



**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™**

MEGGLE products:

- Lactose Monohydrate USP-NF / Ph. Eur. / JP: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- 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