



Product Specification

Product group: Inhalation
Brand name: Respitose® ML001
Article code: 659178
Product description: Lactose monohydrate
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Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands

Product name: Respitose® ML001

Conforms to USP - NF, Ph.Eur., JP 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

(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. 0.1 %
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 ml
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	40 - 60
% < 100 µm	min. 75
% < 150 µm	min. 90
% < 315 µm	min. 100

Laser diffraction (dry)

d ₁₀	3 - 7 µm
d ₅₀	37 - 61 µm
d ₉₀	124 - 194 µm

Morphology & shape

Premilled Tomahawk

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 4 x 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

Packaging: Polyethylene inner liner in a HDPE drum, 50 kg net

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

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