Product Specification

Product group:	Inhalation
Brand name:	Respitose® SV003
Article code:	0659173
Product description:	Lactose monohydrate
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Manufacturing site:	FrieslandCampina DMV BV, Veghel, The Netherlands
Product name:	Respitose® SV003 Conforms to USP – NF (requirements for inhalation use), Ph.Eur, JP, ChP 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	(ICH Guideline Q3C, USP General Chapter <467>, and Ph. Eur. General Chapter 5.4.): No class 1,2,3 solvents are used during production

	Specification
Infrared absorption Spectrum / Id A	Conforms to reference
Water (KF)	4.5 - 5.5 %
Appearance of solution	Not more intensely coloured than ref. BY 7
Lactose Clarity of Solution	Clear
Lactose Colour of Solution	Nearly colourless
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
[A] 10%, 1 cm at 400 nm	max. 0.04
Acidity or Alkalinity	max. 0.4 ml 0.1 N NaOH/6 g
Specific optical rotation:	
$[\alpha]^{20}_{D}$, anhydrous basis	+54.4° to +55.9°
Heavy metals	max. 5 ppm
Loss on drying	max. 0.5 % (m)
Residue on ignition/Sulphated ash	max. 0.10 % (m)
Related sugars:	
Glucose	max. 200 ppm
Galactose	max. 200 ppm
Arsenic	≤2 ppm
Assay by HPLC	98.0 – 102.0 %
Identification by HPLC	Pass
Related substances by HPLC	max. 0.5 % w/w

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Particle shape and Morphology		Premilled Tomahawk
Particle size distribution Laser diffraction (dry)	d10	19 - 43 µm
	d50	53 - 66 µm
	d90	75 - 106 µm
	Span	
Particle size distribution (Air jet sieve)	% < 32 µm	5 – 10 %(m)
	% < 63 µm	min. 70 %(m)
	% < 100 µm	100 %(m)

Total aerobic microbial count	max. 10 cfu/g
Total yeasts and moulds	max. 10 cfu/g
Escherichia coli	neg. in 10 g
Salmonella	neg. in 50 g
Bile-tolerant gram-negative bacteria	neg. in 1 g
Pseudomonas aeruginosa	neg. in 10 g
Staphylococcus aureus	neg. in 10 g
Bacterial endotoxin	max. 5 EU/g
Burkholderia cepia,	neg. in 10 g

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

Name : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature :



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