



# Product Specification

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** : Sander van Gessel  
**Job Title** : Director ITS  
**Signature** :

A blue ink facsimile signature of Sander van Gessel, consisting of several overlapping, stylized lines.

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