



Specification

1.07654.0000 Sucrose (saccharose) for density gradient ultracentrifugation EMPROVE®
EXPERT Ph.Eur.,BP,NF,JP

Specification		
Description	white crystalline powder	
Identity (IR-spectrum)	passes test	
Appearance of solution (50 %; water)	passes test	
Color number	≤ 45	
Spec. rotation (.a. 20/D;26% water)	+66.3 - +67.0	°
Conductivity (20 °C)	≤ 35	μS/cm
Sulfite (as SO ₂)	≤ 10	ppm
Dextrins	passes test	
Reducing sugars	passes test	
Residual solvents (ICH Q3C) class 3 (Ethanol)	≤ 0.5	%
Other residual solvents (ICH Q3C)	excluded by manufacturing process	
Loss on Drying (105 °C)	≤ 0.1	%
Endotoxins	< 0.25	I.U./mg
Absorbance (260 nm; 50 %; 1 cm; water)	≤ 0.07	
Absorbance (280 nm; 50 %; 1 cm; water)	≤ 0.05	
Colony count (aerobic bacteria (TAMC))	≤ 10 ²	CFU/g
Colony count (Yeasts and moulds (TYMC))	≤ 10 ¹	CFU/g
Salmonella spp.	absent in 10 g	
E.coli	absent in 1 g	
Staphylococcus aureus	absent in 1 g	
Pseudomonas aeruginosa	absent in 1 g	
Candida albicans	absent in 1 g	
Bile tolerante gram negative bacteria	absent in 1 g	
DNases (Exo- and endonucleases)	not detected	
Proteases	not detected	
RNases	not detected	

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 (*).
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Responsible laboratory manager quality control

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