

Product group: Inhalation
 Brand name: Respitose® MLo03
 Article code: 659181
 Product description: Lactose monohydrate
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Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
 Product name: Respitose® MLo03
 Conforms to USP - NF, Ph.Eur., JP Lactose monohydrate monograph, current at time of manufacture
 Product description: A white or almost white, 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

| | <u>Specification</u> |
|--|--|
| 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. 0.10 % |
| 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 |
| 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 % < 100 µm % < 150 µm | 50 - 65 min. 90 min. 96 |
| Particle size distribution (Sympatec) | µm D10 µm D50 µm D90 | 1 - 6 20 - 50 65 - 140 |
| Morphology & shape Endotoxins | | complies 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 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 |

Storage:

Keep in original, unopened packing and away from strongly odorous materials
 Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

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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