

Product group: Lactose
Brand name: Lactochem® Extra Fine Powder
Product description: Lactose monohydrate
Article No: 504181
Document No.: PD-0376 Page 1 of 2

Description:

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

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
Arsenic
Assay by HPLC
Identify material by HPLC
Related substances by HPLC

Specification

conform USP - NF, Ph.Eur, JP, ChP
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
max. 2 ppm
98.0 – 102.0 %
pass
max. 0.5 %

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)

< 53 micron
< 125 micron

Specification

min. 90 %
min. 99 %

Product group: Lactose
Brand name: Lactochem® Extra Fine Powder
Product description: Lactose monohydrate
Article No: 504181
Document No.: PD-0376 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.
Store at room temperature (normal warehouse conditions), allowing temporary
excursions.

Retest date: For storage periods exceeding 12 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 : 

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