Product Specification

Product group:	Lactose
Brand name:	SuperTab® 40LL
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® 40LL 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:	**Specification**
Appearance of solution	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.0.1 w/w %
Water (KF)	max. 2.0 w/w %
Loss on drying	max. 0.5 w/w%
Acidity or alkalinity	max. 0.4 ml
Specific optical rotation	+51.9 to +54.3°
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
Arsenic	max. 2 ppm
Assay by HPLC	98 – 102 %
Identification by IR	Conforms
Identification by HLPC (assay)	Conforms
Related substances by HLPC	max. 0.5 %
Lactitol content	4.0 – 6.0 w/w %
Lactose content	min. 94.0 w/w%

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 500 g
Pseudomonas aeruginosa	neg. In 10 g

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Release date: 03-01-2025

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Particle size distribution	Typical range
(Sympatec laser diffraction, dry dispersion)	
x_{10}	40 – 120 µm
x_{50}	120 – 280 µm
x_{90}	280 – 530 µm

Functional related characteristics	
Bulk density	Value reported g/ml
Tapped density	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 : 

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