

Product group: Lactose
Brand name: Lactochem® Fine Crystals
Product description: Lactose monohydrate
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 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

Specification

conform USP - NF, Ph.Eur, JP
clear and nearly colourless
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 %

Product Specification

Product group: Lactose
Brand name: Lactochem® Fine Crystals
Product description: Lactose monohydrate
Document No.: PD-0379 Page 2 of 2

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.
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

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 : Rutger Drost
Job title : Global Marketing, Innovation & Technology Director
Signature : 

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