



Ciba^â Testing Services

Case Study

Investigations and Analytical Support under Good Manufacturing Practice (GMP)

Problem

The successful registration of an Active Pharmaceutical Ingredient (API) or a pharmaceutical formulation (as a drug) needs a well-defined set of analytical studies and investigations, which have to be performed according to GMP-requirements. Especially innovative small- and mid size pharmaceutical companies can often not utilize the necessary lab capacities for all required investigations in the area of analytical development, validation and stability tests in an appropriate time frame.

Solution

Ciba Expert Services offers the full range of analytical support covering successful GMP registration. Typical GMP-Studies, which could be conducted in our labs are:

- Method development for Assay and Impurity tests
- Validation of analytical methods
- Qualification of Reference Materials ("in-house" primary standards)
- Stress Test
- Stability Studies according to the ICH requirement at different conditions
- Analysis of Residual Solvents
- Trace and ultra trace analysis of toxic organic compounds (e.g. PCDD/Fs, PCBs, aromatic amines etc.)
- Extractables, leachables and migration studies for medical devices and medicinal packaging

Analytics in Regulated Areas – Studies under Good Manufacturing Practice

Head space GC for performing traditional on-column GC injections and headspace injections



Your Advantage

With Ciba Expert Services as partner our customers can utilize highly specialized laboratories and experienced personnel for their GMP-studies. We perform quality control analysis, stability tests and other GMP-studies since many years. We have a modern state-of-the-art equipments and appropriate laboratory environments.

Examples

Small-sized Pharmaceutical Manufacturer in Germany	Stability Test for 3 years, including the entire method development plus validation for all necessary analytical tests
Mid-sized Pharmaceutical Manufacturer in USA	Method development for preliminary studies in the area of a NDA registration in US.
Pharmaceutical Industries in Switzerland	Determination and validation of PCDD/F analysis in new APIs.
Cosmetics Industry	Determination of PCDD/F in toothpaste samples

The Ciba GMP laboratories are approved by the US-FDA and in Switzerland also by SwissMedic.

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