

Analytical methods development and validation

Outsource the development and management of the analytical controls and the validation of analytical methods for active ingredients and dosage forms.



To compete in the fine chemicals, pharmaceutical and biotechnology markets, companies seek to become more flexible and specialized. The outsourcing of certain activities such as development, validation and analytical controls allows them to increase their speed and efficiency in both, their routine analysis procedures and those that require the development of new methods. Outsourcing also lets them handle seasonal increases in these activities.

Our solution

Applus+ Laboratories offers analytical methods quality control, development and validation services for both, raw materials and finished products.

We work under the standards of the European and American pharmacopoeias (EMA, FDA)

Among others, we collaborate on projects for:

- Development of analytical methods
- Characterization of active pharmaceutical ingredients (API) for quality control or DMF (Drug Master File) production
- Dosage form analysis for quality control or the development of the pharmaceutical file
- Validation of different analytical methods

Our analytical services include:

- Physical-chemical control
- Stability studies under ICH
- Analytical methods validation

Highly specialized laboratories:

- Liquid chromatography (HPLC-DAD, UPLC-DAD)
- Gas chromatography (GC-MS, GC-FID)
- Spectrophotometry (ICP, FT-IR, UV-VIS)

Our expertise and our facilities allow us to participate in all the stages of the development of chemical processes:

- Fine chemistry process development
- Scale-up of chemical processes
- Analytical methods development and validation
- Production under GMP

Applus+ has worked for over 15 years with companies in the fine chemicals, pharmaceutical and biotechnology industries offering services from the research stage to the product marketing stage.

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

Benefits

- Ensure product quality and safety
- Speed up the time-intensive activities during project development
- Increase the flexibility of human and material resources