

INFORMATION

Quality Management



EIP-0051-USA

Revision 5

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GMP GDP

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70, GranuLac® 140, GranuLac® 200

- Anhydrous Lactose: DuraLac® H

For product 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 Chapter <1078> is installed.

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

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