Product Specification

Product group: Lactose

Brand name: Lactopress® Anhydrous Powder

Product description: Anhydrous lactose

Article No: 661112

Document No.: PD-0357

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:	**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 %
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

Particle size (Airjet sieve analysis, Alpine)	**Specification**
< 75 µm	65 – 80 %
< 150 µm	85 – 95 %
< 250 µm	min. 95 %

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Release date: 30-05-2022

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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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