

Product Specification

Product group: Lactose

Brand name: Lactochem® Powder

Product description:Lactose monohydrate

Article No: 504143

Document No.: PD-0385 Page 1 of 2

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

Specification

conform USP - NF, Ph.Eur, JP

Clear and not more coloured than ref. BY 7

max. o.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

Microbiological data:

TAMC

Bile tolerant gram negative bacteria

Escherichia coli Salmonellae TYMC **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 65 – 80 % < 106 micron min. 85 % < 150 micron min. 95 %



Product Specification

Product group: Lactose

Brand name: Lactochem® Powder

Product description:Lactose monohydrate

Article No: 504143

Document No.: PD-0385 Page 2 of 2

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

B. Diskliff

Signature

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