

# Product Specification

Product group: Lactose  
Brand name: SuperTab®50 ODT  
Product description: Lactose monohydrate  
(modified)  
Article No: 1148010, 1153667  
Document No.: PD-0747 Page 1 of 2

## Description :

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

### Physical-Chemical data:

Identification  
Appearance of solution (Ph.Eur.)  
Residue on ignition  
Total Water  
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

### Specification

conform USP-NF, Ph.Eur, JP  
Clear and not more coloured than ref. BY 7  
max. 0.1 %  
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 %

### Microbiological data:

TAMC  
Escherichia coli  
Salmonellae  
TYMC

### Specification

max. 100 / g  
absent in 10 g  
absent in 5x25 g  
max. 10 / g

### Particle size (Airjet sieve analysis, Alpine)

< 45 micron  
< 106 micron  
< 250 micron

### Specification

max 20 %  
30 – 60 %  
> 90 %

### Particle size (Laser diffraction, dry)

D 10  
D 50  
D 90

Value reported micron  
Value reported micron  
Value reported micron

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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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