



To whom it may concern

Dr. Gabriele Müller
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 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food is implemented. Products are food grade and are manufactured in facilities using HACCP programs and risk based preventive controls to ensure food safety compliance.

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.

Best regards

MEGGLE USA inc.



Dr. Gabriele Müller