



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020
Page 1/1
Doc.-No. EIP-0006 -A
Revision 1

GMP, GDP, EXCiPACT™

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
- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 150, InhaLac® 160, InhaLac® 230, InhaLac® 250, InhaLac® 251
- Co-processed excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, StarLac®

For products manufacturing, release and distribution by **MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg, Germany** of the above mentioned products:

GMP according to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and USP General Information Chapter <1078> is implemented.

GDP principles, based on the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients, are implemented.

MEGGLE GmbH & Co. KG is GMP and GDP certified according to EXCiPACT™ standard for the manufacturing, testing, storage and distribution of lactose and co-processed excipients used as pharmaceutical excipient or claimed for pharmaceutical use.

Best regards

MEGGLE GmbH & Co. KG

Dr. Stefan Dreiheller
Dr. Stefan Dreiheller