



Drug safety – A major issue in the patient protection worldwide

Globalization has many advantages. Products and services are available around the world. At the same time, standards have to be harmonized in order to ensure uniform quality and safety parameters. One particularly sensitive area is drug safety. The DiapharmGroup is an alliance of consulting and service companies who are active in the pharmaceutical and health products industry. The Zentralinstitut Arzneimittelforschung GmbH (Central Institute for Drug Research) is the service laboratory of the DiapharmGroup and is responsible for quality control of its products. It is certified in accordance with Good Manufacturing Practice (GMP) and is authorized to approve drugs for the market pursuant to the German Drug Law.

ICH stability tests

The ICH stability tests are performed at the Zentralinstitut Arzneimittelforschung GmbH using KBF series constant climatic test chambers from BINDER GmbH. The ICH tests are a significant component in the process of certifying or registering a product; the characteristic to be documented in this particular case is product stability with respect to a defined climatic condition over a specific time period (shelf life). In addition to the tests for drug certification/registration, “ongoing stability tests” have become increasingly important. These tests are part of the continuous monitoring of drug quality in accordance with Good Manufacturing Practice (GMP). Their purpose is to substantiate that

Requirements

- ▶ Method development
- ▶ Method validation
- ▶ Quality control for drug approval
- ▶ Stability testing for certification and/or registration, pharmacovigilance
- ▶ Precision
- ▶ Standard compliance

BINDER Solutions

- ▶ Constant climate conditions
- ▶ Norm-compliant work according to ICH guideline Q1A (R2)
- ▶ Temperature and humidity in one chamber
- ▶ Photostability testing
- ▶ Documentation and software FDA and GMP/GLP compliance
- ▶ Temperature range: 0 C° to 70 C°
- ▶ Humidity range: 10 % to 80 % RH



the pharmaceutical product has the stability (quality) appropriate to its indicated shelf life. At the same time, any negative influences on stability, e.g., due to a change of suppliers, should be detected or, even better, prevented from occurring at all. Since 2006, the GMP guideline has stipulated new obligatory specifications for the preparation of product quality reviews and the ongoing stability testing incorporated in them. Consequently, as part of periodic inspection, the regulatory authorities also focus on the special equipment required for stability testing, in this case primarily chambers for constant climatic conditions.

BINDER covers not only the climatic range required by ICH guidelines, but also a far larger climatic spectrum.

Best climatic condition in accordance to ICH-Q1A

The test climates pursuant to ICH-Q1A must be maintained reliably and accurately. Stability experiments can extend over a period of three to five years. Such requirements are no problem for BINDER from the KBF series constant climate test chambers. Between 5 and 15 product batches are stored in each constant climate test chamber, where they are exposed to defined climates for specific time periods.

International standards

Another important item is compliance with international standards. BINDER covers not only the climatic range required by ICH guide-



▲ Stability test according to ICH-Q1A

lines, but also a far larger climatic spectrum. Tests can be run humidity-free at temperatures between 0 °C to 70 °C. Climatic testing with humidity covers a temperature range of 10 °C to 70 °C, with a relative humidity range of 10 % RH to 80 % RH.

An optional lighting system in accordance with ICH Q1B, Option 2, is available for the KBF constant climate test chamber. Here, pharmaceutical products are exposed to defined light quantities from defined lighting sources under constant climatic conditions; under ICH-Q1B, Option 2, separate lighting sources are provided for visible and UV light.

Advantages

- ▶ Unconditionally reliable stability testing
- ▶ Precise maintenance of constant climate conditions
- ▶ Quality "Made in Germany"
- ▶ Complete Solution in one chamber

Areas of application

- ▶ Cosmetics industry
- ▶ Food/Beverage
- ▶ Pharmaceuticals industry
- ▶ Packaging industry



▲ Constant climate chamber KBF

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Product Request Series KBF