# Stability studies

# SHELF LIFE AFTER OPENING

## Background

**Apart from (long-term) studies conducted under defined conditions, it is also necessary to carry out studies on shelf life after opening for medicinal products packaged in multidose containers. This is governed by the "Note for guidance on in-use stability testing of human medicinal products" (CPMP/QWP/2934/99).**

## Strategic evaluation

Unfortunately, the Note for guidance only outlines a few basic aspects, and does not contain any details concerning the study concept. These have to be devised and formulated individually for each medicinal product, whereby the study design is oriented to the nature of the dosage form, the dosage, the planned duration of use, the packaging and other product-specific factors.

## Study concept and implementation

A good study concept encompasses many different aspects. In order to document stability after the container has been opened for the first time in the context of a so-called "in-use stability study" within the framework of the marketing authorisation procedure, use of the product in practice must be simulated as realistically as possible in order to establish a reference to the instructions for use. A good study concept also combines the most practically relevant opening, removal and closing actions that can be expected in the hands of the user, with an economically expedient implementation, as certain dosage regimes can give rise to very complex removal cycles, which impose high demands on the deployment of human resources. The challenge lies in finding the right balance between a realistic in-use design, cost-effective implementation and an expedient quantity structure for the analytical tests. As always, you can rely on PhytoLab's long-standing expertise, reliability and diligence with respect to every aspect of the study concept.

## Scope of testing

We have recently established the Test for Efficacy of Antimicrobial Preservation in accordance with Ph. Eur. 5.1.3 at the PhytoLab laboratory. This test is particularly important for liquid or semi-solid products, which may come into contact with the user's skin microflora (e.g., bacteria, yeasts, fungi). Other tests relevant for stability are derived from the product specification as applicable. PhytoLab offers a wide range of pharmacopoeial methods for these tests. We develop individual product-specific identity and assay methods for your product or apply your methods following the transfer to our laboratory.

## Need for action

In-use studies are a prerequisite for marketing authorisation of medicinal products in multi-dose containers. And, even when marketing authorisation has been obtained, it is necessary to check the shelf life after opening on many occasions: if packaging materials or package sizes are changed, the formulation is revised, or the shelf-life duration is changed.

**Our experts will be happy to advise you.**

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