Eur.]	≤ 100 CFU/g
Escherichia coli [Ph.Eur.]	Absent
>>> Continued on page 2 >>>	

For Professional use in Laboratory or Manufacturing. Not for use as an Active Pharmaceutical Ingredient or Food or Animal Feed. Suitability and intended use of the product remains the responsibility of the user.



Characteristics	Specifications
Salmonella [Ph.Eur.]	Absent
USP specifications:	.
Assay (calculated on dried basis) [USP]	97.0 - 102.0 %
Identification A	Passes test USP
Disregard limit [USP]	≤ 0.05 %
Sorbitol [USP]	≤ 2.0 %
Sum of isomalt and maltitol [USP]	≤ 2.0 %
Unspecified impurities [USP]	≤ 0.10 %
Total impurities [USP]	≤ 2.0 %
Reducing sugars (as C ₆ H ₁₂ O ₆) [USP]	≤ 0.1 %
Ni (Nickel) [USP]	≤ 1 µg/g
Melting point [USP]	165 - 170 °C
Appearance of solution	Passes test USP
Loss on drying (105°C; 4 h) [USP]	≤ 0.5 %
Conductivity (25°C; 20 %) [USP]	≤ 20 µS/cm
TAMC [USP]	≤ 1000 CFU/g
TYMC [USP]	≤ 100 CFU/g
Escherichia coli [USP]	Absent

Signature

We certify that this batch conforms to the specifications listed above.

This document has been produced electronically and is valid without a signature.

Jessie Pijck, Head of Laboratory - Haasrode
VWR International bv; Geldenaaksebaan 464; BE-3001
Leuven; Belgium

Additional information

Appearance: White or almost white crystals or powder.

Not for use as Active Pharmaceutical Ingredient (API)

The material is tested, relabeled and repacked in a management system certified to EXCiPACT. Registration No. 530841 EXCI.