

# Product Specification

Product group: Inhalation

Brand name: Lactohale® 230

Product description: Lactose monohydrate

Document No.: PD-0146 Page 1 of 2

## Description :

$\alpha$ -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 R2 lens)

D 10  
 D 50  
 D 90

1.0 – 3.0  $\mu$ m  
 < 10  $\mu$ m  
 < 30  $\mu$ m

### Target

–  
 8 – 9 micron  
 < 25 micron

# Product Specification

Product group: Inhalation  
Brand name: Lactohale® 230  
Product description: Lactose monohydrate  
Document No.: PD-0146 Page 2 of 2

**Packaging:** A polyethylene inner liner in an aluminium foil in a multiply paper box, 10 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.