

Product Specification

Product group: Inhalation

Brand name: Lactohale® 210

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. 0.5 %
 max. 0.4 ml 0.1 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 R4 lens)

D 10 2.0 – 3.5 μm
 D 50 14.0 – 19.0 μm
 D 90 35 – 50 μm

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Packaging: A polyethylene inner liner in an aluminium foil in a multiply paper box, 15 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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