



## 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:

$\alpha$ -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.