

Product Specification

Product group: Lactose
Brand name: Lactopress® Granulated
Product description: Lactose monohydrate
Article code: 743735
Document No.: PD-0454 Page 1 of 2

Manufacturing site: DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany
Product name: Lactopress® Granulated
Conforms to USP - NF, Ph.Eur., JP Lactose monohydrate monograph,
current at time of manufacture
Product description: A white or almost white, crystalline powder freely soluble in
water, practically insoluble in ethanol
Residual solvents
(CPMP/ICH/283/95): No class 1,2,3 solvents are used during production
Identification: Complies with Pharmacopoeia when tested

Physical-Chemical data:

Appearance of solution (Ph.Eur.)
Clarity and Colour of Solution
Residue on ignition/Sulphated ash
Water (KF) USP/NF, Ph.Eur.
Water (KF) JP
Loss on drying
Acidity or Alkalinity (ml 0.1 N NaOH/6 g)
Specific Optical Rotation (on anhydrous basis)
Absorbance between 210-220 nm (1%, 1 cm)
Absorbance between 270-300 nm (1%, 1 cm)
Absorbance at 400 nm (10%, 1 cm)
Heavy metals

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Clear and not more coloured than ref. BY 7
Clear and colourless or nearly colourless
max. 0.10 %
4.5 - 5.5 %
4.0 - 5.5 %
max. 0.5 %
max. 0.4
+54.4° to +55.9°
max. 0.25
max. 0.07
max. 0.04
max. 5 ppm

Microbiological data:

Total aerobic microbial count
Yeasts and moulds
E. coli
Salmonella

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max. 100 cfu/g
max. 10 cfu/g
neg. in 10 g
neg. in 500 g

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Particle size (Rotap sieve)

< 63 µm	max 20 %
<180 µm	40 – 75 %
<400 µm	min. 85 %
<630 µm	min. 97 %

Storage: Keep in original, unopened packing and away from strongly odorous materials. Store at room temperature (normal warehouse conditions), allowing temporary excursions.

This document substitutes all previous versions issued for the brand names mentioned above. We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature : 

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