

Product Specification

Product group: Inhalation

Brand name: Lactohale® 100

Product description:Lactose monohydrate

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Description:

 α -lactose monohydrate pharmaceutical grade conform **USP - NF, Ph.Eur, JP**

Physical-Chemical data:

Identification

Appearance in solution

Assay

Residue on ignition

Total Water Loss on drying

Acidity

Specific Optical Rotation (on anhydrous basis) Absorbance between 210-220 nm (1%, 1 cm)

Absorbance between 270-300 nm (1%, 1 cm)

Absorbance at 400 nm (10%, 1 cm)

Protein content (Bradford)

Heavy metals

Chromatography impurity

Specification

conform USP - NF, Ph.Eur, JP clear and nearly colourless

97 – 103%

max. 0.1 %

4.5 - 5.5 %

max. o.5 %

max. o.4 ml o.1 N NaOH

+54.4° to +55.9°

max. 0.25

max. 0.07

max. 0.04

max. 0.02 %

max. 5 ppm

max. 0.2 %

Microbiological data:

TAMC

Bile tolerant gram negative bacteria

Escherichia coli Salmonellae

TYMC

Staphylococcus aureus Pseudomonas aeruginosa

Burkholderia cepacia

Bacterial endotoxine

Specification

max. 10/g absent in 10 g

absent in 10 g

absent in 5x25 g

max. 10/g absent in 10 g

absent in 10 g

absent in 10 g less than 5 EU /g

Particle size distribution (Sympatec)

D 10 45 – 65 μm D 50 125 – 145 μm D 90 200 – 250 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.

Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

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 : Rutger Drost

Job title : Global Marketing, Innovation & Technology Director

Signature

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