

INFORMATION

Quality / Regulatory Affairs



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Stability Tests, Shelf Life

MEGGLE Products:

- Lactose Monohydrate: CapsuLac® 60, FlowLac® 90, FlowLac® 90 MS, FlowLac® 100, FlowLac® 100 MS, FlowLac® 100 SD, GranuLac® 70, GranuLac® 70 MS, GranuLac® 80, GranuLac® 140, GranuLac® 140 S, GranuLac® 200, GranuLac® 200 MS, GranuLac® 200 S, GranuLac® 230, InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 145, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 230, InhaLac® 240, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS

- Co-processed Excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, MicroceLac® Plus, RetaLac®, StarLac®

All "Low Nitrite" Grades are included.

Stability studies according to the Excipient Stability Guide for Pharmaceutical Excipients published by IPEC have been performed for defining a shelf life for the above mentioned MEGGLE Products.

An Ongoing Stability Program is implemented.

Results can be given on request.

The assigned shelf life is expressed for specific production batches as expiry date or retest date.

MEGGLE does not perform any retesting and stability data for the time period after shelf life are not available. Under the full responsibility of the customer, the customer may retest and use the above mentioned products after the defined shelf life. For this MEGGLE will not accept any liability.

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