

INFORMATION

Quality Management



EIP-0071-USA

Revision 5

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BSE / TSE, Japanese Requirements

MEGGLE USA Products:

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

It is certified that the MEGGLE USA Products fulfill the requirements set up in Notice of the MHLW, No. 210, established on 20.5.2003, and revised on 26.09.2014 with Notice of the MHLW, No. 375.

The above mentioned products are Pharmaceutical grade Lactose Monohydrate / Anhydrous Lactose as the only “ruminant-derived raw material” as defined in Article 4 1. (1) of above mentioned Notice.

Pharmaceutical grade Lactose Monohydrate / Anhydrous Lactose is obtained from processed milk. According to Article 4 No. 1 (2) milk is regarded as “low risk raw material” for which restrictions regarding the country of origin do not apply.

The requirements mentioned in Article 4 Nr. 1 (3) do also not apply to low risk raw materials. Nevertheless it is confirmed, that, based on the information on the product (e.g. lot number), MEGGLE USA Products can be identified and traced back to raw material including production date of the product by relevant documentation. All traceability data are recorded and stored at the manufacturer according to the installed quality system for 7 years. In case Japanese authorities request traceability data they will be made available in appropriate time.

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