

Product group: Lactose  
Brand name: Pharmatose® 350M (NZ)  
Product description: Lactose monohydrate  
Article code: 743827  
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Manufacturing site: Fonterra Limited, Kaponga, New Zealand  
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

#### **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 or Alkalinity (ml 0.1 N NaOH/6 g)  
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

#### **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  
+54.4° to +55.9°  
max. 0.25  
max. 0.07  
max. 0.04  
max. 5 ppm

#### **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

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

|            |         |
|------------|---------|
| % < 106 µm | min. 94 |
| % < 75 µm  | min. 88 |

**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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