



## Pharmaceutical Sciences

### FACTSHEET



## Biopharmaceutical and Biotechnology Support

Aptuit is focused on streamlining and supporting the drug development process for biotechnology and pharmaceutical innovators worldwide by providing a comprehensive suite of drug development services and competencies. Aptuit will help design product programs that compress timelines, maintain quality, and reduce the costs of commercialization.

### Services

Aptuit's Pharmaceutical Sciences group offers a broad range of analytical services necessary for the development and registration of biopharmaceuticals, including:

- Method Development, Validation and Transfer
- Reference Standard Qualification
- Preformulation/Formulation
- Lot Release Testing
- Analytical Comparability Studies
- Stability Studies
- Identification of Impurities/Degradation Products
- CMC Documentation for Regulatory Submissions

### Capabilities

#### Analytical Techniques

A wide range of analytical techniques is available, providing a multidisciplinary approach to the analysis and characterization of protein, peptide and oligonucleotide drug candidates.

- Reverse Phase Chromatography
- Ion Exchange Chromatography
- Hydrophobic Interaction Chromatography
- SDS-PAGE
- Western Blot
- In vitro Bioassay (Cell Culture)
- Protein/DNA/RNA Extinction Coefficients
- Moisture Analysis
- Peptide Mapping – ID by HPLC/UV
- N-Terminal Sequence
- MALDI-TOF
- Protein Primary Structure
- Protein Glycosylation Sites

- Oligosaccharide Size or Charge Profile (Chromatographic or Electrophoretic)
- Verification of Oligonucleotide Sequence by LC/MS
- Antibiotic Potency Assay
- Protein Degradation Pathways (LC/MS)
- Size Exclusion Chromatography
- Isoelectric Focusing
- Capillary Electrophoresis (Free Zone, Gel and IEF, Peptide Mapping, Chiral Separations)
- ELISA
- Microbial Testing (e.g. Endotoxin, Sterility)
- Protein Concentration (e.g. UV, Lowry)
- Globule Size Distribution
- Peptide Mapping – HPLC/MS/MS
- Amino Acid Compositional Analysis
- Electrospray MS (Single and Triple Quad, Ion Trap)
- Circular Dichroism (Secondary and Tertiary Protein Structure)
- Oligosaccharide Sequencing and Linkage Determination (Enzymatic)
- Monosaccharide Analysis
- Sialic Acid Analysis
- Disulfide Bond Location (LC-MS)

#### Preformulation

Aptuit's extensive preformulation resources, complemented by PharMaterials, significantly shorten the early development process, accelerating entry into Phase I clinical studies.

Capabilities include:

- Particle Sizing
- Hygroscopicity Determination
- Excipient Compatibility
- Differential Scanning Calorimetry
- Rheology
- Solubility
- pH-Related Stability
- Isothermal Microcalorimetry
- Lyophilization
- Freezing Point Determination



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## Biopharmaceutical And Biotechnology Support cont'd

### Formulation/Manufacturing

Aptuit provides an exhaustive range of sterile and non-sterile dose forms, covering all aspects of pharmaceutical dosage form development and manufacturing with the use of experimental design to identify the optimum combination of variables with the minimum number of experiments.

- Formulation development and process development of parenteral dose forms as well as oral and topical
- Aseptic manufacturing capabilities
- Formulation development of liquid fill capsules
- Solutions for nebulization
- Extensive experience in the development of sustained release products
- Technology transfer from Phase I/II facilities to manufacturing plants

### Stability Testing

- Design of Stability Protocols
- Drug Substance and Drug Product
- Post Marketing Stability Requirements

- ICH Conditions Including Photostability
- Clinical Trial Drug Product Monitoring Studies
- Full, Bracket and/or Matrix Designs

### Quality Assurance

All laboratory activities are designed to support IND, NDA, and international submissions and are conducted in accordance with the appropriate regulatory requirements.

For information about Aptuit's services, please call or email:

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**Engineering a better drug development process.**