

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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