

Product group: Inhalation

Brand name: Lactohale® 100

Product description: Lactose monohydrate

Document No.: PD-0381 Page 1 of 2

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)

D 10 45 – 65 µm
D 50 125 – 145 µm
D 90 200 – 250 µm

Product Specification

Product group: Inhalation

Brand name: Lactohale® 100

Product description: Lactose monohydrate

Document No.: PD-0381 Page 2 of 2

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 : 

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.