



# Product Specification

Product group: Lactose  
 Brand name: Pharmatose® 200M (NZ)  
 Article code: 0743728, 0743729, 0743731, 0743732  
 Product description: Lactose monohydrate  
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Manufacturing site: Fonterra Limited, Kaponga, New Zealand  
 Product name: Pharmatose 200M  
 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:	
$[\alpha]^{20}_D$ , anhydrous basis	+54.4° to +55.9°
Residue on ignition/Sulphated ash	max. 0.10 %
Proteins and Light Absorbing Impurities	
[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
Clarity and Colour of Solution	Clear and colourless or nearly colourless
[A] 10%, 1 cm at 400 nm	max. 0.04
Acidity or Alkalinity (ml 0.1 N NaOH/6 g)	max. 0.4
Heavy metals	max. 5 ppm



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Particle size distribution (Sonic sifter)	% < 180 µm % < 75 µm	min. 98 78 - 86
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. 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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