

LACTOCHEM® Crystals

Description : α -lactose monohydrate pharmaceutical grade conform **USP/NF, EP, 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, EP, 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

Total viable count
Enterobacteriaceae
Escherichia coli
Salmonellae
Yeasts
Moulds

Specification

max. 100 / g
absent in 1 g
absent in 10 g
absent in 5x25 g
max. 5 / g
max. 5 / g

Particle size distribution (Airjet sieve analysis, Alpine)

< 250 micron	min. 90 %
< 150 micron	55 – 95 %
< 75 micron	5 - 30 %

Packaging : a multiply paper bag with polyethylene inner liner, 25 kg net

Storage : keep in cool, clean and dry conditions and away from strongly odorous materials

Retest date : for storage periods exceeding 36 months we recommend re-testing

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Friesland Foods Domo

Hanzeplein 25, 8017 JD Zwolle, P.O. Box 449 8000 AK Zwolle, The Netherlands,
Telephone: +31 38 46 77 444, Fax: +31 38 46 77 555, www.domo.nl, e-mail: info.domo@frieslandfoods.com