

INFORMATION

Quality Management



EIP-0055-USA

Revision 5

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Nanotechnology

MEGGLE USA Products:

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

It is the aim of nanotechnology to achieve new material properties which were previously unknown via building up nanostructures in materials.

The mentioned MEGGLE USA Products are not engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm).

The products are not engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).

The products do not contain any other material as constituents as mentioned in the MEGGLE Specification.

Furthermore, the mentioned MEGGLE USA Products are not manufactured with “nanotechnology” according EMEA/CHMP/79769/2006.

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