

Product group: Lactose
Brand name: Lactopress® Anhydrous
Product description: Anhydrous lactose
Article No: 661111
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Manufacturing site: DFE Pharma GmbH & Co.KG, Borculo, The Netherlands
Product name: Lactopress® Anhydrous
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 in solution
Residue on ignition
Total 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 nearly colourless
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

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Particle size (Airjet sieve analysis, Alpine)

< 250 micron

< 53 micron

Specification

min. 80 %

max. 30 %

Packaging: a carton box with polyethylene inner liner

Storage: Keep in original, unopened packing and away from strongly odorous materials
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

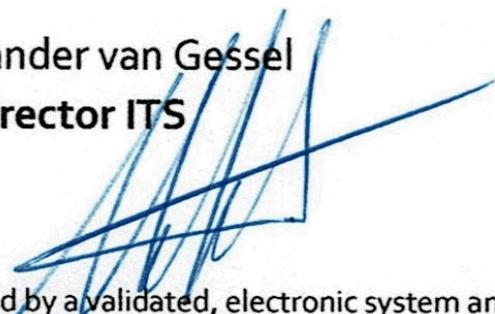
Retest date: Products has a retest date of 24 months.

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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