

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

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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