



Product Specification

Product group: Lactose
Brand name: Lactochem® Fine Crystals
Product description: Lactose monohydrate
Article No: 743603
Document No.: PD-0379 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. 0.1 %
4.5 – 5.5 %
max. 0.5 %
max. 0.4 ml 0.1 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 (Airjet sieve analysis, Alpine)

< 75 micron
< 250 micron

max. 30 %
min. 90 %



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Packaging: A multiply paper box with polyethylene inner line, 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 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 :

A handwritten signature in blue ink, appearing to read 'B. Dickhoff'.

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