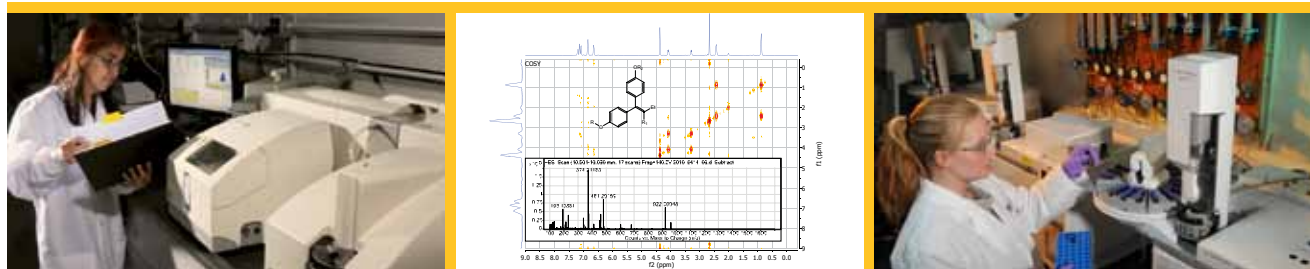


# Analytical Chemistry and Pharmaceutical Development Services



RTI International provides analytical support and consultation to pharmaceutical, chemical, and biotechnology companies. Our experienced scientists offer a full range of analytical services, from lead discovery chemistry to cGMP release of finished products. RTI's familiarity and compliance with regulatory requirements of the Food and Drug Administration and other agencies enable our clients to have complete confidence in the quality and acceptability of all analytical data.

## Preformulation Services

- Solubility, pH, solution stability
- Moisture content, sorption analysis
- Thermal analysis (thermal behavior, melting point)
- Structural characterization—FTIR, UV/Vis, fluorescence, NMR, MS<sup>n</sup>
- Particle morphology, size, and size distribution
- X-ray powder diffraction (XRPD)
- Polymorph screening
- Solid state stability
- Drug-excipient compatibility and packaging component compatibility

## Formulation Development Services

- Solutions, suspensions
- Emulsions and self-emulsifying drug delivery systems (SEDDS)
- Semisolids for softgel fills
- Powders—blends and lyophilized
- Stability studies—informal and formal studies (ICH) including elevated, ambient, and subambient temperatures, photostability
- Degradation studies—temperature, pH, light, oxidation
- Dosage form design and evaluation: suspensions, solutions, emulsions/SEDDS

## Analytical Services

- Method development and validation for drug substance, impurities, and stability-indicating analysis
- Reference standard characterization, impurity identification, and release testing
- Drug substance characterization—identity, assay, impurities, moisture, pH, residual solvents
- Chiral analysis
- Ion chromatographic analysis
- Excipient characterization—compendial testing
- Drug product characterization—identity, assay, content uniformity, moisture, dissolution
- Test article and dose formulation analysis—purity, homogeneity, and stability
- Degradation studies on drug substance and drug product
- Capability to synthesize impurities available within RTI

## Customized Ancillary Services

- Experimental design approach
- Inventory management
- Repository storage
- Stability storage
- Specialized shipping services
- Chemical synthesis, radiolabeling
- Regulatory consulting



## Compliance

- Registered with FDA as an analytical testing facility
- Registered with DEA for scheduled drug substances
- cGMP/GLP-compliant or R&D-type feasibility studies

## Instrumentation

DSC, TGA	Fluorescence
VTI-SA	Rheometer
FTIR	pH meter
UV/Vis	Karl Fischer titrators (volumetric, coulometric)
ESEM	XRD
Polarimeter (Rudolph Autopol IV)	Particle size distribution (laser, sieve)
ICP-high resolution MS, OES	Refractrometry (Rudolph J57)
Dissolution apparatus (USP, apparatus 1 and 2)	Disintegration apparatus (USP)
Optical microscope with hot-stage and digital imaging	
Capillary GC with FID, NPD, TCD, ECD, and MS	
Capillary Electrophoresis with PDA, Variable $\lambda$ UV (CZE, cIEF, SDS-PAGE)	
UPLC and HPLC with LC/MS, PDA, UV, ELSD, RI, fluorescence, and mass spectrometry	
Ion chromatography with conductivity, UV	
Multi-nuclear, 2D NMR	
– 500 MHz (grCOSY, TOCSY, NOESY, ROESY, grHSQC, grHMBC, DEPT135)	
– 300 MHz (hetcorr)	
Validated LC/MS Systems (MS/MS, high-resolution MS)	
– Sciex API 4000 (2), 5000 LC/MS/MS	
– Sciex API 4000Q-trap UPLC/MS/MS (2)	
– Agilent 6230 MS-TOF with Agilent 1290 UHPLC	
Research LC/MS Systems (MS/MS, high-resolution MS, ion mobility)	
– Waters Synapt G2 HCMS	
– Thermo Electron LTQ Orbitrap	
– Agilent 6410 LC/MS/MS	
– Waters Acquity TQD LC/MS/MS	
– Thermo Electron LTQ, LTQ ETD, and LCQ Deca LC/MS <sup>n</sup>	

## Equipment

Freeze dryer	Silverson homogenizer
Propeller mixer	Polytron homogenizer
Rotary evaporator	Ovens
V-shell blenders	Fitz mill
Stability chambers	Laminar flow hoods
Freezers	Refrigerators
Stand-alone barrier facility for toxic compounds	

## Leadership Team

- **Brian F. Thomas**, PhD—Dr. Thomas has nearly 20 years of experience in analytical chemistry and mass spectroscopy. He oversees the development of chromatographic and spectrophotometric assays for the qualitative and quantitative analysis of drug substances and drug products.
- **Poonam Pande**, PhD, RPh, RAC—Dr. Pande has expertise in preformulation, formulation development, and manufacturing with almost 10 years of pharmaceutical experience with various dosage forms. She also serves as consultant on regulatory compliance and submissions.
- **John W. Hines**, PhD—Dr. Hines has more than 25 years of experience in the application of physical, chemical, spectroscopic, and chromatographic techniques to the solution of problems in drug development and IND submission. He currently oversees both government and commercial projects at all levels of complexity and regulatory compliance.

## Working Closely with Our Clients

RTI's technical, research, and development services meet the highest standards of professional performance to satisfy the unique requirements of our clients. We work closely with our clients to identify their requirements and clarify their expectations, including cost and time constraints.

RTI extends its excellence in research and technical services to its business systems and processes, making it easy for clients, subcontractors, and vendors to partner with us. We have the contractual, legal, and business structures to serve any client with projects of all sizes. RTI is a 501(c)(3) nonprofit corporation.

### More Information

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