



Product group: Lactose  
Brand name: Lactopress® Anhydrous  
Fine Powder  
Product description: Anhydrous lactose  
Article No: 661113  
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Manufacturing site: DFE Pharma GmbH & Co.KG, Borculo, The Netherlands  
Product name: Lactopress® Anhydrous Fine Powder  
Conforms to Ph.Eur Lactose monograph / USP - NF, JP 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

**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

**Specification**



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**Particle size** (Airjet sieve analysis, Alpine)

< 150 micron	greater than 99 %
< 100 micron	greater than 95 %

**Packaging:** A carton box with polyethylene inner line

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

**Signature** :

A handwritten signature in blue ink that reads 'B. Dickhoff'.

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