

Product group: Lactose
 Brand name: Lactopress® Anhydrous Powder
 Product description: Anhydrous lactose
 Article No: 661112
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Manufacturing site : DFE Pharma GmbH & Co.KG, Borculo, The Netherlands
 Product name: Lactopress® Anhydrous Powder
 Conforms to Ph.Eur Lactose monograph / USP - NF, JP, ChP Anhydrous Lactose 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

Physical-Chemical data:

Identification
 Appearance of solution (Ph.Eur.)
 Residue on ignition
 Water
 Loss on drying
 Acidity
 Isomer ratio (Alpha lactose)
 (Beta-lactose)
 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
 Arsenic
 Assay by HPLC
 Identify material by HPLC
 Related substances by HPLC

Specification

conform USP - NF, Ph.Eur, JP
 Clear and not more coloured than ref. BY 7
 max. 0.1 %
 max. 1.0 %
 max. 0.5 %
 max. 0.4 ml 0.1 N NaOH
 (max. 50%)
 (min. 50%)
 +54.4° to +55.9°
 max. 0.25
 max. 0.07
 max. 0.04
 max. 5 ppm
 max. 2 ppm
 98 – 102 %
 pass
 max. 0.5 %

Microbiological data:

TAMC
 Bile tolerant gram negative bacteria
 Escherichia coli
 Salmonellae
 TYMC

Specification

max. 100 / g
 absent in 10 g
 absent in 10 g
 absent in 5x25 g
 max. 10 / g

Particle size (Airjet sieve analysis, Alpine)

< 75 µm
 < 150 µm
 < 250 µm

Specification

65 – 80 %
 85 – 95 %
 min. 95 %

Product Specification

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Packaging: A carton box with polyethylene inner liner

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

Retest date: Product has a retest date of 24 months.

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 : Sander van Gessel
Job Title : Director ITS
Signature :



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