



## Product Specification

Product group: Lactose  
Brand name: SuperTab® 4oLL  
Product description: Anhydrous lactose with  
Lactitol monohydrate  
Article code: 733728  
Document No.: PD-0675 Page 1 of 2

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



## Product Specification

Product group: Lactose  
Brand name: SuperTab® 40LL  
Product description: Anhydrous lactose with  
Lactitol monohydrate  
Article code: 733728  
Document No.: PD-0675 Page 2 of 2

### 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.