

# Product Specification

Product group: Inhalation  
Brand name: Lactohale® 210  
Product description: Lactose monohydrate  
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## Description :

$\alpha$ -lactose monohydrate pharmaceutical grade  
conform **USP - NF, Ph.Eur, JP**

### Physical-Chemical data:

Identification  
Appearance in solution  
Assay  
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)  
Protein content (Bradford)  
Heavy metals  
Chromatography impurity

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conform USP - NF, Ph.Eur, JP  
clear and nearly colourless  
97 – 103%  
max. 0.1 %  
4.5 – 5.5 %  
max. 0.5 %  
max. 0.4 ml 0.1 N NaOH  
+54.4° to +55.9°  
max. 0.25  
max. 0.07  
max. 0.04  
max. 0.02 %  
max. 5 ppm  
max. 0.2 %

### Microbiological data:

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

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

### Particle size distribution (Sympatec R4 lens)

D 10 2.0 – 3.5  $\mu$ m  
D 50 14.0 – 19.0  $\mu$ m  
D 90 35 – 50  $\mu$ m

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**Packaging:** A polyethylene inner liner in an aluminium foil in a multiply paper box, 15 kg net

**Storage:** Keep in original, unopened packing and away from strongly odorous materials. Temperature averaging between 5 and 25 °C, relative humidity of max. 70%.

**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** : Rutger Drost  
**Job title** : Global Marketing, Innovation & Technology Director  
**Signature** :

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