



# Product Specification

Product group: Lactose  
 Brand name: SuperTab® 21AN  
 Product code: 743713/659165/1238775/  
 1154965/1154964  
 Product description: Anhydrous lactose  
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Manufacturing site: DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany  
 Product name: SuperTab® 21AN  
 Conforms to Ph.Eur. Lactose monograph / USP - NF, JP, ChP Anhydrous Lactose 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  
 Content of Alpha and Beta Lactose  
 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)<sup>1</sup>

## Specification

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

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

<sup>1</sup>: Currently for product code 659165 only



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

% < 45 µm

% < 150 µm

% < 250 µm

**Specification**

max. 20

40 – 65

min. 80

**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 blue ink facsimile signature of B. Dickhoff, written in a cursive style.

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