

INFORMATION

Quality / Regulatory Affairs



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Microbial Testing Program

MEGGLE Products:

Lactose Monohydrate: InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 145, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 230, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin

The MEGGLE Products conform to the monograph "Lactose Monohydrate" in the USP-NF, Ph. Eur, and JP. The monograph has undergone pharmacopoeial harmonisation. 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	Method	Requirement	Frequency
Total aerobic microbial count (TAMC)	Ph. Eur. 2.6.12	NMT 10 cfu/g	Every batch
Total combined yeast and mold count (TYMC)	Ph. Eur. 2.6.12	NMT 10 cfu/g	Every batch
Bile-tolerant gram-negative bacteria	Ph. Eur. 2.6.13	absence /10 g	Every batch
<i>Escherichia coli</i>	Ph. Eur. 2.6.13	absence /10 g	Every batch
<i>Salmonella spp.</i>	Ph. Eur. 2.6.13	absence /100 g	Every batch
<i>Pseudomonas aeruginosa</i>	Ph. Eur. 2.6.13	absence /10 g	Every batch
<i>Staphylococcus aureus</i>	Ph. Eur. 2.6.13	absence /10 g	Every batch
<i>Burkholderia cepacia</i>	USP-NF (60)	absence /10 g	Every batch
Bacterial endotoxins	Ph. Eur. 2.6.14	NMT 5 EU/g	Every batch

In the manufacturing process of the product a heat treatment of min. 72 °C for min. 15 seconds followed by a second heat treatment typically at about 97 °C (and in any case at more than 90 °C) for at least 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 minimised 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

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