

Product group: Inhalation
 Brand name: Respitose® SV003
 Article code: 659173
 Product description: Lactose monohydrate
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Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
 Product name: Respitose® SV003
 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

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. 0.10 % |
| 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 |
| Particle size distribution d10 | 19 - 43 μm |
| Laser diffraction (dry) d50 | 53 - 66 μm |
| d90 | 75 - 106 μm |

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|--------------------------------------|------------|---------------|
| Particle size distribution | % < 32 µm | 5 - 10 |
| (Air jet sieve) | % < 63 µm | min. 70 |
| | % < 100 µm | 100 |
| Morphology & shape | | complies |
| 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 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%

Name : Rutger Drost
Job title : Global Marketing, Innovation & Technology Director
Signature :

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