

INFORMATION

Quality / Regulatory Affairs



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Microbial Testing Program

MEGGLE Product:

Co-processed Excipient: MicroceLac® 100

The MEGGLE Product is a co-processed, directly compressible spray agglomerate containing
- 75 % Lactose Monohydrate (Ph. Eur / USP-NF / JP) and
- 25 % Cellulose Microcrystalline (Ph. Eur / USP-NF / JP).

These compounds are in compliance with the respective monographs as follows:

Parameter	Lactose Monohydrate	Cellulose Microcrystalline
Total aerobic microbial count (TAMC)	Max. 100 CFU/g	Max. 1000 CFU/g
Total combined yeast and mold count (TYMC)	Max. 50 CFU/g	Max. 100 CFU/g
<i>Escherichia coli</i>	Absence in 10 g	Absence in 10 g
<i>Pseudomonas aeruginosa</i>	No requirement	Absence in 10 g
<i>Staphylococcus aureus</i>	No requirement	Absence in 10 g
<i>Salmonella spp.</i>	Absence in 10 g	Absence in 10 g

The compound Lactose Monohydrate is manufactured and released at MEGGLE. Additional monitoring on pathogenic microorganisms is installed as follows:

Parameter	Limit	Frequency
<i>Listeria monocytogenes</i>	Absence in 25 g	2 / year
<i>Staphylococcus aureus</i>	Absence in 10 g	2 / year
<i>Pseudomonas aeruginosa</i>	Absence in 10 g	2 / year

The compound Cellulose Microcrystalline is manufactured and released at approved suppliers. The compliance with the monograph is documented on the CoA of each delivery.

The microbiological properties of the product is specified and tested as follows:

Parameter	Limit	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 in 10 g	Every 10 th batch
<i>Salmonella spp.</i>	Absence in 10 g	Every batch

Due to manufacturing procedure and hygiene measures it is confirmed that other microbiological parameters of the compounds defined in the monographs are also fulfilled by the final product. 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.