



Weleda tests anthroposophic medicine in line with ICH guidelines

The work of the holistic natural cosmetics and anthroposophic medicine manufacturer Weleda is based on the spiritual philosophy of Rudolf Steiner and aims to unite humankind and nature in perfect harmony. The company was founded in Arlesheim (Switzerland), with two further hubs added in Huningue, (France) and Schwäbisch Gmünd (Germany) over the years. These three sites are where the majority of the around 1,000 natural raw materials are turned into 120 natural cosmetic products and several thousand medicines. These products are manufactured on a purely natural basis without any artificial preservatives, and to this end,

Weleda even has its own biodynamic horticulture and tincture production facilities .

Medicine testing in line with ICH guidelines

Weleda's Quality Control Analysis Service handles not only analytical and microbiological release testing and methodology development, but also medicinal stability studies in line with ICH guidelines (International Conference on Harmonisation) in a GMP-compliant (Good Manufacturing Practice) environment. The ICH guidelines stem from the European Union's GMP (EU-GMP). The purpose of standardizing technical standards across

Requirements

- ▶ Stability testing in line with ICH guidelines for medicine
- ▶ Testing for stability after opening
- ▶ Accelerated aging process
- ▶ Controlled microbiological infestation
- ▶ Constant climatic conditions
- ▶ Cyclical temperature and humidity values

BINDER solutions

- ▶ Climatic conditions compliant with ICH guidelines
- ▶ KBF 720 constant climate chamber
- ▶ MKF 240 dynamic climate chamber
- ▶ BD and KB incubators
- ▶ Variable temperature and humidity settings
- ▶ Homogeneous temperature distribution inside the chamber
- ▶ Fast recovery time
- ▶ Incubation with cooling function



▲ Jochen Grimm, Weleda Qualification Team Leader for Schwäbisch Gmünd, Germany

the pharmaceuticals industry is to ensure that medicines can be clearly recognized by the respective regulatory authorities in Europe, Japan, and the USA. Weleda has been using BINDER's KBF 720 constant climate chambers and MKF 240 dynamic climate chambers for years to carry out these studies, not to mention several incubators from the BD and KB series. "We have been working with BINDER units for years now and have total confidence in the high levels of reliability, service and support that go hand in hand with the chambers," explains Jochen Grimm, Qualification Team Leader responsible for manufacturing, validating, and qualifying cooling and air conditioning units. The medicines are subject to stringent safety precautions and are therefore also tested in accordance with the European Pharmacopoeia (Ph. Eur.), the German Homeopathic Pharmacopoeia (HAB), or the German Pharmacopoeia (DAB) depending on requirements.

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*Jochen Grimm,
Qualification Team Leader*

In accordance with ICH guidelines and depending on the specified climate zone, the compounds remain in a BINDER con-



▲ *Medicine stability test in a KMF constant climate chamber*

stant climate chamber with constant conditions of 25 °C / 40 % RH; 25 °C / 60 % RH; 30 °C / 65 % RH; or 40 °C / 75 % RH for a period of 6 to 120 months. The investigation cycles are also performed in line with the specifications listed in the ICH guidelines. Tests for stability after opening – also known as "in-use" tests – are oriented toward the use of compounds and aim to establish their shelf-life in relation to their actual conditions of use.

Accelerated aging process

In addition to the stability test, laboratory staff also perform long-term simulations with dynamic climatic conditions in a MKF 240 dynamic climate chamber. The specimens are exposed to extreme climatic conditions under cyclical temperature and humidity values to accelerate the aging process and allow staff to investigate the behavior of the products in cases of heavy exposure. Jochen Grimm believes that the ability to vary the temperature and

humidity settings presents a real advantage. "The chambers maintain the set values with the utmost precision. Not only that, but the temperature and humidity are distributed homogeneously throughout the inner chamber."

Unmatched safety

Medicines are subject to stringent safety standards, yet in spite of these precautions, the specimens still have to undergo regular checks for germs. To this end, BINDER laboratory staff use BD incubators and KB cooling incubators.

At the heart of every interaction between Weleda and its partners, suppliers, and employees lies its underlying ambition to unite humankind, the company, and nature in perfect harmony. The company has upheld this philosophy for over 90 years and never faltered from its renowned quality standard.

Advantages

- ▶ Extended temperature range from -10 °C to 100 °C
- ▶ Large climate range of up to 90 % RH
- ▶ Automatic water and waste water management
- ▶ Precise climate conditions
- ▶ Fast and precise humidification

Areas of application

- ▶ Pharmacy
- ▶ Automotive
- ▶ Packaging



▲ *KBF 720 constant climate chamber*

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