

# Stability studies under GMP conditions

**CURRENTA Analytics**

## **We offer:**

- Stability and influencing factor studies according to ICH guidelines e.g., Q1A/Q1F, Q1B and VICH GL 3.
- Accompanying analytics (chromatographic procedures, determination of chemical indicators, XRD etc.)
- Many years of experience in the coordination, conduct and evaluation of stability studies and related analyses.

## **This means for you:**

- Analytical support for ensuring the quality of your active ingredient or drug product from development through to market authorization and launch.

## **Benefit from our expertise:**

- Comprehensive counselling by our experts.
- Customized project planning and analytics.

**Samples such as tablets, solutions, active ingredients, and other matrices arranged in various packages can be stored and analyzed.**

## Choose your study design

| Stability studies                | Influencing Factor studies  | Freeze and thaw studies  |
|----------------------------------|---|--|
| 25°C / 60% rh                    | Photostability testing  | Storage at up to -20°C for short-time periods and ensuing storage at higher temperatures for e.g. 40°C |
| 30°C / 75% rh<br>(30°C / 65% rh) | Thermal stressing <ul style="list-style-type: none"> <li>• temperature</li> <li>• humidity</li> </ul> |  |
| 40°C / 75% rh                    |   |  |

→ If you cannot find the study design or condition required, please contact us. We are sure to find a solution!

### Process of your product study



**1.** Customized order coordination



**2.** You receive your individual study quotation



**3.** Creation of the respective project plan



**4.** Preliminary testing and performance of GMP validations



**5.** Conduct of the study under the required conditions



**6.** Continuous review of the quality management



**7.** Accompanying evaluation and creation of product reports

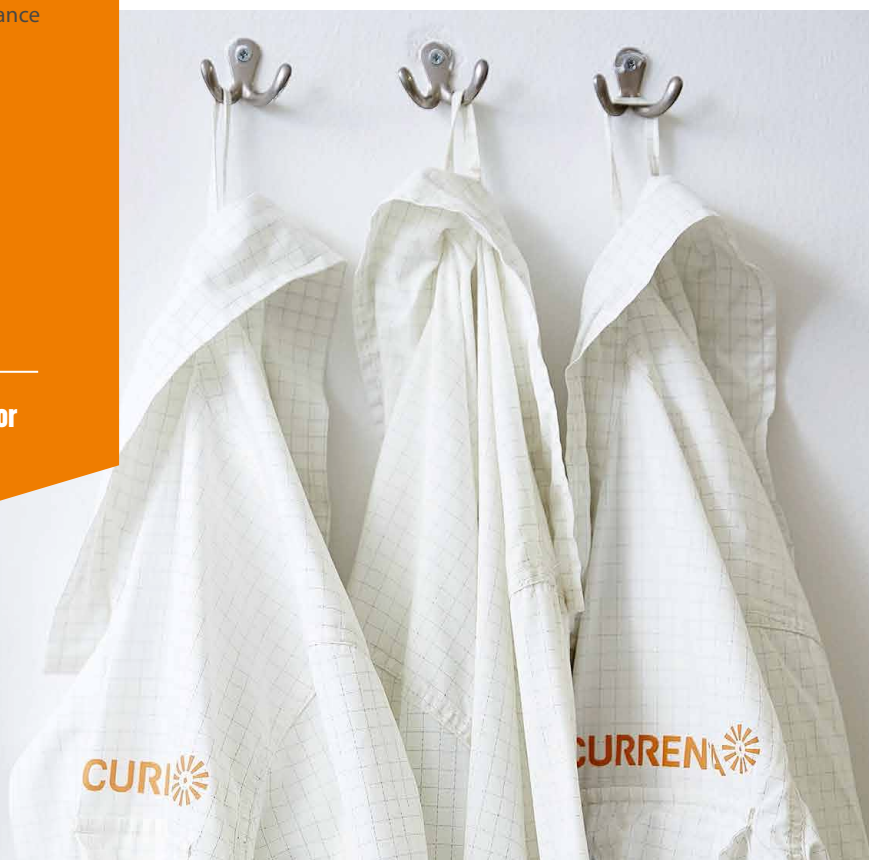
We are at your side as a reliable partner for the analyses of your product.

Furthermore, we can support you with the evaluation as we can perform expiry dating simulations/calculations, poolability testing or calculations according to ICH Q1E guideline in general with the obtained data in our laboratories.

### What do we need from you?

#### Information about

- the required study design
- the product characteristics
- the analytics which need to be tested



Feel free to contact us!

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