ALTASCIENCES

MANUFACTURING AND ANALYTICAL SERVICES

Our team offers drug development, manufacturing, and analytical services, including formulation development, Phase I through large scale commercial manufacturing, and ICH stability storage and testing, to pharmaceutical and biotech companies worldwide. We also provide analytical method development, qualification, and validation, as well as finished product and release testing. Equipped with a DEA manufacturing and analytical license (Schedules I-V), we have formulated, tested, and/or manufactured almost every pharmaceutical dosage form on the market. This includes tablets, liquid and powder-filled capsules, over-encapsulated capsules, nanomilled suspensions, creams, gels, powders, and terminally sterilized injectables.

Our purpose-built facility includes state-of-the-art Grade C and D cleanrooms, R&D and formulation laboratories, ICH stability chambers, a cGMP warehouse, and shipping capabilities to help you in every aspect of your project.

Manufacturing Services Offering

Product Development and Manufacturing Capabilities

- Formulation and development
- Process optimization
- GMP clinical supply and manufacturing for Phases I-IV
- Scale-up and engineering batch manufacturing
- Validation batch manufacturing
- Commercial batch manufacturing

Controlled Substance Manufacturing Capabilities

- DEA ¸manufacturing license (Schedules I-V)

Additional Client Support Services

- Facility expansion capabilities, including dedicated space and equipment, as required to meet project demands
  - Man-in-plant
  - Perform supplier audits

Dosage Types and Process Capabilities

- Tablets
- Liquid-filled hard shell capsules
- Capsule banding
- Particle size reduction (wet milling/nanomilling)
- Spray-dried dispersions
- Powder blending
- Powder-filled capsules
- Over-encapsulation
- Injectable vial filling (pre-sterilized)
- Solutions and suspensions
- Gels and creams
- Clinical packaging (bottles and blisters)
- Potent product handling

contact@altasciences.com
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FROM FORMULATION TO COMMERCIALIZATION, WE ARE YOUR CDMO PARTNER.

Capability Overview

Liquid-filled Capsule Expertise

Analytical Services Offering

Development and Validation of Critical Methodologies

- Cleaning methods for the detection of API on manufacturing equipment
- API methods for assay/related substance
- Finished dosage products (assay/degradation, dissolution)

Stability Testing

- ICH environment stability chambers

Controlled Substance Testing

- DEA analytical license (Schedules I-V)

Drug Product Release Testing

- High Performance Liquid Chromatography (HPLC) and Ultra Performance Liquid Chromatography (UPLC)
- Dissolution and disintegration
- Moisture analysis (Gravimetric and Karl Fischer [KF] Titratron)
- Spectroscopy (Ultraviolet/Visible [UV/VIS] and Infrared [FTIR])
- Total Organic Carbon (TOC)
- Viscosity
- Particle size analysis
  - Malvern
  - Horiba
  - AccuSizer (USP<788>)

Quality Assurance Services

Quality Systems

- Product release
- Standard Operating Procedures (SOPs)
- Equipment and facility qualification documentation
- GMP audits
- Regulatory inspections

Data Management Systems

- Agilent enterprise content management (OpenLab ECM) and chromatography data system (CDS)
- Secured client portal for 24-hour off-site access to data and documentation

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