

# Product Specification

Product group: Inhalation  
Brand name: Respitose® ML003  
Article code: 659181  
Product description: Lactose monohydrate  
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Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands  
Product name: Respitose® ML003  
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

	<u>Specification</u>
Water (KF)	4.5 - 5.5 %
Loss on drying	max. 0.5 %
Specific optical rotation: [ $\alpha$ ] <sup>20</sup> <sub>D</sub> , 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

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Particle size distribution (air jet sieve)	% < 45 µm % < 100 µm % < 150 µm	50 - 65 min. 90 min. 96
Particle size distribution (Sympatec)	µm D <sub>10</sub> µm D <sub>50</sub> µm D <sub>90</sub>	1 - 6 20 - 50 65 - 140
Morphology & shape Endotoxins		complies max. 5 EU/g
Total aerobic microbial count Yeast and moulds		max. 10 cfu/g max. 10 cfu/g
Bile-tolerant gram-negative bacteria E. coli		neg. in 1 g 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%

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 :

This document is controlled by a validated, electronic system and is valid without signature.  
The above facsimile signature is only for display.