Product Specification

Product group: Inhalation
Brand name: Lactohale® 210
Article code : 0743633
Product description: Lactose monohydrate

Description : α-lactose monohydrate pharmaceutical grade conform **Ph.Eur, JP, ChP, USP – NF (requirements for inhalation use)**

Physical-Chemical data:	**Specification**
Infrared absorption spectrum / Id A	conforms to reference
Appearance in solution	clear and nearly colourless
Assay	97 – 103% (m)
Residue on ignition	max. 0.1 % (m)
Water (KF)	4.5 – 5.5 % (m)
Loss on drying	max. 0.5 % (m)
Acidity or Alkalinity	max. 0.4 ml 0.1 N NaOH/6g
Specific optical rotation:	
$[\alpha]^{20}_{D}$ anhydrous basis	+54.4° to +55.9°
Proteins and Light Absorbing Impurities	
[A] 1%, 1 cm at 210 - 220 nm	max. 0.25
[A] 1%, 1 cm at 270 - 300 nm	max. 0.07
[A] 10%, 1 cm at 400 nm	max. 0.04
Protein content (Bradford)	max. 0.02 %
Heavy metals	max. 5 ppm
Chromatography impurity	max. 0.2 % (m)
Arsenic	≤2 ppm
Assay by HPLC	98.0 – 102.0 %
Identification by HPLC	Pass
Related substances by HPLC	max. 0.5 % w/w

Microbiological data:	**Specification**	
Total aerobic microbial count	max.	10 cfu/ g
Total yeasts and moulds	max.	10 cfu/ g
Bile tolerant gram negative bacteria	absent in	10 g
Escherichia coli	absent in	10 g
Salmonellae	absent in	5x25 g
Staphylococcus aureus	absent in	10 g
Pseudomonas aeruginosa	absent in	10 g
Burkholderia cepacia	absent in	10 g
Bacterial endotoxin	less than	5 EU /g

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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
Span	1.7 – 3.3 µm

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. 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 : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature :

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