



To whom it may concern

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Quality Unit / Regulatory Affairs

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Content of Lactose

MEGGLE Products:

- Lactose Monohydrate (Ph. Eur. / USP-NF / JP): CapsuLac® 60, FlowLac® 90, FlowLac® 100, GranuLac® 70, GranuLac® 80, GranuLac® 140, GranuLac® 200, GranuLac® 230, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100

The products conform to the monograph "Lactose Monohydrate" in the Ph. Eur, USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation.

The content of lactose is minimum 99%. This is based on the following specification parameters:

All mentioned trade names, except: FlowLac® 90, FlowLac® 100

Specification parameter	Value	Method
Specific optical rotation	+54.4° - +55.9° (anhydrous substance)	Ph. Eur. 2.2.7
Loss on drying	max. 0.5%	USP-NF <731>
Sulphated ash	max. 0.1%	Ph. Eur. 2.4.14

Only FlowLac® 90, FlowLac® 100:

Specification parameter	Value	Method
Specific optical rotation	+54.4° - +55.9° (anhydrous substance)	Ph. Eur. 2.2.7
Loss on drying	max 1.0%	USP-NF <731>
Sulphated ash	max. 0.1%	Ph. Eur. 2.4.14

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller