

INFORMATION

Quality Management



EIP-0063-USA

Revision 3

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Preparation of Documents

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70, GranuLac® 140, GranuLac® 200
- Anhydrous Lactose: DuraLac® H

MEGGLE USA Specifications for MEGGLE USA Products are generated within a validated document management system.

Check and approval of documents is conducted via electronic signature. Electronic signature meets the requirements of 21 CFR Part 11.

Product release is conducted and the issue of MEGGLE USA Certificates of Analysis are generated within a validated ERP system.

This MEGGLE USA Information was electronically released and is valid without signature.