



Product Specification

Product group: Lactose
Brand name: Pharmatose® 350M (NZ)
Product description: Lactose monohydrate
Article code: 743827
Document No.: PD-0092 Page 1 of 2

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

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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 strokes.

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