

Product Specification

Product group: Lactose

Brand name: SuperTab® 24AN

Product description: Anhydrous lactose, granulated

Article code: 743723

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

Product name: SuperTab® 24AN

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

monograph, current at time of manufacture

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

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.) Clarity and Colour of Solution

Residue on ignition/Sulphated ash

Water (KF) Loss on drying

Acidity or Alkalinity (ml o.1 N NaOH/6 g)

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

Microbiological data:

Total aerobic microbial count

Yeasts and moulds

E. coli

Salmonella

Specification

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. o.4

+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 %

Specification

max. 100 cfu/g max. 10 cfu/g neg. in 10 g neg. in 500 g



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 $\begin{array}{lll} \textbf{Particle size distribution} \ (\text{Rotap sieve}) & \textbf{Specification} \\ \% < 75 \ \mu\text{m} & \text{max. 30} \\ \% < 150 \ \mu\text{m} & 55 - 80 \\ \% < 250 \ \mu\text{m} & \text{min. 85} \\ \% < 400 \ \mu\text{m} & \text{min. 97} \\ \end{array}$

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 name 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. Diskhaf

Signature

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