

Product group: Lactose  
 Brand name: Pharmatose® 350M (EU)  
 Article code: 659127/659129/659130  
 Product description: Lactose monohydrate  
 Document No.: PD-0056 Page 1 of 2

Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands  
 Product name: Pharmatose 350M  
 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] <sup>20</sup> <sub>D</sub> , anhydrous basis	+54.4° to +55.9°
Residue on ignition/Sulphated ash	max. 0.10 %
<b>Proteins and Light Absorbing Impurities</b>	
[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
<b>Clarity and Colour of Solution</b>	
[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

# Product Specification

Product group: Lactose  
Brand name: Pharmatose® 350M (EU)  
Article code: 659127/659129/659130  
Product description: Lactose monohydrate  
Document No.: PD-0056 Page 2 of 2

Particle size distribution	% < 45 µm	min. 60
(Air jet sieve)	% < 100 µm	min. 96
	% < 250 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** :

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