



# 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 description : A white or almost white, crystalline powder freely soluble in water, practically insoluble in ethanol  
 Residual solvents (CPMP/ICH/283/95) : No class 1,2,3 solvents are used during production

## **Physical-Chemical data:**

Appearance of solution  
 Clarity and Colour of Solution  
 Residue on ignition/sulphated ash  
 Water (KF)  
 Loss on drying  
 Acidity or alkalinity  
 Specific optical rotation  
 Absorbance between 210-220 nm (1%, 1 cm)  
 Absorbance between 270-300 nm (1%, 1 cm)  
 Absorbance at 400 nm (10%, 1 cm)  
 Arsenic  
 Assay by HPLC  
 Identification by IR  
 Identification by HPLC (assay)  
 Related substances by HPLC  
 Lactitol content  
 Lactose content

## **Specification**

Clear and not more coloured than ref. BY 7  
 Clear and colourless or nearly colourless  
 max. 0.1 w/w %  
 max. 2.0 w/w %  
 max. 0.5 w/w %  
 max. 0.4 ml  
 +51.9 to +54.3°  
 max. 0.25  
 max. 0.07  
 max. 0.04  
 max. 2 ppm  
 98 – 102 %  
 Conforms  
 Conforms  
 max. 0.5 %  
 4.0 – 6.0 w/w %  
 min. 94.0 w/w %

## **Microbiological data:**

Total aerobic microbial count  
 Yeasts and moulds max.  
 E. coli  
 Salmonella  
 Pseudomonas aeruginosa

## **Specification**

max. 100 cfu/g  
 10 cfu/g  
 neg. in 10 g  
 neg. in 500 g  
 neg. In 10 g



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### Particle size distribution

(Sympatec laser diffraction, dry dispersion)

X<sub>10</sub>

X<sub>50</sub>

X<sub>90</sub>

Typical range

40 – 120 µm

120 – 280 µm

280 – 530 µm

### Functional related characteristics

Bulk density

Tapped density

Value reported g/ml

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

**Signature** :

A handwritten signature in blue ink that reads 'B. Dickhoff'.

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