

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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