



# Product Specification

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

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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

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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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