Product Specification

Product group: Lactose
Brand name: SuperTab® 14 SD
Product description: Lactose monohydrate
Article code: 743721
Document No.: PD-0074

Manufacturing site:	DFE Pharma GmbH & Co.KG, Nörten Hardenberg, Germany
Product name:	SuperTab® 14SD 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:	**Specification**
Identification:	Complies with Pharmacopoeia when tested
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	max. 0.4 ml 0.1 N NaOH
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
Heavy metals	max. 5 ppm
Arsenic	max. 2 ppm
Assay by HPLC	98 – 102 %
Identify material by HPLC	pass
Related substances by HPLC	max. 0.5 %
Nitrite content (ppm)	reported value

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 (Air jet sieve)	**Specification**
% < 45 µm	max. 15
% <100 µm	30 – 60
% <250 µm	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

Signature : 

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