



# 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** :

A handwritten signature in blue ink, appearing to read 'B. Dickhoff'.

This document is controlled by a validated, electronic system and is valid without signature.

The above facsimile signature is only for display.