

Product Specification

Product group: Inhalation

Brand name: Lactohale® 206

Product description:Lactose monohydrate

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Description:

Ph.Eur, JP, Ch.P

Lactohale® 206, lactose monohydrate USP - NF,

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 (o.1N NaOH/6q)

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)

Coaqulase positive Staphylococcus (10 g)

Endotoxines

Specification

≤ 10 cfu/q ≤ 10 cfu/q Negative Negative Negative Negative Negative

≤ 5 EU /q

Particle size distribution (Sympatec)

D 10 20 - 50 μm D 50 $75 - 95 \mu m$ 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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