

Product Specification

Product group: Lactose

Brand name: Lactochem® Extra Fine Powder

Product description:Lactose monohydrate

Article No: 504181

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Description:

Physical-Chemical data:

Identification Appearance in solution Residue on ignition

Total Water Loss on drying

Acidity

Specific Optical Rotation (on anhydrous basis) Absorbance between 210-220 nm (1%, 1 cm) Absorbance between 270-300 nm (1%, 1 cm)

Absorbance at 400 nm (10%, 1 cm)

Heavy metals Arsenic Assay by HPLC

Identify material by HPLC Related substances by HPLC

Microbiological data:

TAMC

Bile tolerant gram negative bacteria

Escherichia coli Salmonellae TYMC

<u>Particle size</u> (Airjet sieve analysis, Alpine)

< 53 micron < 125 micron

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

Specification

conform USP - NF, Ph.Eur, JP, ChP

Clear and not more coloured than ref. BY 7

max. 0.1 % 4.5 – 5.5 % max. 0.5 %

max. o.4 ml o.1 N NaOH

+54.4° to +55.9° max. 0.25 max. 0.07

max. 0.04 max. 5 ppm max. 2 ppm 98.0 – 102.0 %

pass

max. 0.5 %

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max. 100 / g absent in 1 g absent in 10 g absent in 5x25 g max. 10 / g

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min. 90 % min. 99 %



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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

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Signature

This document is controlled by a validated, electronic system and is valid without signature. The above facsimile signature is only for display.