

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 | conform USP - NF, Ph.Eur, JP |
| Appearance of solution (Ph.Eur.) | Clear and not more coloured than ref. BY 7 |
| Residue on ignition | max. 0.1 % |
| Total Water | max. 1.0 % |
| Loss on drying | max. 0.5 % |
| Acidity | max. 0.4 ml 0.1 N NaOH |
| Isomer ratio (Alpha lactose) (Beta-lactose) | (max. 50%) (min. 50%) |
| Specific Optical Rotation (on anhydrous basis) | +54.4° to +55.9° |
| Absorbance between 210-220 nm (1%, 1 cm) | max. 0.25 |
| Absorbance between 270-300 nm (1%, 1 cm) | max. 0.07 |
| Absorbance at 400 nm (10%, 1 cm) | max. 0.04 |
| Heavy metals | max. 5 ppm |
| Arsenic | max. 2 ppm |
| Assay by HPLC | 98 – 102 % |
| Identify material by HPLC | pass |
| Related substances by HPLC | max. 0.5 % |

Specification

Microbiological data:

| | |
|--------------------------------------|------------------|
| TAMC | max. 100 / g |
| Bile tolerant gram negative bacteria | absent in 10 g |
| Escherichia coli | absent in 10 g |
| Salmonellae | absent in 5x25 g |
| TYMC | 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.
Store at room temperature (normal warehouse conditions), allowing temporary excursions.

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

Signature :



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