



To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

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Revision 1

Microbial Testing Program

MEGGLE Product: CombiLac®

The product is a directly compressible spray agglomerate comprising 70 % Lactose Monohydrate (Ph. Eur / USP-NF/ JP), 20% Cellulose Microcrystalline (Ph. Eur / USP-NF/ JP) and 110 % Maize Starch (Ph. Eur / USP-NF/ JP). These compounds are in compliance with the respective monographs as follows:

Parameter	Lactose Monohydrate	Cellulose Microcrystalline	Maize Starch
Total aerobic microbial count (TAMC)	Max. 100 CFU/g	Max. 1000 CFU/g	Max. 1000 CFU/g
Total combined yeast and mould count (TYMC)	No requirement	Max. 100 CFU/g	Max. 100 CFU/g
<i>Escherichia coli</i>	Absence in 10 g	Absence in 10 g	Absence in 10 g
<i>Pseudomonas aeruginosa</i>	No requirement	Absence in 10 g	No requirement
<i>Staphylococcus aureus</i>	No requirement	Absence in 10 g	No requirement
<i>Salmonella</i>	Absence in 10 g	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 compounds Cellulose Microcrystalline and Maize Starch are 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. 1000 CFU/g	Every Batch
Total combined yeast and mould count (TYMC)	Max. 100 CFU/g	Every Batch
<i>Escherichia coli</i>	Absence in 10 g	Every Batch
<i>Salmonella</i>	Absence in 10 g	Every Batch



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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.

Best regards

MEGGLE GmbH & Co. KG

i.v. Stefan Dreiheller
Dr. Stefan Dreiheller