

Product group: Lactose
 Brand name: Pharmatose® 90M
 Article code: 659138
 Product description: Lactose monohydrate
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Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
 Product name: Pharmatose® 90M
 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 but slowly 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] _D ²⁰ , 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	
[A] 10%, 1 cm at 400 nm	Clear and colourless or nearly colourless max. 0.04
Acidity or Alkalinity (ml 0.1 N NaOH/6 g)	max. 0.4
Heavy metals	max. 5 ppm

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Particle size distribution	% < 63 µm	max. 15
(Air jet sieve)	% < 100 µm	15 - 30
	% < 150 µm	55 - 90
	% < 315 µm	100

Total aerobic microbial count	max. 100 cfu/g
Yeasts and moulds	max. 10 cfu/g
E. coli	neg. in 10 g
Salmonella	neg. in 100 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 : 

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