DRUG FORMULATION SERVICES

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SUMMARY
Neo-Advent Technologies, LLC (NAT) was incorporated in 2003 and is led by our President and CEO, Mr. Nelson Landrau. The founding group of company principals have decades of combined experience in the fields of polymer science, advanced materials, drug discovery, and development. One of our strongest lines of business and expertise is drug delivery and formulation, including nutraceuticals and cannaceuticals. NAT quickly grew from a consulting services model to an integrated business with a strong internal experimental base, and became a profitable operation with an extended base of clients.

NAT provides a full set of services to efficiently move APIs from the pre-formulation stage through formulation concept and optimization all the way to readiness for commercial manufacturing. NAT takes pride in delivering high quality and high impact results in the most cost- and time-effective manner, building relations that last and flourish.

OVERVIEW OF FACILITIES AND SERVICES

NAT's 6500-square-foot facility at 410 Great Road in Littleton, MA is designed for formulation work and small scale manufacturing. It is subdivided into multiple suites equipped with state-of-the-art instrumentation, and it holds the company offices. NAT offers a wide spectrum of services and expertise in scientific, professional, technical, manufacturing, quality control, and regulatory fields. Our services include formulation development, drug delivery design, analytical methods development, validation, drug stability assessment, among other tasks.

SELECTED CAPABILITIES AND SPECIFIC PROJECTS

Full Testing and Method Development for APIs and Excipients

- HPLC
- LC-MS
- Spectral analysis (UV, FT-IR)
- Thermal analysis (TGA, DSC)
- Gas Chromatography
- NMR
- Atomic Absorption (AA)
- Particle size analysis

Pre-formulation Studies

- Solubility profile
- Polymorphism
- Partition coefficient
- Particle size distribution
- Drug-excipient interactions
- pH profile

- Flow properties
- Log pKa
- Bulk/tap density
- Residual solvents

Formulation Studies (Tablets)

- Hardness
- Friability
- Dissolution
- Disintegration

Development of Dosage Forms and Specific Drug Delivery Systems

Optimization of enhanced solubility, sustained delivery, controlled release, enhanced stability, targeted delivery, improved bioavailability, microencapsulation, acceptability for specialized use, and administration for alternate routes.

- Oral dosage forms – tablets, capsules, liquids
- Sublingual, buccal – tablets, lozenges
- Transdermal semi-solids – gels, ointments, creams
- Rectal/vaginal – suppositories, solutions, ointments

Analytical Method Validation

- Repeatability
- Recovery
- Accuracy
- Precision
- System suitability
- Specificity
- Forced degradation
- Solution stability
- Ruggedness
- Robustness

Stability Studies

Standard and custom-order protocols:

- Long-term: 25° ± 2°C, 60% ± 5% RH for 3, 6, 9, 12, 18, 24, and 36 months
- Intermediate: 30° ± 2°C, 60% ± 5% RH / 65% ± 5% RH for 1, 2, 3, and 6 months
- Accelerated: 40° ± 2°C, 75% ± 5% RH for 1, 2, 3, and 6 months
- Accelerated: 50° ± 2°C, 75% ± 5% RH for 1, 2, 3 months
- Freeze-thaw (-20°C to ambient)
- Photostability

Clinical and Commercial Manufacturing Liaison

NAT has all the key equipment for manufacturing pilot batches of solid oral dosage forms, including tablets and capsules of various sizes. For advanced stages of the project, NAT developed an extensive network and practices for transferring technology to the manufacturers of the cGMP supplies intended for all phases of clinical trials.

For other dosage forms, including semi-solid preparation, NAT can manufacture pilot batches. In the case of larger production runs, NAT will employ the services of third parties with demonstrated track records and compliance profiles. NAT can coordinate scale-up manufacturing and technology transfer activities to maintain continuity as well as to ensure agreed deliverables and time schedules.