



Specification

1.12635.9025 Parteck® Delta M (Mannitol) EMPROVE® ESSENTIAL Ph Eur,BP,USP,JP,
E 421

	Specification	
Assay (HPLC, calc. on dried substance)	98.0 - 101.0	%
Identity (NIR)	passes test	
Appearance of solution (10 %; water)	passes test	
pH-value (10 %; water)	4.5 - 7.5	
Melting point	165 - 169	°C
Conductivity (25°C) (20 %; water)	≤ 20	μS/cm
Heavy metals (as Pb)	≤ 5	ppm
Ni (Nickel)	≤ 1	ppm
Pb (Lead)	≤ 0.5	ppm
Ru (Ruthenium) (#)	≤ 1	ppm
Related substances (HPLC) (Sorbitol (Impurity A))	≤ 2.0	%
Related substances (HPLC) (Sum of Maltitol and Isomalt (Impurities B and C))	≤ 2.0	%
Related substances (HPLC) (Major unspecified impurity)	≤ 0.10	%
Related substances (HPLC) (Sum of all impurities)	≤ 2.0	%
Reducing sugars (as glucose)	≤ 0.05	%
Reducing sugars after hydrolysis/total sugar (as glucose)	≤ 1	%
Sulfated ash	≤ 0.1	%
Water	≤ 0.5	%
Loss on Drying (105 °C)	≤ 0.30	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	

	Parameter with periodic testing	
Microbiological test	passes test	
Colony count (aerobic bacteria (TAMC))	≤ 10 ³	CFU/g
Colony count (Yeasts and moulds (TYMC))	≤ 10 ²	CFU/g
Salmonella spp.	in 10g Substance not detectable	
E.coli	in 1g Substance not detectable	
Staphylococcus aureus	in 1g Substance not detectable	
Pseudomonas aeruginosa	in 1g Substance not detectable	
Candida albicans	In 1g Substance not detectable	

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Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities).
Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (#).
Corresponds to Ph. Eur., BP, USP, JP, E 421
Conforms to the purity criteria on food additives according to the current European Commission Regulation.

Jennifer Standare

Responsible laboratory manager quality control

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