Product Specification

Product group: Lactose
Brand name: Lactochem® Extra Fine Powder
Product description: Lactose monohydrate
Article No: 504181
Document No.: PD-0376

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	98.0 – 102.0 %
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 (Airjet sieve analysis, Alpine)	**Specification**
< 53 micron	min. 90 %
< 125 micron	min. 99 %

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799
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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. Store at room temperature (normal warehouse conditions), allowing temporary excursions.

Retest date: For storage periods exceeding 12 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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DFE Pharma GmbH & Co. KG
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