

Product Specification

Product group: Lactose

Brand name: Lactopress® Spray Dried

Product description:Lactose monohydrate

Article No: 743593

Document No.: PD-0366 Page 1 of 2

Description:

spray dried lactose 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

Microbiological data:

TAMC

Escherichia coli Salmonellae

TYMC

Particle size (Airjet sieve analysis, Alpine)

< 45 micron

< 106 micron

< 250 micron

Specification

conform USP-NF, Ph.Eur, JP

clear and not more coloured than ref. BY 7

max. o.1 %

4.5 - 5.5 %

max. 1.0 %

max. o.4 ml o.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. o.5 %

Specification

max. 100 / g

absent in 10 g

absent in 5x25 g

max. 10 / g

Specification

max. 25 %

30-60 %

min. 65 %



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Packaging: A multiply paper box with polyethylene inner line, 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 3 years 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

B. Dickhaff

Signature

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