

# Product Specification

Product group: Lactose  
Brand name: SuperTab® 14 SD  
Product description: Lactose monohydrate  
Article code: 743721  
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Manufacturing site: DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany  
Product name: SuperTab® 14 SD  
Conforms to USP - NF, Ph.Eur., JP, ChP 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  
Identification: Complies with Pharmacopoeia when tested

## Physical-Chemical data:

Appearance of solution (Ph.Eur.)	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. 0.10 %
Water (KF)	4.5 - 5.5 %
Loss on drying	max. 1.0 %
Acidity or Alkalinity (ml 0.1 N NaOH/6 g)	max. 0.4
Specific Optical Rotation (on anhydrous basis)	+54.4° to +55.9°
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
Heavy metals	max. 5 ppm
Arsenic	max. 2 ppm
Assay by HPLC	98 - 102 %
Identify material by HPLC	pass
Related substances by HPLC	max. 0.5 %

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## Microbiological data:

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

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**Particle size distribution** (Air jet sieve)

< 45 µm  
<100 µm  
<250 µm

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max. 15 %  
30 – 60 %  
min. 98 %

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

D<sub>10</sub>  
D<sub>50</sub>  
D<sub>90</sub>

Value reported micron  
Value reported micron  
Value reported micron

**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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