ALTASCIENCES

PHARMACEUTICAL ANALYTICAL SERVICES

Altasciences' CDMO has a full range of analytical testing capabilities for pharmaceuticals and nutritional supplements, and an experienced team ready to meet your needs. Your project defines the service model that works best.

Excipient and Active Pharmaceutical Ingredients (APIs)

API (raw material) services are delivered to meet budget and timelines.

Services include:

- Sourcing
- Purchasing
- Logistics
- Receipt
- Transfer
- Sampling
- Testing
  - United States Pharmacopeia/ National Formulary (NSP/NF)
  - European Pharmacopeia (EP)
- Release
- Packaging
- QA approval
- Disposal

Drug Product Release and Stability Testing

Full array of small molecule analytical techniques to evaluate your API and drug products.

- HPLC/UPLC
- Dissolution and disintegration
- Moisture analysis (gravimetric and KF titration)
- Spectroscopy (UV/VIS/IR)
- Total organic carbon analyzer (TOC)
- Viscosity
- Particle size analysis
- FTIR

Monograph release testing per the USP, EP, BP, and JP.

Onsite ICH Environmental Conditions

- 80 °C
- 20 °C
5 °C
25 °C/60% RH
30 °C/65% RH
30 °C/75% RH
40 °C/75% RH
Other conditions can be applied upon request

Our facility offers:

- Standard ICH conditions
- Custom storage conditions
- Continuous monitoring of environmental chambers
- Backup generator

Analytical Method Development and Validation of Residual Cleaning Methods

We perform **validations of analytical methods** in any formulation, reducing the development time to achieve a validated method, and accelerating your product to the marketplace.

Our SOPs for validation methods are modeled after the guidelines in the USP chapter of Validation of Compendial Procedures <1225>. Accuracy, precision, specificity, detection limit, quantification limit, linearity, range, and robustness are evaluated in each validation procedure.

Cleaning validations are also critical, especially in a multi-product facility. At completion of any campaign, cleaning verifications are performed on all equipment to ensure the complete removal of any active ingredient and cleaning agent.

We take pride in the development of robust and rugged analytical procedures to ensure the quality of your products, and qualification and validation of the analytical procedures to meet both your requirements and those of regulatory agencies worldwide.

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