



## Product Specification

Product group: Lactose  
Brand name: SuperTab® 11SD (EU)  
Product code: 743720  
Product description: Lactose monohydrate  
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Manufacturing site: DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany  
Product name: SuperTab® 11SD  
Conforms to USP - NF, Ph.Eur., JP, Ch.P. Lactose monohydrate monograph, 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:**

Identification:  
Appearance of solution (Ph.Eur.)  
Clarity and Colour of Solution  
Residue on ignition/Sulphated ash  
Water (KF)  
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  
Nitrite content (ppm)

### **Specification**

Complies with Pharmacopoeia when tested  
Clear and not more coloured than ref. BY 7  
Clear and colourless or nearly colourless  
max. 0.10 %  
4.5 - 5.5 %  
max. 1.0 %  
max. 0.4 ml 0.1 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. 0.5 %  
reported value

### **Microbiological data:**

Total aerobic microbial count  
Yeasts and moulds  
E. coli  
Salmonella

### **Specification**

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



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**Particle size** (Airjet sieve analysis, Alpine)

% < 45 µm

% <100 µm

% <250 µm

**Specification**

max. 15

30 – 60

min. 98

**Particle size distribution** (Laser diffraction, dry)

D10

D50

D90

**Specification**

reported value

reported value

reported value

**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.