



## Stability test of hemp flowers in accordance with ICH

### **On the trail of the medical use of cannabis**

**After a world-wide ban of cultivating cannabis, the restrictions have been loosened recently, so that companies such as Ai Fame are on legally safe ground to extract and research active substances of the cannabis plant. In a Memmert climate chamber ICH, the necessary stability tests are performed in accordance with ICH.**

### **Cannabis is one of the oldest cultivated plants**

The first Gutenberg Bible was printed on hemp paper, as was the United States Declaration of Independence. Clothes and marine ropes were made of hemp and it was also used in pharmaceuticals in the ancient Chinese and Egyptian high cultures as well as in the medieval European monasteries.

For many decades, cannabis was one of the most important cultivated plants of humanity until cultivating cannabis was prohibited world-wide in 1961 after a decade-long anti-drug campaign. Naturally, the pharmaceutical research on the



Climate chamber ICH

cannabis plant came to an almost complete halt as a consequence.

## **Even the body “produces” cannabis-like substances**

The discovery of a natural endocannabinoid system in the body of mammals was the catalyst for intensified research. It was discovered that the contents of the hemp flower, the so-called cannabinoids, such as THC and cannabidiol, attached to specific cell receptors. Subsequently, substances that are produced by the body and also activate these cannabinoid receptors – endocannabinoids (“naturally produced cannabinoids in the body”) – were focused on in research. So far, not much is known about the effective mechanisms of this system. Eating disorders, pains, depressions or anxiety disorders are discussed as possible indications for pharmaceuticals made of cannabis.

## **Ai Fame develops own procedure to extract cannabinoids**

Due to its intoxicating effect, tetrahydrocannabinol (THC) is probably the most known content of **cannabis**. In many countries, different regulations about the maximum THC content of industrial hemp exist. These limitations call for costly procedures to extract THC and other **cannabinoids** from the hemp flower. [Ai Fame GmbH](#) in the Swiss canton of St. Gallen has succeeded in making the active herbal substances of the **cannabis plant** water-soluble and thus more readily processable for the first time in the world. Currently, leaves, buds, pollen and seeds of the indoor-cultivated **cannabis plants** are sold for the production of liqueur or as a basis for pest control in the agricultural sector.

## **Stability test in the climate chamber ICH**



**Hemp-cheese**

Back in 2010, GMP (good manufacturing practice) was introduced in the company, paving the way for the approval of active substances for the pharmaceutical industry. The aim for the future is to extract various pharmaceutical ingredients from the flower and pollen of the **cannabis plant** by means of high pressure extraction. For stability testing of the cannabis flowers in accordance with the **ICH guideline**, the test laboratory Ai Lab Swiss uses a **Memmert climate chamber ICH**. Samples are exposed to a climate of 25 °C and 60% rh for up to one year. Due to the long test duration, the consistently good and thus standard-compliant temperature and humidity distribution in the chamber and the uninterrupted logging and documentation of all test parameters in the chamber was of particular importance to the company.

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#### **An overview of the main topics**

- Cannabis, hemp, hemp flower
- Pharmaceutical product, medicinal plant, medical use
- Cannabinoids
- Stability testing, ICH guideline
- Climate chamber, constant climate chamber

Sources:

[Wikipedia on Cannabinoids](#)

[Cannabis in medicine](#)

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#### **Stability test of soya products**

In the microbiological laboratories of the Belgian headquarters of Alpro, accelerated tests and further microbiological tests are performed in Memmert heating ovens and cooled incubators.

[more information](#)

#### **Memmert climate chambers**

[Constant climate chamber HPP](#)

[Climate chamber ICH](#)

[Temperature test chamber TTC](#)

[Climatic test chamber CTC](#)

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