

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 %

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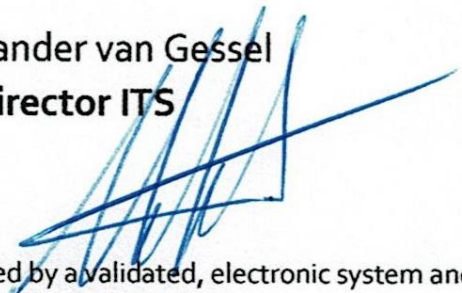
**Packaging:** A carton box with polyethylene inner liner

**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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