



Microbial Testing Program

MEGGLE Products:

- Lactose Monohydrate: CapsuLac® 60, FlowLac® 90, FlowLac® 90 MS, FlowLac® 100, FlowLac® 90 MS, FlowLac® 100 SD, GranuLac® 70, GranuLac® 70 MS, GranuLac® 80, GranuLac® 140, GranuLac® 140 S, GranuLac® 200, GranuLac® 200 MS, GranuLac® 200 S, GranuLac® 230, Lactose Monohydrate Impalpable, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS

The MEGGLE Products conform to the monograph "Lactose Monohydrate" in the Ph. Eur, USP-NF 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	max. 100 cfu/g	Every batch
Total combined yeast and mold count (TYMC)	Ph. Eur. 2.6.12	max. 10 cfu/g	Every batch
<i>Escherichia coli</i>	Ph. Eur. 2.6.13	absence /10 g	Every 10th batch
<i>Salmonella spp.</i>	Ph. Eur. 2.6.13	absence /100 g	Every batch
<i>Listeria monocytogenes</i>	ISO 11290-1	absence /25 g	2 / year
<i>Staphylococcus aureus</i>	Ph. Eur. 2.6.13	absence /10 g	2 / year
<i>Pseudomonas aeruginosa</i>	Ph. Eur. 2.6.13	absence /10 g	2 / year

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 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 Information was electronically released and is valid without signature.