Product Specification

Product group: Inhalation
Brand name: Respitose® ML001
Article code: 0659178
Product description: Lactose monohydrate
Document No.: PD-0063

Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
Product name: Respitose® ML001
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, odourless, 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 % (m)
Appearance of solution	Not more intensely coloured than ref. BY 7
Lactose Clarity of Solution	Clear
Lactose Colour of Solution	Nearly colourless
Loss on drying	max. 0.5 % (m)
Specific optical rotation: $[\alpha]^{20}_{D}$ anhydrous basis	+54.4° to +55.9°
Residue on ignition/Sulphated ash	max. 0.1 % (m)
Proteins and Light Absorbing Impurities	
[A] 1%, 1 cm at 210 - 220 nm	max. 0.25
[A] 1%, 1 cm at 270 - 300 nm	max. 0.07
[A] 10%, 1 cm at 400 nm	max. 0.04
Acidity or Alkalinity	max. 0.4 ml 0.1 N NaOH/6 g
Heavy metals	max. 5 ppm
Related sugars:	
Glucose	max. 200 ppm
Galactose	max. 200 ppm
Arsenic	max. 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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Morphology & shape	Premilled Tomahawk
Particle size distribution (Air jet sieve)	
% < 45 µm	40 – 60 % (m)
% < 100 µm	75 – 100 % (m)
% < 150 µm	90 - 100 % (m)
% < 315 µm	min. 100% (m)
Particle size distribution Laser diffraction (dry)	
d10	3 - 7 µm
d50	37 - 61 µm
d90	124 - 194 µm
Span	Reported value
Endotoxin	max. 5 EU/g
Total aerobic microbial count	max. 10 cfu/g
Total yeasts and moulds	max. 10 cfu/g
Bile-tolerant gram-negative bacteria	neg. in 4 x 1 g
Escherichia coli	neg. in 10 g
Staphylococcus aureus	neg. in 10 g
Pseudomonas aeruginosa	neg. in 10 g
Salmonella	neg. in 50 g
Burkholderia cepacia	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

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

Signature : 

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