

Specification

Assay (HPLC, calc. on anhydrous substance)	97,0-100,5	%
Identity	passes test	
pH-value (10%, water)	3,5-7,0	
Spec. rotation ($\alpha_{20/D}$, 10%, borate complex, cal. on anhydrous substance)	+4,0 - +7,0	°
Conductivity (25°C, 20%, water)	≤20	μS/cm
Chloride (Cl)	≤0,002	%
Sulfate (SO ₄)	≤0,006	%
Heavy metals (as Pb)	≤5	ppm
As (Arsenic)	≤1,0	ppm
Ni (Nickel) (#)	≤1	ppm
Related substances (HPLC, Ph., Eur.) (major impurity)	≤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	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Microbiological test	passes test	
Colony count (aerobic bacteria (TAMC))	≤10 ²	CFU/g
Colony count (Yeast and moulds (TYMC))	≤10 ²	CFU/g
<i>Salmonella</i> spp.	In 10 g substance not detectable	
<i>E. coli</i>	In 1 g substance not detectable	
<i>Pseudomonas aeruginosa</i>	In 1 g substance not detectable	
<i>Staphylococcus aureus</i>	In 1 g substance not detectable	
<i>Candida albicans</i>	In 1 g substance not detectable	
Endotoxins	≤1	I.U./g

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, NF, JP

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