Product Specification

Product group: Inhalation

Brand name: Lactohale® 300

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**
Identification	conform USP - NF, Ph.Eur, JP
Appearance in solution	clear and nearly colourless
Assay	97 – 103%
Residue on ignition	max. 0.1 %
Total Water	4.5 – 5.5 %
Loss on drying	max. 0.5 %
Acidity	max. 0.4 ml 0.1 N NaOH
Specific Optical Rotation (on anhydrous basis)	+54.4° to +55.9°
Absorbance between 210-220 nm (1%, 1 cm)	max. 0.25
Absorbance between 270-300 nm (1%, 1 cm)	max. 0.07
Absorbance at 400 nm (10%, 1 cm)	max. 0.04
Protein content (Bradford)	max. 0.02 %
Heavy metals	max. 5 ppm
Arsenic	≤2
Assay by HPLC	98.0 – 102.0
Identification by HPLC	Pass
Related substances by HPLC	Pass

Microbiological data:	**Specification**	
TAMC	max.	10 / g
Bile tolerant gram negative bacteria	absent in	10 g
Escherichia coli	absent in	10 g
Salmonellae	absent in	5x25 g
TYMC	max.	10 / g
Staphylococcus aureus	absent in	10 g
Pseudomonas aeruginosa	absent in	10 g
Bacterial endotoxin	less than	5 EU /g

Particle size:	
D 50	≤ 5 micron
D 90	≤ 10 micron
Span	1.7 - 3.3

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Release date: 10-08-2026

Product Specification

Packaging: An aluminium foil + PE liner in a multiply paper box, 12.5 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: Typically 6 months from day of dispatch when kept unopened, for storage periods exceeding 6 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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