

Product group: Lactose  
Brand name: Lactopress® Anhydrous  
Product description: Anhydrous lactose  
Article No: 661111  
Document No.: PD-0351 Page 1 of 2

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

# Product Specification

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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%

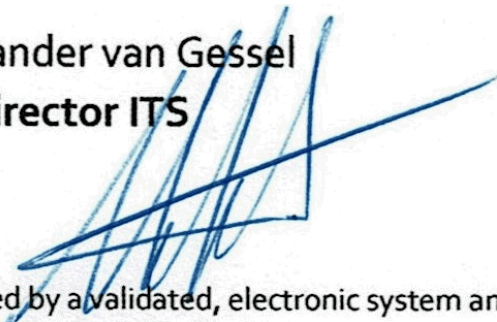
**Retest date:** Products has a retest date of 24 months.

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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