

ANALYTICAL DEVELOPMENT CAPABILITIES

ADVANCED ANALYTICAL TESTING SERVICES FOR API

KEY CAPABILITIES

RAPID TURN QC/COMPENDIAL TESTING

7-10 day turn time

- Chromatography
- Residual solvents
- Elemental impurities
- Particulate matter
- Sodium content
- pH, viscosity, osmolality

ANALYTICAL DEVELOPMENT TESTING

- Chromatographic assays
- Mass spectrometry

MICRO STERILITY TESTING

- Bioburden
- Sterility
- Endotoxin testing
- Container Closure Integrity Testing (CCIT)
- Compendial and custom method development

BIPHARMA TESTING SERVICES

- Cell-based bioassays
- Protein testing and analysis

API AND ICH STABILITY

- On-site ICH stability chambers
- Supported by the aforementioned laboratories

EXTRACTABLES AND LEACHABLES

- Comprehensive analysis of materials for safety and compliance

WE OFFER

We're dedicated to advancing your analytical development needs with a wide range of cutting-edge testing services.

SERVICE OPTIONS

MASTER QUOTES

- Per sample analysis costing
- Subset of tests as per your requirements
- Turnaround Time: 1-2 days
- Pricing: Stable for one year

STAND-ALONE PROPOSALS

- Detailed proposal based on a defined scope
- Specific deliverables and costs
- Ideal For: Non-standard analytical projects requiring complex testing or development work

FULL-TIME EQUIVALENT (FTE) AGREEMENTS

- Dedicated scientists for your projects
- Flexible scope and requirements

REGULATORY SUPPORT

- Capabilities: Support for pre-clinical, clinical, and commercial testing
- Approval: FDA-approved testing facility

MODALITIES

- ADC (Antibody-Drug Conjugates)
- mAbs (Monoclonal Antibodies)
- Gene Therapy (AAV and up to BSL2 viral vectors.)
- Small Molecules
- DNA Plasmids
- mRNA
- Therapeutic Proteins
- Biosimilars

Nitto

Avecia
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