

Product Specification

Product group: Lactose

Brand name: SuperTab® 14 SD

Product description:Lactose monohydrate

Article code: 743721

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DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany Manufacturing site:

Product name: SuperTab® 14SD

Conforms to USP - NF, Ph.Eur., JP, ChP Lactose monohydrate monograph,

current at time of manufacture

A white or almost white, crystalline powder freely soluble in Product description:

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:

Specification

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 o.1 N NaOH/6 g) max. o.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 max. 5 ppm

Heavy metals Arsenic max. 2 ppm Assay by HPLC 98-102% Identify material by HPLC pass

Related substances by HPLC max. 0.5 %

Microbiological data:

Specification 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)Specification< 45 μm</td>max. 15 %<100 μm</td>30 - 60 %<250 μm</td>min. 98 %

Particle size (Laser diffraction, dry)

D 10 Value reported micron
D 50 Value reported micron
D 90 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

B. Dickhaff

Signature :

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