



Product group: Lactose
Brand name: Pharmatose® 125M
Product code: 659132
Product description: Lactose monohydrate
Document No.: PD-0049 Page 1 of 2

Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
Product name: Pharmatose 125M
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

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	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
 Particle size distribution	
% < 45 µm	max. 40
(Air jet sieve) % < 63 µm	40 - 70
% < 100 µm	min. 90

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Page 2 of 2

% <150 µm

97 - 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 : Wouter H. Noordman, PhD
Job title : Global Technology & Innovation Director
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