

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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