



PHARMA LACTOSE 200 mesh

Code 37102d
v. 1/06

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 BP/USP/EP.

Analysis:

Physical-chemical tests:

	<u>methodology:</u>	<u>specification:</u>
Description	USP29/EP5	white crystalline powder
Clarity of solution	USP29/EP5	clear
Color of solution	USP29/EP5 (extinction 400 nm)	≤ 0.04
Proteins and light	210-220 nm	≤ 0.25
absorpting impurities	270-300 nm	≤ 0.07
Acidity or alkalinity	ml 0,1 N NaOH	≤ 0.4 ml
Spec optical rotation	USP29/EP5	between +54.4° and +55.9°
Residue on ignition	USP29/EP5	max 0.1 %
Loss on drying	USP29/EP5	max 0.5 %
Total water	n. Karl Fisher	max 5.5 %
pH	10% solution	3.8 – 5.5
Heavy metals	par. 35 LMBG	≤ 5 ppm

Microbiological tests:

Total plate count	CASO-Agar, 30°C/48 hr	≤ 100 /gr
Yeasts	YGC-Agar, 25° C/7 days	≤ 10 /gr
Moulds	YGC-Agar, 25° C/7 days	≤ 10 /gr
Coli-test	LST-Bouillon, 30°C/48 hr	negative /gr
Salmonella	par. 35 LMBG	negative /25 gr

Uses:

Supplementary ingredient for pharmaceutical products, basically as excipient in tablet manufacturing.

Packing:

Multiply polylined paper bags of 25 kilos net.

Storage:

Preferably store in its original packing, in a dry and cool warehouse, protected from light and humidity. Store lactose well away from strong smelling products.

Safety data:

No health hazards should exist, subject to normal standards of personal hygiene. No special instructions for first aid and no special precautions are necessary. Specific data available.

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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