



An die interessierte Partei / To whom it may concern

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Quality Unit / Regulatory Affairs

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Page 1/1
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GMP, GDP, EXCiPACT™

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: GranuLac® 70 (13007038), GranuLac® 200 (13006747), GranuLac® 200 (13007039)
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac® H

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.

Molkerei MEGGLE Wasserburg 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.

Subcontracted production and release site:
Agropur inc., 719 North Main Street, Le Sueur, MN 56058-1404, USA

Freundliche Grüße / Best regards

Molkerei MEGGLE Wasserburg GmbH & Co. KG


Dr. Stefan Dreiheller