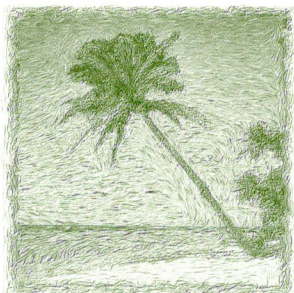


LACTOSE MONOHYDRATE 200 mesh



**Product description:**

Lactose monohydrate, pharmaceutical 200 mesh, is a fine, white powder with neutral taste and odour. This sugar, uniquely found in milk, is produced from fresh cheese whey, refined, then crystallized and dried on a fluid bed dryer, after which it is milled, sieved and packed. The product complies with latest editions of Ph.Eur, USP/NF and JP.

**SPECIFICATION:**

**PHYSICAL-CHEMICAL:**

**SPECIFICATION:**

Appearance		White crystalline powder.
Solubility		Freely soluble in water.
Identification		Complies with pharmacopeia.
Water	Karl Fisher	4.5% to 5.5%
Loss on drying		Max. 0.5%
Specific optical rotation	Basis anhydrous	+ 54.4° to 55.9°
Residue on ignition / sulphated ash		Max. 0.1%
Appearance of solution	Ph.Eur	Clear and not more intensively coloured than the reference solution BY7.
Clarity and colour of solution	USP/JP	Clear and colourless or nearly colourless.
Acidity or alkalinity	MI 0,1 N NaOH	Max. 0.4
Heavy metals		Max. 5 ppm.

**MICRO BIOLOGICAL:**

Total aerobic microbial count		Max. 100 CFU/gr
Total yeast and moulds count		Max. 50 CFU/gr
Escherichia coli		Negative in 1 gr.
Salmonella		Negative in 10 gr.

**ADDITIONAL:**

Particle size distribution	Air jet sieve	< 65 µm: 70 – 90%   < 90 µm: 80 – 100%   < 150 µm: 96 – 100%
Solvents	ICH Q3C	No solvents as listed in the guidelines are used.

**Packing:**

Multiply polylined paper bags of 20 and/or 25 kg net weight.

**Storage:**

Keep in original unopened packing, away from strongly odorous material, humidity and direct sunlight.

**Note:**

Preparation and publication of this information has been done with all possible care. It is advised, however, that users convince themselves of the convenience to incorporate this product in their manufacturing process.

This data is for information purposes only and may change without notice.

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