



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

23 APR 2025

Certificate of Analysis

1.15079.2500 Pardeck® SI 200 (Sorbitol) IMPROVED ESSENTIAL Ph Eur, BP, JP, NF,
E 420

Batch MP22012679

	Spec. Values		Batch Values	
Assay (HPLC, calc. on anhydrous substance)	97.0 - 100.5	%	99.8	%
Identity	passes test		passes test	
pH-value (10 %; water)	3.5 - 7.0		5.6	
Appearance of solution (25 %; water)	passes test		passes test	
Spec. rotation ($\alpha_{20/D}$, 10 %, borate complex, calc. on anhydrous substance)	4.0 - 7.0	°	4.6	°
Conductivity (25°C) (20 %; water)	≤ 20	μS/cm	0.9	μS/cm
Chloride (Cl)	≤ 0.002	%	≤ 0.002	%
Sulfate (SO ₄)	≤ 0.005	%	≤ 0.005	%
Heavy metals (as Pb)	≤ 5	ppm	≤ 5	ppm
As (Arsenic)	≤ 1.0	ppm	≤ 1.0	ppm
Ni (Nickel) (#)	≤ 1	ppm	≤ 1	ppm
Pb (Lead)	≤ 0.5	ppm	≤ 0.5	ppm
Ru (Ruthenium) (#)	≤ 1	ppm	≤ 1	ppm
Related substances (HPLC, Ph. Eur.) (major impurity)	≤ 2.0	%	0.6	%
Related substances (HPLC, EP) (Sum of all impurities)	≤ 3.0	%	1.3	%
Reducing sugars after hydrolysis/total sugar (as glucose)	≤ 0.8	%	< 0.40	%
Reducing sugars (as glucose)	≤ 0.11	%	0.03	%
Sulfated ash	≤ 0.02	%	< 0.01	%
Loss on drying	≤ 2.0	%	0.2	%
Water	≤ 1.5	%	0.2	%
Particle size (< 100 μm)	≤ 15	%	≤ 15	%
Particle size (> 200 μm)	35 - 70	%	35 - 70	%
Particle size (> 500 μm)	≤ 6	%	≤ 6	%
Residual solvents (ICH Q3C)	excluded by manufacturing process		passes test	

Parameter with periodic testing

Microbiological test	passes test		passes test	
Colony count (aerobic bacteria (TAMC))	≤ 5*10 ²	CFU/g	≤ 5*10 ²	CFU/g
Colony count (Yeasts and moulds (TYMC))	≤ 10 ²	CFU/g	≤ 10 ²	CFU/g
Salmonella spp.	in 10g Substance not detectable		in 10g Substance not detectable	
E.coli	in 1g substance not detectable		in 1g substance not detectable	
Staphylococcus aureus	in 1g substance not detectable		in 1g substance not detectable	

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Pseudomonas aeruginosa	in 1g substance not detectable	in 1g substance not detectable
Candida albicans	In 1g substance not detectable	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.

Date of manufacture (DD.MM.YYYY) 08.03.2022

Date of examination (DD.MM.YYYY) 29.03.2022

Minimum shelf life (DD.MM.YYYY) 31.03.2027

Jennifer Standare

Responsible laboratory manager quality control

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