

Product group: Inhalation
 Brand name: Respitose® MLo01
 Article code: 659178
 Product description: Lactose monohydrate
 Document No.: PD-0063 Page 1 of 2

Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
 Product name: Respitose® MLo01
 Conforms to USP - NF, Ph.Eur., JP Lactose monohydrate monograph, current at time of manufacture
 Product description: A white or almost white, odourless, crystalline powder freely soluble in water, practically insoluble in ethanol
 Residual solvents
 (CPMP/ICH/283/95): No class 1,2,3 solvents are used during production
 Identification: Complies with Pharmacopoeia when tested

Specification

| | |
|--|--|
| Water (KF) | 4.5 - 5.5 % |
| Loss on drying | max. 0.5 % |
| Specific optical rotation: [α] ²⁰ _D anhydrous basis | +54.4° to +55.9° |
| Residue on ignition/Sulphated ash | max. 0.1 % |
| Proteins and Light Absorbing Impurities | |
| [A] 1%, 1 cm at 270 - 300 nm | max. 0.07 |
| [A] 1%, 1 cm at 210 - 220 nm | max. 0.25 |
| Appearance of solution (Ph.Eur.) | Clear and not more coloured than ref. BY 7 |
| Clarity and Colour of Solution | Clear and colourless or nearly colourless |
| [A] 10%, 1 cm at 400 nm | max. 0.04 |
| Acidity or Alkalinity (ml 0.1 N NaOH/6 g) | max. 0.4 ml |
| Heavy metals | max. 5 ppm |
| Related sugars: | |
| Glucose | max. 200 ppm |
| Galactose | max. 200 ppm |

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Particle size distribution (Air jet sieve)

| | |
|------------|----------|
| % < 45 µm | 40 - 60 |
| % < 100 µm | min. 75 |
| % < 150 µm | min. 90 |
| % < 315 µm | min. 100 |

Laser diffraction (dry)

| | |
|-----|--------------|
| d10 | 3 - 7 µm |
| d50 | 37 - 61 µm |
| d90 | 124 - 194 µm |

Morphology & shape

Premilled Tomahawk

Endotoxins

max. 5 EU/g

Total aerobic microbial count

max. 10 cfu/g

Yeasts and moulds

max. 10 cfu/g

Bile-tolerant gram-negative bacteria

neg. in 4 x 1 g

E. coli

neg. in 10 g

St. aureus

neg. in 10 g

Pseudomonas aeruginosa

neg. in 10 g

Salmonella

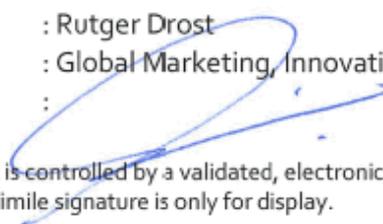
neg. in 50 g

Packaging: Polyethylene inner liner in a HDPE drum, 50 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

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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