Product Specification

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

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

Physical-Chemical data:	**Specification**
Identification	conform USP - NF, Ph.Eur, JP
Appearance in solution	clear and nearly colourless
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

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 (Airjet sieve analysis, Alpine)

< 75 micron	max. 30 %
< 250 micron	min. 90 %

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Packaging: A multiply paper bag with polyethylene inner liner, 25 kg net; alternative packaging available on request

Storage: Keep in original, unopened packing and away from strongly odorous materials. Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

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 : Rutger Drost
Job title : Global Marketing, Innovation & Technology Director
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
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