



Specification

1.15079.9028 Parteck® SI 200 (Sorbitol) EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF,
E 420

Specification

Assay (HPLC, calc.on anhydrous substance)	97.0 - 100.5	%
Identity	passes test	
pH-value (10 %; water)	3.5 - 7.0	
Appearance of solution (25 %; water)	passes test	
Spec. rotation ($\alpha_{20/D}$, 10 %, borate complex, calc. on anhydrous substance)	4.0 - 7.0	°
Conductivity (25°C) (20 %; water)	≤ 20	μS/cm
Chloride (Cl)	≤ 0.002	%
Sulfate (SO ₄)	≤ 0.005	%
Heavy metals (as Pb)	≤ 5	ppm
As (Arsenic)	≤ 1.0	ppm
Ni (Nickel) (#)	≤ 1	ppm
Pb (Lead)	≤ 0.5	ppm
Ru (Ruthenium) (#)	≤ 1	ppm
Related substances (HPLC, EP) (Major impurity (Mannitol))	≤ 2.0	%
Related substances (HPLC, EP) (Sum of all impurities)	≤ 3.0	%
Reducing sugars after hydrolysis/total sugar (as glucose)	≤ 0.8	%
Reducing sugars (as glucose)	≤ 0.11	%
Sulfated ash	≤ 0.02	%
Loss on drying	≤ 2.0	%
Water	≤ 1.5	%
Particle size (< 100 μm)	≤ 15	%
Particle size (> 200 μm)	35 - 70	%
Particle size (> 500 μm)	≤ 6	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	

Parameter with periodic testing

Microbiological test	passes test	
Colony count (aerobic bacteria (TAMC))	≤ 5*10 ²	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	

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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, JP, NF, E 420

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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