Product Specification

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

Description:

Lactohale® 206, lactose monohydrate
conform **Ph.Eur, JP, Ch.P**
USP – NF (requirements for inhalation use)

Physical-Chemical data:	**Specification**
Infrared absorption spectrum/Id A	conform to reference
Water / Id D Ph. Eur.	4.5 – 5.5%
Appearance of solution	Not more intensely coloured than ref. BY7
Lactose colour of sol.	Nearly colourless
Lactose clarity of sol.	Clear
UV-Abs. 10% sol. 400 nm	≤ 0.04
UV-Abs 1% sol. 210 – 220 nm	≤ 0.25
UV-Abs 1% sol. 270 – 300 nm	≤ 0.07
Acidity (0.1N NaOH/6g)	≤ 0.4 ml
Specific optical rotation (anhydrous bas)	54.4 – 55.9°
Heavy Metals	max. 5 ppm
Loss on Drying (2 hrs, 80°C)	≤ 0.5%
Residue on ignition / Sulfated ash	≤ 0.1%
Lactose	97 – 103%
Chromatography impurity	≤ 0.2 %
Protein (Bradford)	≤ 0.02%
Arsenic	≤2
Assay by HPLC	98.0 – 102.0
Identification by HPLC	Pass
Related substances by HPLC	Pass

Microbiological data:	**Specification**
Total Aerobic Micro Count	≤ 10 cfu/g
Total Yeast & Mould Count	≤ 10 cfu/g
Escherichia coli (10 g)	Negative
Salmonellae (5 * 25 g)	Negative
Gram negative bile tolerant m.o. (10 g)	Negative
Pseudomonas aeruginosa (10 g)	Negative
Coagulase positive Staphylococcus (10 g)	Negative
Endotoxines	≤ 5 EU /g

Particle size distribution (Sympatec)	
D 10	20 – 50 µm
D 50	75 – 95 µm
D 90	115 – 170 µm
Span	0.7 –2.0

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Release date: 25-06-2026

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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 : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature :

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