

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	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	max. 0.1 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 HPLC (assay)	Conforms
Related substances by HPLC	max. 0.5 %
Lactitol content	4.0 – 6.0 w/w %
Lactose content	min. 94.0 w/w%

#### Specification

Microbiological data:  
Total aerobic microbial count  
Yeast 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

# Product Specification

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## Particle size distribution

(Sympatec laser diffraction, dry dispersion)

$X_{10}$

Typical range

40 – 120  $\mu\text{m}$

$X_{50}$

120 – 280  $\mu\text{m}$

$X_{90}$

280 – 530  $\mu\text{m}$

## 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

**Signature** :



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