



Pharmaceutical Sciences

FACTSHEET



Analytical Chemistry – Respiratory Technology

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.

Experience and Services

Aptuit offer a range of analytical services in support of **product development** and **stability testing** of pressurized Metered-Dose Inhalers, Dry Powder Inhalers and Intranasal Products.

- Experienced in DPI, MDI, nasal sprays and nebulizers
- Highly skilled scientists dedicated to respiratory product analysis
- State-of-the-art instrumentation to provide solutions to your challenging problems

Capabilities

Product Tests

- Assay/Total Can/Device Content
- Related Substances and Degradation Products
- Dose Delivery
 - Uniformity of delivered dose/through life
- Particle Size
 - Microscopy
 - Laser Light Scattering – Sympatec and Malvern Mastersizer
 - Cascade Impaction Techniques – NGI, ACI and MSLI
- Moisture
- Colour
- Spray Pattern
- Morphology
- Leakage
- Foreign Particulate Matter

Stability Storage and Stability Testing Services

- All phases of development: preclinical through registration and post approval
- ICH conditions including photostability
- Cycling and accelerated temperature and humidity conditions

Applications

Analytical Development and Testing Services

- Method Development, Validation and Technical Transfer
- Final Product Testing
- Process Scale-up/Validation Support
- Stability Testing

Extractables and Leachables

- Controlled Extraction Studies – Accelerated Solvent Extraction, Sonication, Soxhlet
- Leachables Method Development, Validation and Transfer
- Leachables Testing on Stability

Quality Assurance

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

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

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

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Engineering a better drug development process.