



An die interessierte Partei / To whom it may concern

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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[®] 140, GranuLac[®] 200, GranuLac[®] 230, PrismaLac[®] 40, SacheLac[®] 80, SorboLac[®] 400, SpheroLac[®] 100, Tablettose[®] 70, Tablettose[®] 80, Tablettose[®] 100

The above mentioned designations are MEGGLE's brand names for "Lactose Monohydrate" as defined in the monograph "Lactose Monohydrate" in the European Pharmacopoeia (Ph. Eur.).

This monograph is harmonized with USP-NF and JP.

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

Specification parameter	Value	Method
Specific optical rotation	+54.4° - +55.9° (anhydrous substance)	Ph. Eur. 2.2.7
Loss on drying	Monohydrate: max. 0.5%, Monohydrate, modified: max 1.0%	USP-NF (731)
Sulphated ash	max. 0.1%	Ph. Eur. 2.4.14

Freundliche Grüße / Best regards


Dr. Stefan Dreiheller