



**DRUG FORMULATION &  
BIOANALYTICAL DEVELOPMENT**

**Achieving Your Goals Quickly**

**Neo-Advent Technologies, LLC**  
[www.NATinnovations.com](http://www.NATinnovations.com)  
[www.Neo-AdventTec.com](http://www.Neo-AdventTec.com)



## ABOUT US

**Neo-Advent Technologies, LLC (NAT) is a Life & Material Sciences Integrated Research Organization with a Strong R&D Core and Product Development Focus.**

NAT enterprise has been incorporated in 2003 by a founding group of principals with decades of experience in the fields of polymer science, advanced materials, and drug formulation, discovery, and development. In pharmaceutical applications, NAT quickly grew up from a consulting services model to a profitable integrated business with a strong internal experimental base and an extended base of clients.

The Company currently provides a comprehensive set of professional services to efficiently move client's API's (including small molecules, peptides, and biologics) from pre-formulation stage and formulation concept, to product candidate optimization in advanced stages of pre-clinical development. These offerings are naturally bundled with a capability to cover a wide range of analytical and bioanalytical tasks including method development and support of the in vivo testing programs. We operate a wet chemistry lab and a scale-up synthetic suite (5-50 L reactors) to allow our clients additional opportunities in synthetic and medicinal chemistry and pilot manufacturing.

NAT takes a pride in delivering high quality and high impact results to its clients and partners in the most cost and time-effective manner. We cultivate a project environment with "open doors" to our operations and tight interactions of the project teams permitting our partners and clients to be on the top of the game 24/7.

## SELECTED CAPABILITIES IN DRUG FORMULATION

### Full Testing and Method Development for API's and Excipients

- HPLC (UV-Vis, Luminescence, ELSD detection)
- GC-MS
- LC-MS (MDS SCIEX 4000 QTrap, QStar Elite)
- Spectral analysis (UV, FT-IR)
- Thermal analysis (TGA, DSC)
- Atomic Absorption (AA)
- Particle size analysis

### Biologics

- Lyophilization process development
- Proteins and peptides analytical methods
- Stability studies

### Small Molecules Pre-formulation and Formulation Studies

- Solubility profile
- Polymorphism
- Partition coefficient
- Particle size distribution
- Drug-excipient interactions
- pH profile, log pKa
- Flow properties
- Bulk/tap density
- Residual solvents
- Hardness, friability
- Dissolution
- Disintegration



### Dosage Forms and Drug Delivery Systems

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

- Oral Dosage Forms - Tablets, Capsules, Liquids
- Sublingual, Buccal –Tablets, Lozenges, Films
- Trans-dermal semi-solids - Gels, Ointments, Creams
- Rectal/Vaginal - Suppositories, Solutions, Ointments
- Parenteral Formulations

### Stability Evaluation

Standard and custom-order protocols:

- Freeze-thaw (-20 °C to ambient)
- Photostability
- Three standards humidity/temperature chambers

### Clinical and Commercial Manufacturing Liaison

NAT possesses 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 the technology transfer to the manufacturers of the cGMP supplies intended for all phases of clinical trials.





## ANALYTICAL AND BIOANALYTICAL DEVELOPMENT

Our analytical and bioanalytical services utilize a state-of-the-art instrumentation and support a variety of tasks such as:

- Chromatographic separation and quantitation of major and minor components in raw API and formulated drug products.
- Identification of new impurities generated during manufacturing, stress testing and stability studies.
- Analytical support for the design, synthesis, and scale-up of new chemical entities.
- Development of qualitative and quantitative analytical HPLC, LC/MS or LC-MS/MS methods of small molecule drugs in support of preclinical drug discovery studies.
- Acquisition, processing and reporting pre-clinical and pharmacokinetic and toxicokinetic data, including ADME, protein binding and metabolites identification.
- Development of qualitative and quantitative bioanalytical LC-MS/MS methods of small molecule drugs and metabolites in biological matrices (plasma, urine, and various tissues).
- Analytical support for pharmacokinetics studies, dose formulation and dose verification, metabolite identification, stability, solubility, and other experimental needs.
- Development of extraction protocols for various biological matrices using liquid-liquid extraction (LLE), solid phase extraction (SPE) and protein precipitation techniques.
- PK data generation and interpretation for non-compartmental analysis using WinNonlin software.

## CUSTOM SYNTHESIS SUPPORT

NAT offer a scope of portfolio services ranging from exploratory chemistry for the early stages of pre-clinical development to pilot manufacturing and process development of APIs. Our scale-up purification suite includes a Varian Dynamax Preparative HPLC system complemented by the two Varian Load & Lock columns with packing station.

### Custom Synthesis Expertise:

- Medicinal Chemistry
- Stable Isotopes Labeled Compounds
- Carbohydrates
- Advanced Intermediates
- Natural Products
- Amino Acids
- Polymer Building Blocks
- Biopolymers and Building Blocks
- Process Development (5-50 L reactors)



## SELECTED INSTRUMENTATION

NAT uses state-of-the-art instrumentation in the areas of chromatography, spectroscopy, microscopy, drug and polymer testing.

### Separation

- Analytical (Agilent 1100, 1200) and Preparative (Varian Dynamax) High Performance Liquid Chromatography (HPLC)
- Varian Load&Lock columns with packing station
- Separation Detection Systems
  - Spectrophotometric (UV-Vis)
  - Fluorescence
  - Evaporative Light Scattering (ELSD)
  - Electrospray Ionization-Ion Trap Mass Spectrometry (ESI-IT-MS)
  - Atmospheric Pressure Chemical Ionization-Ion Trap Mass Spectrometry (APCI-IT-MS)

### Mass-Spectroscopy

- Quadrupole/Linear ion trap (MDS SCIEX 4000 QTRAP)
- QStar Elite MDS SCIEX
- MALDI Macromass Q-TOF Ultima

### Gas Chromatography

- Varian Saturn III GC/MS

### Molecular Spectroscopy

- Ultraviolet-Visible Spectrophotometry (UV-Vis)
- Fourier Transform Infrared Spectroscopy, FT-IR (Nicolet Spectrum 100)

### Atomic Spectroscopy

- Flame Atomic Absorption (FAA)

## Microscopy and Surface Analysis

- Optical Microscopy
- Heated Table Polarized Light Optical Microscopy

## Physical and Thermal Testing

- Thermogravimetric Analysis, TGA (TA Instrument Q500TGA)
- Differential Scanning Calorimetry, DSC (TA Instrument Q1000)
- Particle Size Analysis (Malvern, Mastersizer)

## Wet Chemical Techniques and Other Equipment

- Karl Fischer Volumetric Titration
- pH
- Ion Selective Electrodes (ISE)
- Soxhlet Extraction
- Accelerated Solvent Extraction
- Brookfield Viscometers
- Weathering Chambers (Temperature, Humidity Control)

## Drug Formulation

- Bench Tablet Press
- Carver Press (Heated Plates)
- Films Casting Table
- Homogenizer (Polytron 10/35)
- Osmomolality
- Tablet Hardness
- Tablet Friability
- Tap Density, Flow Density
- Dissolution (Distek 2100)
- Lyophilization (VirTis Genesis)
- Microfluidizer (Microfluidics, M-110S)
- Lipex Extruder (100 mL)



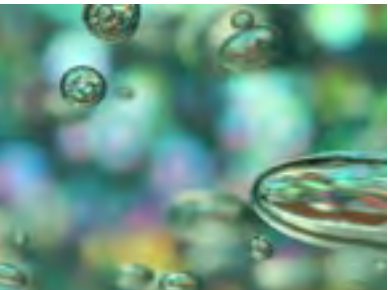
## **DRUG FORMULATION**

We provide an expertise in drug formulation of small molecules, peptide and biologics, at all stages of preclinical development from concept design to cGMP technology transfer, including solid dosage forms, topical, ocular, and parenteral compositions.



## **BIOANALYTICAL DEVELOPMENT**

Our analytical and bioanalytical services span from the HPLC method development to TGA/DSC, and particle size analysis to metabolite characterization and profiling by LC/MS. We conduct a full range of the GLP stability studies and thoroughly analyze (bio)polymers and raw ingredients.



## **DRUG DELIVERY**

NAT developed particular expertise in several specialized areas of controlled drug release and delivery including smart hydrogels and biomaterials in support of peptide drug candidates and biologics, as well as tissue engineering scaffolds and stem cells.



## **CUSTOM SYNTHESIS SUPPORT**

NAT operate a fully equipped synthetic scale-up facility (5-50 L reactors, Load & Lock purification columns) and carry out work on synthetic optimization of drug candidates and intermediates, as well as polymer and biopolymer building blocks.



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