

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	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
Chromatography impurity	max. 0.2 %

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	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
Burkholderia cepacia	absent in 10 g
Bacterial endotoxine	less than 5 EU /g

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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