



Ciba^â Testing Services

Case Study

GLP Studies for Notification/Registration

Problem

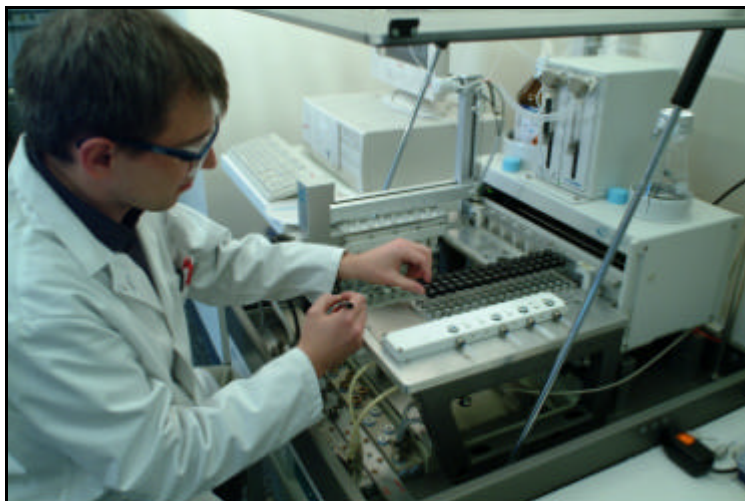
A successful notification of a new chemical requires analytical studies and investigations. Depending on the country these studies have to be performed under GLP-requirements. Especially small- and mid size companies can often not utilize the necessary lab capacities or even have no own GLP testing facilities.

Solution

The Testing Services group of Ciba Expert Services offers the full range of analytical support covering a successful GLP registration. Our Scientists at various testing facilities can conduct GLP Studies as Study Directors or act as Principal Investigator; fortunately within Ciba Expert Services there are not only GLP testing facilities but also PS&R specialists, who are experienced with the notification of new chemicals in all countries all over the world.

Analytics in Regulated Areas – Good Laboratory Practice (GLP) Studies

SPE clean up of migration extracts prior to measurement



Application/Use

Typical GLP studies, which are conducted in our labs, are:

- Certificate of Analysis including structure elucidation, impurity profile, metal & elemental analysis, water content, residual solvents etc.
- Determination of physico-chemical properties (melting point, vapor pressure, water solubility, log K_{OW} and other OECD tests). We are specialized in the determination of low vapor pressures and water solubility at extreme low levels (ng/L).
- Analytical support in tox.-studies and eco-tox.-studies (OECD-Tests).
- Migration tests (BfR (old BGVV), FDA).
- Qualification of Reference Materials and metabolites used in GLP Studies (CoA for references).
- Special trace and ultra trace analysis of toxic organic compounds (e.g. PCDD/Fs, PCBs, aromatic amines etc.).

Your Advantage

With Ciba Expert Services as partner you can not only utilize highly specialized and experienced laboratories with top scientific support **but** you have also access to our regulatory experts for your GLP-studies and registration.

The Ciba GLP testing facilities in Switzerland are approved by the Swiss authorities (BUWAL and BAG).

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