



Product Specification

Product group: Lactose
Brand name: SuperTab® 22AN
Product description: Anhydrous lactose
Article code: 743714
Document No.: PD-0071 Page 1 of 2

Manufacturing site: DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany
Product name: SuperTab® 22AN
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
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 0.1 N NaOH/6 g)
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

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. 0.4
Report 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 %

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 distribution (Air jet sieve)

< 45 µm
<150 µm
<250 µm

Specification

max. 7 %
25 – 50 %
min. 65 %

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.