

Analytical Method Development and Validation

Eurofins provides development and validation of analytical methods according Pharmacopeia (EP, USP, BP, JP, etc.), FDA and ICH guidelines (Q2A, Q2B), considering always the specific needs of the Sponsor in each step of product development and/or marketing: R&D, stability testing, quality control, validations, etc.

The studies are carried out by professionals with a deep knowledge of pharmaceutical regulations with a vast range of analytical techniques and state of the art equipment.

Eurofins provides a detailed report of the set up, optimization and validation phases, performing the studies according to GLP regulations

Analytical methods are developed and validated for drug substances (API), excipients, drug products, degradation products and related substances, residual solvents, etc.

Development of analytical methods for identification, purity and concentration:

- Separation and characterization of impurities and degradation products
- Analytical investigations and identification studies
- Set up and optimization of the parameters of the analytical methods according to specific requirements of the Sponsor

Method validation:

- Specificity
- Linearity
- Range
- Accuracy
- Precision
- LOD/LOQ
- Robustness
- System suitability

Once the method is validated, Eurofins supports the Sponsor during method transfer with specific tests, analysis, training and advisory.