

INFORMATION

Quality Management



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Stability Tests, Shelf Life

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose: DuraLac® H

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 USA 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 USA 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 USA will not accept any liability.

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