

Product Specification

Product group: Lactose

Brand name: Lactopress® Anhydrous

Fine Powder

Product description: Anhydrous lactose

Article No: 661113

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DFE Pharma GmbH & Co.KG, Borculo, The Netherlands Manufacturing site:

Product name: Lactopress® Anhydrous Fine Powder

Conforms to Ph.Eur Lactose monograph / USP - NF, JP Anhydrous Lactose

Specification

monograph, current at time of manufacture

A white or almost white, crystalline powder freely soluble in Product description:

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. o.4 ml o.1 N NaOH

(Alpha lactose) (max. 50%) Isomer ratio

(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

Microbiological data:

max. 100 / g TAMC Bile tolerant gram negative bacteria

absent in 10 g Escherichia coli absent in 10 g Salmonellae absent in 5x25 q

TYMC max. 10 / g



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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

B. Dickhaff

Signature

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