



Specification

1.00419.0000 Parteck® M 200 (Mannitol) EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JP, USP, E 421

	Specification	
Assay (HPLC, calc. on dried substance)	98.0 - 101.0	%
Identity (NIR)	passes test	
Identity (IR-spectrum)	passes test	
Identity (wet chemistry)	passes test	
Appearance of solution (13 %; water)	passes test	
Free acid	passes test	
pH-value (10 %; water)	4.5 - 7.5	
Melting point	166 - 169	°C
Spec. rotation (α 25/D; 1 %; molybdate complex, calc. on anhydrous substance)	137 - 145	°
Conductivity (25°C) (20 %; water)	≤ 20	μS/cm
Arsenic (As)	≤ 2	ppm
Ni (Nickel) (#)	≤ 1	ppm
Pb (Lead)	≤ 0.5	ppm
Chloride (Cl)	≤ 0.003	%
Sulfate (SO ₄)	≤ 0.01	%
Heavy metals (as Pb)	≤ 5	ppm
Oxalate (C ₂ O ₄)	≤ 0.02	%
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	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Related substances (HPLC) (Sum of all impurities)	≤ 2.0	%
Reducing sugars after hydrolysis/total sugar (as glucose)	≤ 1	%
Reducing sugars (as glucose)	≤ 0.05	%
Sulfated ash	≤ 0.1	%
Loss on Drying (105 °C)	≤ 0.30	%
Water	≤ 0.5	%
Particle size (< 53 μm)	≤ 15	%
Particle size (> 500 μm)	≤ 15	%
Parameter with periodic testing		
Microbiological test	passes test	

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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	

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, ChP, JP, USP, 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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