

INFORMATION

Quality Management



EIP-1034-USA-LM

Revision 3

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Microbial Testing Program

MEGGLE USA Products:

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

The MEGGLE USA Products conform to the monograph “Lactose Monohydrate” in the USP-NF, Ph. Eur, and JP. The monograph has undergone pharmacopoeial harmonization. The products conform to the monograph “Lactose Monohydrate” in the Chinese Pharmacopoeia (ChP). Testing is performed using the methods indicated in the respective product specification.

Monitoring of the specified and other microbiological parameters is performed as follows:

Parameter	Requirement	Frequency
Total aerobic microbial count (TAMC)	NMT 100 cfu/g	Every batch
Total combined yeast and mold count (TYMC)	NMT 10 cfu/g	Every batch
<i>Escherichia coli</i>	absence /10 g	Every 10 th batch
<i>Salmonella spp.</i>	absence /100 g	Every batch
<i>Listeria monocytogenes</i>	absence /25 g	2 / year

In the manufacturing process of the MEGGLE USA Products a heat treatment of min. 161.6 °F (72 °C) for min. 15 seconds followed by a second heat treatment of min. 194 °F (90 °C) for min. 30 minutes is performed. Measurements are installed to prevent recontamination of the product, e.g. closed production line and hygiene rules. It is ensured that the risk of microbiological contamination is minimized as far as possible.

Regarding Anaerobe Sporeformers (incl. *Clostridium spp.*):

The risk evaluation in the HACCP framework lead to the result that there is no strong increase in vegetative cells at any time and that the presence of *Botulinum* and *C. perfringens* toxins in the products can be excluded.

Furthermore, the following hygiene monitoring measures are installed:

- Environmental pathogen monitoring
- Microbiological air analysis
- Monitoring of hand cleaning and disinfection
- Water monitoring

The product is intended for oral application. Tests on endotoxin / pyrogen contamination are not conducted.

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