

Product Specification

Product group: Lactose
Brand name: Lactochem® Coarse Powder
Product description: Lactose monohydrate
Article No: 0502040
Document No.: PD-0387 Page 1 of 2

Description:

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

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
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 – 102 %
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 distribution: (Airjet sieve analysis, Alpine)

< 75 micron	15 – 50 %
< 150 micron	min. 75 %
< 250 micron	min. 98 %

Product Specification

Product group: Lactose
Brand name: Lactochem® Coarse Powder
Product description: Lactose monohydrate
Article No: 0502040
Document No.: PD-0387 Page 2 of 2

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

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