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Product Specification

Product group:	Inhalation	
Brand name:	Lactohale [®] 2	220
Product description:Lactose monohydrate		
Document No.:	PD-0493	Page 1 of 2

 α -lactose monohydrate pharmaceutical grade conform USP - NF, Ph.Eur, JP, Ch.P

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. 0.02 % max. 5 ppm max. 1 ppm max. 0.2 %

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 R4 lens)	
D 10	1.5 – 3.0 micron
D 50	11.0 – 15.0 micron
D 90	25.0 – 40.0 micron

Description:

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 Arsenic Chromatography impurity

Microbiological data:

TAMC Bile tolerant gram negative bacteria Escherichia coli Salmonellae TYMC Staphylococcus aureus Pseudomonas aeruginosa Burkholderia cepacia Bacterial endotoxine The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 26-07-2025; 22:04 UTC



Product Specification

Product group:InhalationBrand name:Lactohale® 220Product description:Lactose monohydrateDocument No.:PD-0493Page 2 of 2

- **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	: Rutger Drost
Job title	: Global Marketing, Innovation & Technology Director
Signature	:/ / .
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