



To whom it may concern

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Revision 1

Microbial testing program

MEGGLE Product:

Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

The product conforms to the monograph "(Anhydrous) Lactose" in the Ph. Eur, USP-NF and JP. The monograph has undergone pharmacopoeial harmonization.

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

| Parameter | Requirement | Frequency |
|--|----------------|-------------|
| Total aerobic microbial count (TAMC) | Max. 100 cfu/g | Every Batch |
| Total combined yeast and mold count (TYMC) | Max. 50 cfu/g | Every Batch |
| <i>Escherichia coli</i> | absence / 10 g | Every Batch |
| <i>Salmonella spp.</i> | absence / 10 g | Every Batch |
| <i>Listeria monocytogenes</i> | absence / 25 g | 2 / year |
| <i>Staphylococcus aureus</i> * | absence / 10 g | 2 / year |
| <i>Pseudomonas aeruginosa</i> * | absence / 10 g | 2 / year |

* in unrefined material

In the manufacturing process of the product a heat treatment of min. 72 °C for min. 15 seconds followed by a second heat treatment of min. 90 °C for min. 30 minutes is performed. Furthermore, the product is drum dried at high temperatures. 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.

Best regards

MEGGLE USA inc.

Dr. Gabriele Müller