Product Specification

Manufacturing site: Fonterra Limited, Kaponga, New Zealand
Product name: Pharmatose® 70M
                       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	% < 600 µm	min. 98
(Sonic sifter)	% < 250 µm	60 - 80
	% < 150 µm	25 - 45
	% < 75 µm	5 - 13

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.
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

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Job title   : Global Marketing, Innovation & Technology Director
Signature   :
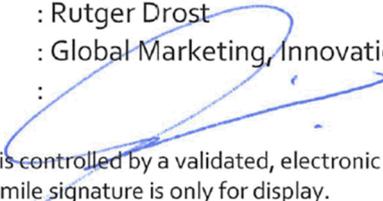
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