Quality control, development and validation of analytical methods for medicines

To compete in the fine chemicals, pharmaceutical and biotechnology markets, companies are looking for more flexibility and specialisation. Outsourcing certain activities such as analytical development, validation and control allows them to gain agility and efficiency in both routine analytical processes and those requiring the development of new methods. Outsourcing also makes it possible to cope with seasonal increases in these activities.

Attentive to the demands of the sector, Applus+ Laboratories offers a service for the development and validation of analytical methods, quality control of raw materials and medicines and stability studies.

We are a Pharmaceutical Laboratory accredited by the AEMPS for the Physical-Chemical Quality Control (GMP) of investigational medicinal products for human and veterinary use. In addition, we work under the standards of the European (EMEA) and American (FDA) pharmacopoeias.

Applus+ Laboratories quality control, development and validation services for analytical methods for medicines

The main analytical services we offer are:

- Analytical method development and validation (ICH Q2)
- Optimisation of existing analytical methods
- Characterisation of Active Pharmaceutical Ingredients (APIs)
- Analysis of raw materials (Eur. and US Pharmacopeia)
- Batch testing of APIs and Medicinal Products for release

- Stability studies (ICH Q1)
- Forced degradation studies
- Identification, Synthesis and Characterisation of impurities

Highly specialised laboratories

Our laboratories also have the following analytical techniques and instrumentation available:

- Liquid chromatography (HPLC-DAD, UPLC-DAD)
- Gas chromatography (GC-MS, GC-FID)
- Spectrophotometry (ICP, FT-IR, UV-VIS)
- Potentiometric titrations
- Karl Fischer titration

Chemical process development

Applus+ Laboratories has been working for more than 30 years with companies in the fine chemicals, pharmaceutical and biotechnology sectors, offering services from product development to commercialisation. Our expertise and facilities allow us to intervene in all phases of chemical process development. This includes:

- Fine chemical process development.
- Scale-up of chemical processes.
- Development and validation of analytical methods, and quality control for batch testing.
- Production under GMP.

We work under global reference standards. We apply the highest criteria of confidentiality.

Benefits of choosing Applus+ Laboratories as a GMP Chemical Analysis Laboratory

Pharmaceutical companies can receive several benefits from choosing Applus+ Laboratories to outsource their development, validation and quality control activities, including:

- Increased agility and efficiency in both routine analytical processes and those requiring new method development.
- Coping with seasonal increases in these activities.
- Ensuring the quality and safety of your product.
- Accelerate time-intensive activities in project development.
- Increase the flexibility of human and material resources.