Product Specification

Product group: Inhalation
Brand name: Lactohale® 230
Article code : 0743600
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
Water (KF)	4.5 – 5.5 % (m)
Appearance in solution	Not more intensely coloured than ref.BY7
Lactose colour of solution	Nearly colourless
Lactose clarity of solution	Clear
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
Acidity or Alkalinity	max. 0.4 ml 0.1 N NaOH/6g
Specific Optical Rotation (on anhydrous basis)	+54.4° to +55.9°
Heavy metals	max. 5 ppm
Loss on drying	max. 0.5 % (m)
Residue on ignition / Sulfated ash	max. 0.1 % (m)
Assay	97 – 103% (m)
Chromatography impurity	max. 0.2 % (m)
Protein content (Bradford)	max. 0.02 % (m)
Arsenic	≤2 ppm
Assay by HPLC	98.0 – 102.0 %
Identification by HPLC	max. 0.5 % w/w
Related substances by HPLC	

Microbiological data:	**Specification**	
Total aerobic microbial count	max.	10 cfu / g
Total yeasts and moulds	max.	10 cfu / g
Escherichia coli	absent in	10 g
Salmonellae	absent in	5x25 g
Bile tolerant gram negative bacteria	absent in	10 g
Pseudomonas aeruginosa	absent in	10 g
Staphylococcus aureus	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 R2 lens)	**Specification**
D 10	1.0 – 3.0 µm
D 50	< 10 µm
D 90	< 30 µm
Span	1.9 - 3.3 µm

Packaging: A polyethylene inner liner in an aluminium foil in a multiply paper box, 10 kg net

Storage: Keep in original, unopened packing and away from strongly odorous materials. Store at room temperature (normal warehouse conditions), allowing temporary excursions

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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