Shelf-Life Statement

Product group: Lactose and Inhalation

Brand name: Lactochem®, Lactohale®, Lactopress®, Pharmatose®, Respitose®, SuperTab®

Document No.: PD-0115

Dear Customer,

DFE Pharma GmbH & Co. KG has defined a shelf life for all its products based on a stability testing program conform to IPEC Excipient Stability Program Guide 2026. DFE Pharma guarantees that its products comply with all pharmacopeial specifications up until the end of their shelf-life period (the expiry date / retest date respectively), when stored in the original unopened packaging at room temperature (normal warehouse conditions).

For pharmaceutical grade lactose products the established shelf life is listed below:

Brand Name	**Shelf Life**	**Expressed as Expiry Date / Retest Date**
Pharmatose®	3 years	Expiry Date
Respitose®	3 years	Expiry Date
SuperTab® AN	2 years	Expiry Date
SuperTab® SD EU	2 years	Expiry Date
SuperTab® SD NZ	3 years	Expiry Date
SuperTab® GR	3 years	Expiry Date
SuperTab® 24AN	2 years	Expiry Date
SuperTab® 40LL	3 years	Retest Date
SuperTab® 50 ODT	3 years	Retest Date
SuperTab® LM75	18 months	Retest Date
Lactohale® NZ	3 years	Expiry Date
Lactohale® 100/200 grades	3 years	Retest Date
Lactohale® 300	1 year	Retest Date
Lactohale® 400	1 year	Retest Date
Lactochem®	3 years	Retest Date
Lactochem® Extra/Super Fine Powder	1 year	Retest Date
Lactochem® Microfine	6 months	Retest Date
Lactopress® AN	2 years	Retest Date
Lactopress® GR	3 years	Expiry Date
Lactopress® SD/ SuperTab SD NL	3 years	Retest Date

Shelf life of customized products may differ from the above list.

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Dates of production and expiry date / retest date respectively are printed on every packing unit and on the corresponding Certificate of Analysis.

DFE Pharma does not perform retesting at the end of the shelf-life period. It is the customer's responsibility to determine if the product can still be used in their application after the end of the shelf-life period.

This statement substitutes all previous versions issued for the brand names mentioned above.

We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : Peter Ebben
Job title : Global Quality Control Manager
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

DFE Pharma GmbH & Co. KG

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