Product Specification

Product group: Lactose
Brand name: Lactochem® Fine Powder
Product description: Lactose monohydrate

Description: α-lactose monohydrate pharmaceutical grade conform **USP - NF, Ph.Eur, JP, ChP**

Physical-Chemical data:	**Specification**
Identification	conform USP - NF, Ph.Eur, JP, ChP
Appearance in solution	Clear and not more coloured than ref. BY 7
Residue on ignition	max. 0.1 %
Total Water	4.5 – 5.5 %
Loss on drying	max. 0.5 %
Acidity	max. 0.4 ml 0.1 N NaOH
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 1 g
Escherichia coli	absent in 10 g
Salmonellae	absent in 5x25 g
TYMC	max. 10 / g

Particle size distribution: (Airjet sieve analysis, Alpine)

< 53 micron	55 – 80 %
< 75 micron	min. 80 %
< 150 micron	min. 98 %

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Document No.: PD-0386

Packaging: A multiply paper bag with polyethylene inner liner, 25 kg net; or Big Bag 500kg/ 1,000kg net; or HDPE drum with polyethylene inner liner, 20kg net.

Storage: Keep in original, unopened packing and away from strongly odorous materials. Store at room temperature (normal warehouse conditions), allowing temporary excursions.

Retest date: For storage periods exceeding 36 months we recommend re-testing

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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