Product Specification

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

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:	**Specification**
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)	(max. 50%)
(Beta-lactose)	(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 %

Microbiological data:	**Specification**
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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Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799
Release date: 06-08-2026

Product Specification

Particle size (Airjet sieve analysis, Alpine)	**Specification**
< 250 micron	min. 80 %
< 53 micron	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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