

Product Specification

Product group: Lactose

Brand name: Lactochem® Crystals

Product description:Lactose monohydrate

Article No: 0501982

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Description:

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

Physical-Chemical data:

Identification

Appearance of solution (Ph.Eur.)

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

Microbiological data:

TAMC

Bile tolerant gram negative bacteria

Escherichia coli Salmonellae

TYMC

Specification

conform USP - NF, Ph.Eur, JP

Clear and not more coloured than ref. BY 7

max. o.1 %

4.5 - 5.5 %

max. o.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

Specification

max. 100 / g

absent in 1 g

absent in 10 g

absent in 5x25 g

max. 10 / g

Particle size distribution: (Airjet sieve analysis, Alpine)

< 75 micron 5 – 30 % < 150 micron 55 – 95 % < 250 micron min. 90 %



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Packaging: A multiply paper bag with polyethylene inner liner, 25 kg 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

S. Dickliff

Signature

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