

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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