Product Specification

Product group:	Lactose
Brand name:	Lactopress® Anhydrous Fine Powder
Product description:	Anhydrous lactose
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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:		**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

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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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 : B. Dickhoff

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