

## **Product Specification**

Product group: Lactose

Brand name: SuperTab® 4oLL

Product description: Anhydrous lactose with

Lactitol monohydrate

Article code: 733728

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Manufacturing site : DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany

Product name : SuperTab® 4oLL

Agglomerate composed of Lactose Ph.Eur. / Anhydrous lactose USP – NF, JP, ChP with Lactitol monohydrate Ph.Eur., current at time of

manufacture

Product : A white or almost white, crystalline powder freely soluble in water,

description practically insoluble in ethanol

Residual solvents

(CPMP/ICH/283/95) : No class 1,2,3 solvents are used during production

## Physical-Chemical data: Specification

Appearance of solution

Clear and not more coloured than ref. BY 7

Clarity and Colour of Solution

Clear and colourless or nearly colourless

Residue on ignition/sulphated ash

Clear and colourless or nearly colourless

max.o.1 w/w %

Water (KF) max. 2.0 w/w %

Loss on drying max. 0.5 w/w%

Acidity or alkalinity max. 0.4 ml

Specific optical rotation +51.9 to +54.3°

Absorbance between 210-220 nm (1%, 1 cm) max. 0.25

Absorbance between 270-300 nm (1%, 1 cm) max. 0.07
Absorbance at 400 nm (10%, 1 cm) max. 0.04
Arsenic max. 2 ppm
Assay by HPLC 98 – 102 %
Identification by IR Conforms

Identification by HLPC (assay)ConformsRelated substances by HLPCmax. 0.5 %Lactitol content4.0 – 6.0 w/w %Lactose contentmin. 94.0 w/w%

## Microbiological data: Specification

Total aerobic microbial count max. 100 cfu/g
Yeasts and moulds max. 100 cfu/g
E. coli neg. in 10 g
Salmonella neg. in 500 g

Pseudomonas aeruginosa neg. In 10 g



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<u>Particle size distribution</u> Typical range

(Sympatec laser diffraction, dry dispersion)

 $\begin{array}{ccc} x_{10} & & & 40-120\,\mu\text{m} \\ x_{50} & & 120-280\,\mu\text{m} \\ x_{90} & & 280-530\,\mu\text{m} \end{array}$ 

**Functional related characteristics** 

Bulk density Value reported g/ml Tapped density Value reported g/ml

Packaging: A drum with polyethylene inner liner

**Storage:** Keep in original, unopened packing and away from strongly odorous materials.

Store at room temperature (normal warehouse conditions), allowing temporary

excursions.

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

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Signature

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