# Product Specification

Product group: Inhalation
Brand name: Lactohale® 220
Article code : 0743674
Product description: Lactose monohydrate
Document No.: PD-0493 

**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 | clear and nearly colourless |
| 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: | |
| $[\alpha]^{20}_{D}$ anhydrous basis | +54.4° to +55.9° |
| Heavy metals | max. 5 ppm |
| Arsenic | ≤1 ppm |
| Loss on drying | max. 0.5 % (m) |
| Residue on ignition | 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 | Pass |
| Related substances by HPLC | max. 0.5 % w/w |

| **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 |
| Salmonella | 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**

| | |
|---|---|
| D 10 | 1.5 – 3.0 µm |
| D 50 | 11.0 – 15.0 µm |
| D 90 | 25.0 – 40.0 µm |
| Span | 1.5 - 3.5 µm |

**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

**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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