

Product Specification

Product group: Lactose

Brand name: Lactopress® Granulated

Product description:Lactose monohydrate

Article code: 743735

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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 o.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

Microbiological data:

Total aerobic microbial count

Yeasts and moulds

E. coli Salmonella

Specification

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. o.4

+54.4° to +55.9°

max. 0.25

max. 0.07

max. 0.04

max. 5 ppm

Specification

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 :

This document is controlled by a validated, electronic system and is valid without signature. The above facsimile signature is only for display.