



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.