

Product group: Lactose
 Brand name: Pharmatose® 200M (EU)
 Product code: 659113/659114/654817/
 659120/659121/659119/
 659124
 Product description: Lactose monohydrate
 Document No.: PD-0050 Page 1 of 2

Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands
 Product name: Pharmatose 200M
 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

Product Specification

Product group: Lactose
Brand name: Pharmatose® 200M (EU)
Product code: 659113/659114/654817/
659120/659121/659119/
659124
Product description: Lactose monohydrate
Document No.: PD-0050 Page 2 of 2

Particle size distribution	% < 45 µm	50 - 65
(Air jet sieve)	% <100 µm	min. 90
	% <150 µm	min. 96
	% <250 µm	99 - 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 : 

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