



## Product Specification

Product group: Inhalation  
Brand name: Lactohale® 206  
Product description: Lactose monohydrate  
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### Description:

#### Physical-Chemical data:

Infrared absorption spectrum/Id A  
Water / Id D Ph. Eur.  
Appearance of solution  
Lactose colour of sol.  
Lactose clarity of sol.  
UV-Abs. 10% sol. 400 nm  
UV-Abs 1% sol. 210 – 220 nm  
UV-Abs 1% sol. 270 – 300 nm  
Acidity (0.1N NaOH/6g)  
Specific optical rotation (anhydrous bas)  
Heavy Metals  
Loss on Drying (2 hrs, 80°C)  
Residue on ignition / Sulfated ash  
Lactose  
Chromatography impurity  
Protein (Bradford)

#### Microbiological data:

Total Aerobic Micro Count  
Total Yeast & Mould Count  
Escherichia coli (10 g)  
Salmonellae (5 \* 25 g)  
Gram negative bile tolerant m.o. (10 g)  
Pseudomonas aeruginosa (10 g)  
Coagulase positive Staphylococcus (10 g)  
Endotoxines

#### Particle size distribution (Sympatec)

D 10  
D 50  
D 90

Lactohale® 206, lactose monohydrate **USP - NF, Ph.Eur, JP, Ch.P**

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

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≤ 10 cfu/g  
≤ 10 cfu/g  
Negative  
Negative  
Negative  
Negative  
Negative  
≤ 5 EU /g

20 – 50 µm  
75 – 95 µm  
115 – 170 µm



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**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:** Xander van Leeuwen  
**Job title:** Business Unit Director Biopharma and Inhalation  
**Signature:**

A blue ink facsimile signature, appearing as a stylized 'X' or 'R' shape.

This document is controlled by a validated, electronic system and is valid without signature.  
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