

GMP Method Development

Efficient and cost-effective outsourced pharmaceutical analyses begin with the development and validation of methods that provide reliable results time after time, regardless of the analyte class or composition of the product formulation. Because establishing such methods requires significant technical experience, our GMP method development and validation group is staffed by analytical scientists with an average of more than 15 years of experience in this discipline. This expertise allows us to apply lessons learned from a vast array of previous projects to address the challenges you may be experiencing with difficult separations, unusual degradation pathways, or other complex analytical issues in a prompt, professional manner.

Our flexible approach to project management allows us to develop and/or validate analytical methods according to client or Eurofins AvTech SOPs. When complete, methods may be transferred to our own GMP pharmaceutical testing group or back to the client for routine application. The choice is yours, but regardless of the ultimate destination of the final methods, USP and ICH guidelines provide the blueprints for all of our method development efforts.

Specific Expertise

- Potency Assays (Active Ingredients)
- Stability-indicating Assays
 - Active ingredients, impurities, and degradants
 - Forced degradation & peak purity
- Dissolution Methods (Endpoint or Profile Analysis)
- Residual Solvents Methods by GC (Headspace or Direct Injection)

Special Capabilities

- Impurity Identification — Structure determination by LC/MS fragmentation pattern or NMR
- Methods for Cleaning Validation Samples
- In Vitro Drug Release Testing for Semisolid Formulations (Franz Cells)
- Controlled Substance License (Schedules II-V)

Technologies

- UPLC®
- HPLC-UV and HPLC-FL
- GC-FID & GC-MS
- Thin Layer Chromatography — Qualitative or Semi-Quantitative
- USP Dissolution
- Franz Cell Diffusion Apparatus