



To whom it may concern

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## Microbial Testing Program

MEGGLE Product: Reta M®

The product is a directly compressible spray agglomerate comprising

- 50 % Mannitol (Ph. Eur / USP-NF/ JP) and
- 50 % Hypromellose (Ph. Eur / USP-NF/ JP).

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

Parameter	Mannitol	Hypromellose
Total aerobic microbial count (TAMC)	Max. 1000 CFU/g	No requirement
Total combined yeasts/ moulds count (TYMC)	Max. 100 CFU/g	No requirement
Escherichia coli	Absence in g	No requirement
Salmonella	Absence in 10 g	No requirement

The compounds 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 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
Escherichia coli	Absence in g	Every batch
Salmonella	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.

Best regards

**MEGGLE GmbH & Co. KG**

represented by MEGGLE Verwaltungs GmbH

  
Dr. Stefan Dreiheller