

Product group: Lactose
Brand name: SuperTab® 30GR
Product code: 743715/743716
Product description: Lactose monohydrate
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Manufacturing site: DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany
Product name: SuperTab® 30GR
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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<u>Particle size</u> (Rotap sieve)	<u>Specification</u>
% < 75 µm	10 – 30
% <150 µm	40 – 70
% <355 µm	min. 90
% <500 µm	100

Packaging:

A paper bag with polyethylene inner liner or 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 : 

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