Shelf Life – Statement

Product group: Superdisintegrants
Brand name: Primojel® and Primellose®
Document No.: PD-0313

Dear Customer,

DFE Pharma GmbH & Co. KG has defined a shelf life for all of its products based on a stability testing program conform to IPEC Excipient Stability Program Guide 2022. DFE Pharma guarantees that its products comply with all pharmacopeial specifications up until the end of their shelf life period (the expiry date), when stored in the original unopened packaging at room temperature (normal warehouse conditions).

For superdisintegrants the established shelf life is listed below:

Brand Name	Shelf Life
Primojel®	5 years
Primellose®	5 years

Dates of production and expiry date 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 customers' 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.

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