



**To whom it may concern**

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Director Quality MEGGLE USA

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## **GMP, GDP**

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

For products manufacturing at **Agropur inc., 719 North Main Street, Le Sueur, MN 56058-1404, USA** as the subcontracted production and release site as well as distribution by **MEGGLE USA Inc., 592 Route 22, Suite 2B, Pawling, NY 12564, USA** for 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 installed.

Furthermore, 21 CFR Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food is implemented.

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

The United States Food and Drug Administration (FDA) performs periodic inspections/audits. As per FDA policy, GMP certificates are not available.

Additionally, a HACCP plan is in place for the process to ensure product safety.

Best regards

**MEGGLE USA inc.**



Dr. Gabriele Müller