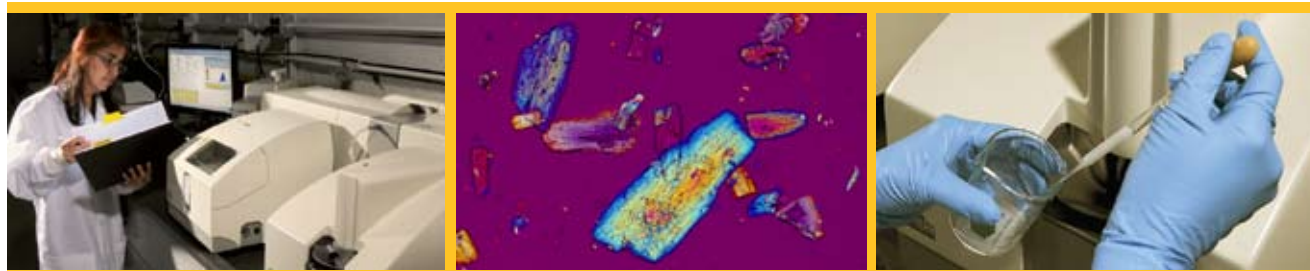


# Analytical Chemistry and Pharmaceutical Development Services



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
- 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 studies or R&D-type feasibility studies

## Instrumentation

DSC, TGA	Fluorescence
VTI-SA	Rheometer
FTIR	pH meter
UV/Vis	Karl Fischer titrators
ESEM	XRD
GC with GC/MS	CE with PDA
ICP-MS	Particle size distribution
ICP-OES	ICP-high resolution MS
Optical microscope with hot-stage and digital imaging	
Disintegration apparatus (USP)	
Dissolution apparatus (USP, apparatus 1 and 2)	
UPLC and HPLC with LC/MS, PDA, UV, ELSD, RI, fluorescence, and mass spectrometry	
– API 3000, 4000 (2), 4000 Q-trap (2) and 5000 LC/MS/MS systems	
– 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.

## 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 to 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.

RTI's mission is to improve the human condition. Through our objective, multidisciplinary research and by helping our clients develop new technologies, RTI is fast becoming the world's preferred resource for turning knowledge into practice.

Please visit our website for more information on RTI drug development services: [www.rti.org/drugdev](http://www.rti.org/drugdev).

## For more information about RTI's Analytical Chemistry and Pharmaceutical Development Services, contact

Health Sciences Business Development

Phone: +1.800.848.4083

E-mail: [HS-Client-Services@rti.org](mailto:HS-Client-Services@rti.org)

RTI International

3040 Cornwallis Road, PO Box 12194

Research Triangle Park, NC 27709-2194 USA

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