Product Specification

Product group:	Lactose
Brand name:	Pharmatose® 200M (NZ)
Product code:	0743728, 0743729, 0743731, 0743732
Product description:	Lactose monohydrate
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Manufacturing site:	Fonterra Ltd., Kaponga, New Zealand
Product name:	Pharmatose® 200M Conforms to USP - NF, Ph.Eur., JP, Ch.P[1]. 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:	Specification
Identification:	Complies with Pharmacopoeia when tested
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
Residue on ignition/Sulphated ash	max. 0.10 %
Water (KF)	4.5 - 5.5 %
Loss on drying	max. 0.5 %
Acidity	max. 0.4 ml 0.1 N NaOH
Specific Optical Rotation (on anhydrous basis)	+54.4° to +55.9°
Absorbance between 210-220 nm (1%, 1 cm)	max. 0.25
Absorbance between 270-300 nm (1%, 1 cm)	max. 0.07
Absorbance at 400 nm (10%, 1 cm)	max. 0.04
Heavy metals[1]	max. 5 ppm
Arsenic[1]	max. 2 ppm
Assay by HPLC[1]	98.0 – 102.0 %
Identify material by HPLC[1]	Pass
Related substances by HPLC[1]	Pass

Microbiological data:	Specification
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

1: Not applicable for 0743732

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Particle size (Sonic sifter)	**Specification**
% < 75 µm	78 – 86
% <180 µm	min. 98

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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