



Product Specification

Product group: Lactose
 Brand name: SuperTab® 4oLL
 Product description: Anhydrous lactose with Lactitol monohydrate
 Article code: 733728
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Manufacturing site : DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany
 Product name : SuperTab® 4oLL
 Agglomerate composed of Lactose Ph.Eur. / Anhydrous lactose USP – NF, JP, ChP with Lactitol monohydrate Ph.Eur., 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:

Appearance of solution
 Clarity and Colour of Solution
 Residue on ignition/sulphated ash
 Water (KF)
 Loss on drying
 Acidity or alkalinity
 Specific optical rotation
 Absorbance between 210-220 nm (1%, 1 cm)
 Absorbance between 270-300 nm (1%, 1 cm)
 Absorbance at 400 nm (10%, 1 cm)
 Arsenic
 Assay by HPLC
 Identification by IR
 Identification by HPLC (assay)
 Related substances by HPLC
 Lactitol content
 Lactose content

Specification

Clear and not more coloured than ref. BY 7
 Clear and colourless or nearly colourless
 max. 0.1 w/w %
 max. 2.0 w/w %
 max. 0.5 w/w %
 max. 0.4 ml
 +51.9 to +54.3°
 max. 0.25
 max. 0.07
 max. 0.04
 max. 2 ppm
 98 – 102 %
 Conforms
 Conforms
 max. 0.5 %
 4.0 – 6.0 w/w %
 min. 94.0 w/w %

Microbiological data:

Total aerobic microbial count
 Yeasts and moulds max.
 E. coli
 Salmonella
 Pseudomonas aeruginosa

Specification

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



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Particle size distribution

(Sympatec laser diffraction, dry dispersion)

X₁₀

X₅₀

X₉₀

Typical range

40 – 120 µm

120 – 280 µm

280 – 530 µm

Functional related characteristics

Bulk density

Tapped density

Value reported g/ml

Value reported g/ml

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.