

Product group: Inhalation

Brand name: Lactohale® 206

Product description: Lactose monohydrate

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Description:

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

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)

Specification

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%

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

Specification

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

Particle size distribution (Sympatec)

D 10 20 – 50 µm
D 50 75 – 95 µm
D 90 115 – 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:



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