



# Product Specification

Product group: Lactose  
 Brand name: Pharmatose® 200M (EU)  
 Product code: 654817/659113/659114/  
 659119/659120/659121  
 Product description: Lactose monohydrate  
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Manufacturing site: FrieslandCampina DMV BV, Veghel, The Netherlands  
 Product name: Pharmatose® 200M  
 Conforms to USP - NF, Ph.Eur., JP, Ch.P. 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

## Physical-Chemical data:

Identification:  
 Appearance of solution (Ph.Eur.)  
 Clarity and Colour of Solution  
 Residue on ignition/Sulphated ash  
 Water (KF)  
 Loss on drying  
 Acidity  
 Specific Optical Rotation (on anhydrous basis)  
 Absorbance between 210-220 nm (1%, 1 cm)  
 Absorbance between 270-300 nm (1%, 1 cm)  
 Absorbance at 400 nm (10%, 1 cm)  
 Heavy metals  
 Arsenic  
 Assay by HPLC  
 Identify material by HPLC  
 Related substances by HPLC  
 Nitrite content (ppm)<sup>1</sup>

## Specification

Complies with Pharmacopoeia when tested  
 Clear and not more coloured than ref. BY 7  
 Clear and colourless or nearly colourless  
 max. 0.10 %  
 4.5 - 5.5 %  
 max. 0.5 %  
 max. 0.4 ml 0.1 N NaOH  
 +54.4° to +55.9°  
 max. 0.25  
 max. 0.07  
 max. 0.04  
 max. 5 ppm  
 max. 2 ppm  
 98 – 102 %  
 pass  
 max. 0.5 %  
 reported value

## Microbiological data:

Total aerobic microbial count  
 Yeasts and moulds  
 E. coli  
 Salmonella

## Specification

max. 100 cfu/g  
 max. 10 cfu/g  
 neg. in 10 g  
 neg. in 100 g

1: Currently for product code 659113 only



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### Particle size (Airjet sieve analysis, Alpine)

% < 45 µm  
% <100 µm  
% <150 µm  
% <250 µm

### Specification

50 - 65  
min. 90  
min. 96  
99 - 100

### Powder properties

Bulk Density reported value  
Tapped Density reported value

### **Storage:**

Keep in original, unopened packing and away from strongly odorous materials.  
Store at room temperature (normal warehouse conditions), allowing temporary excursions.

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** : Dr. Bastiaan Dickhoff  
**Job title** : Director Innovation & Technical Solutions

**Signature** : 

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