Product Specification

Product group: Lactose

Brand name: SuperTab®50 ODT

Product description: Lactose monohydrate (modified)

Article No: 1148010, 1153667

Document No.: PD-0747

Description :

Lactose Monohydrate (modified)
pharmaceutical grade
conform **USP- NF, Ph.Eur, JP, ChP**

Physical-Chemical data:	**Specification**
Identification	conform USP-NF, Ph.Eur, JP
Appearance of solution (Ph.Eur.)	Clear and not more coloured than ref. BY 7
Residue on ignition	max. 0.1 %
Total Water	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 %

Microbiological data:	**Specification**
TAMC	max. 100 / g
Escherichia coli	absent in 10 g
Salmonellae	absent in 5x25 g
TYMC	max. 10 / g

Particle size (Airjet sieve analysis, Alpine)	**Specification**
< 45 micron	max 20 %
< 106 micron	30 – 60 %
< 250 micron	> 90 %

Particle size (Laser diffraction, dry)	
D 10	Value reported micron
D 50	Value reported micron
D 90	Value reported micron

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Release date: 16-01-2025

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Packaging: A multiply paper box with polyethylene inner line, 25 kg net; or Big Bag 600kg

Storage: Keep in original, unopened packing and away from strongly odorous materials. Store at room temperature (normal warehouse conditions), allowing temporary excursions.

Retest date: For storage periods exceeding 36 months we recommend re-testing

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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