

## **Product Specification**

Product group: Lactose

Brand name: Lactochem® Coarse Powder

Product description:Lactose monohydrate

Article No: 0502040

**Specification** 

max. 10 / g

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**Description:** 

 $\alpha$ -lactose monohydrate pharmaceutical grade

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

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**Physical-Chemical data:** 

Identification

Appearance of solution (Ph.Eur.) 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 npm

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

Particle size distribution: (Airjet sieve analysis, Alpine)

< 75 micron 15 – 50 % < 150 micron min. 75 % < 250 micron min. 98 %

**TYMC** 



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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

Signature

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