Microbial Testing Program

MEGGLE USA Product:
Anhydrous Lactose: DuraLac® H

The MEGGLE USA Product conforms to the monograph “(Anhydrous) Lactose” in the USP-NF, Ph. Eur, and JP. The monograph has undergone pharmacopoeial harmonization. The product conforms to the monograph "Anhydrous Lactose" 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
Escherichia coli	absence /10 g	Every batch
Salmonella spp.	absence /100 g	Every batch
Listeria monocytogenes	absence /25 g	2 / year

In the manufacturing process of the MEGGLE USA Product 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. The product is roller-dried at 185 °F (85 °C). 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. Pyrogen and endotoxins testing is not conducted.

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