

Product group: Inhalation
 Brand name: Lactohale® 201
 Product description: Lactose monohydrate
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Description :

α-lactose monohydrate pharmaceutical grade
 conform **USP - NF, Ph.Eur, JP,Ch.P**

Physical-Chemical data:

Infrared absorption spectrum / Id A
 Water / Id D Ph.Eur.
 Appearance in solution

 Lactose colour of sol.
 Lactose clarity of sol.
 Absorbance between 210-220 nm (1%, 1 cm)
 Absorbance between 270-300 nm (1%, 1 cm)
 Absorbance at 400 nm (10%, 1 cm)
 Acidity
 Specific Optical Rotation (on anhydrous basis)
 Heavy metals
 Loss on drying
 Residue on ignition
 Lactose
 Chromatography impurity
 Protein content (Bradford)
 Arsenic
 Assay by HPLC
 Identification by HPLC
 Related substances by HPLC

Specification

conform to reference
 4.5 – 5.5 %
 Not more intensely
 coloured than ref.BY7
 Nearly colourless Pass
 Clear
 max. 0.25
 max. 0.07
 max. 0.04
 max. 0.4 ml 0.1 N NaOH
 +54.4° to +55.9°
 max. 5 ppm
 max. 0.5 %
 max. 0.1 %
 97 – 103%
 max. 0.2 %
 max. 0.02 %
 ≤2
 98.0 – 102.0
 Pass
 Pass

Microbiological data:

TAMC
 TYMC
 Bile tolerant gram negative bacteria
 Escherichia coli
 Salmonellae
 Staphylococcus aureus
 Pseudomonas aeruginosa
 Burkholderia cepacia
 Endotoxines

Specification

max. 10 / g
 max. 10 / g
 absent in 10 g
 absent in 10 g
 absent in 5x25 g
 absent in 10 g
 absent in 10 g
 absent in 10 g
 absent in 10 g
 less than 5 EU / g

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Particle size distribution (Sympatec)

D 10	3 – 6 µm
D 50	20 – 25 µm
D 90	50 – 60 µm

Packaging: A polyethylene inner liner in an aluminium foil in a multiply paper box, 20 kg net

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

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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