



KYMOS

Method Development and Validation

- Analytical Development and Validation supporting your pharmaceutical development
- Analytical Method Transfer to routine testing sites
- Tailored designs fit-for-purpose and comprehensive documentation
- GLP and GMP certification, EMA and FDA inspected laboratory



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METHOD DEVELOPMENT AND VALIDATION

KYMOS and PHARMAPROGRESS have GMP laboratories, EMA and FDA inspected, fully dedicated to method development and validation for CMC purposes.

We develop and/or validate analytical compendial and non-compendial methods for excipients, APIs, preservatives, intermediate and finished pharmaceutical products, according to the ICH Q2(R1), in line with Q6A and Q6B and FDA guidelines. Once validated, methods are ready for transfer to the contract-giver, in compliance with EU-GMP chapter 6, performing a interlaboratory reproducibility test within a co-validation between two sites or a revalidation.

METHOD VALIDATION

We use comprehensive method validation designs fit for purpose depending on test type and pharmaceutical development phase, being flexible to adapt our protocol to different client's requirements. Regulatory validations are carried out following relevant ICH guidelines and published USA and EU compendia guidances. We have large experience with methods used for different purposes such as:

- Identification
- Assay testing
- Related substances
- Residual solvents
- Elemental impurities
- Impurity testing (specifically, genotoxic impurities)
- Dissolution testing
- Stability indicating methods
- Leachables and extractables
- Cleaning and process validation

ADDED VALUE

- Wide experience in extremely challenging projects.
- Dedicated team and instrumentation for Development & Validation.
- Adjusted timelines and competitive prices.

ANALYTICAL TECHNIQUES

The available techniques in our laboratories are the following ones:

- UV/visible spectroscopy
- IR, FTIR
- HPLC with different detectors: Variable wavelength (VWD), diode array (DAD), refraction index (RI), evaporative light scattering (ELSD), amperometric and fluorometric
- LC/MS: single QAD and Triple Quad with QTrap
- GC: Flame ionization detector (FID), electron capture detector (ECD), thermal conductivity detector (TCD), with direct injection and headspace analysis
- GC/MS
- Atomic absorption spectrophotometry (flame with graphite furnace and hydride generator system)
- ICP/MS
- Karl Fisher volumetric and coulometric (with oven sample processor)
- Dissolution testing
- Cascade impactor for OINDPs
- In vitro Release test for semi-solids with vertical diffusion cells

