



Specification

1.03557.0000 Parteck® SI 450 (Sorbitol) EMPROVE® ESSENTIAL NF,FCC,JSFA

Specification		
Assay (HPLC, calc.on anhydrous substance)	91.0 - 100.5	%
Identity	passes test	
pH-value (10 %; water)	3.5 - 7.0	
Free acid	passes test	
Chloride (Cl)	≤ 0.002	%
Sulfate (SO ₄)	≤ 0.010	%
Heavy metals (as Pb)	≤ 5	ppm
As (Arsenic)	≤ 1	ppm
Ni (Nickel) (#)	≤ 1	ppm
Pb (Lead)	≤ 1	ppm
Ru (Ruthenium) (#)	≤ 1	ppm
Reducing sugars after hydrolysis/total sugar (as glucose)	≤ 0.8	%
Reducing sugars (as glucose)	≤ 0.2	%
Sulfated ash	≤ 0.02	%
Water	≤ 1.5	%
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	
Pseudomonas aeruginosa	in 1g substance not detectable	
Candida albicans	In 1g substance not detectable	
Loss on drying	≤ 3.0	%

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 NF, FCC, JSFA

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Jennifer Standare

Responsible laboratory manager quality control

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