

SIPKA LABS ANALYTICAL SERVICES

The Scientists at the Sipka Labs are experienced in developing and validating a variety of cost effective, stability indicative and robust analytical methods for multi-analyte drug products and drug substances. Our staff has experience in developing and validating methods for tablets, capsules, liquids, implants, parenterals, and nasal formulations. Method validations are performed in accordance with the ICH/GMP guidelines or other relevant regulatory guidelines and client SOPS.

A partial list of our services includes:

- ◆ Stability Indicating HPLC methods and Chiral Separations
- ◆ Detection modes available include UV/Vis, ELSD, RI, conductivity and fluorescence
- ◆ Forced degradation studies
- ◆ Method remediation / alternative analytical methods
- ◆ Analytical Methods for controlled drug substances and products of schedules II-V.
- ◆ Cleaning Validations (Specific and Non-specific analysis)
- ◆ Residual Solvents / OVI and assay for small molecules by Gas Chromatography
- ◆ GC/MS Analysis
- ◆ Dissolution methods for Immediate release, Modified release and Poorly soluble drug products.
- ◆ Elemental Analysis
- ◆ Quantitative measurement of active drugs and or their metabolites in biological matrices using LS/MS/MS
- ◆ Analysis of food products, food additives and fragrances

A QUICK LABORATORY REFERENCE

Commonly Used Buffers for Reverse Phase HPLC			
Buffer	pKa	Buffer Range	UV Cutoff (nm)
Phosphate	2.1	1.1-3.1	200
	7.2	6.2-8.2	
	12.3	11.3-13.3	
Formic acid*	3.8	2.8-4.8	210
Acetic acid*	4.8	3.8-5.8	210
Citrate	3.1	2.1-4.1	230
	4.7	3.7-5.7	
	5.4	4.4-6.4	
Tris	8.3	7.3-9.3	205
Triethylamine*	11.0	10.0-12.0	200
Pyrrolidine	11.3	10.3-12.3	200

Commonly Used HPLC Column Specifications		
USP Code	Column Chemistry	pH range
L1	C18	2-8
L3	Silica	2-6
L7	C8	2-8
L9/L14/L52	Ion-exchange	2-8
L10	CN	4-8
L11	Phenyl	2-8
L60	Amide	2-8
-	Zirconia	1-13

Preparation of a liter of 1N solution from concentrated chemicals				
Chemical (Concentrated)	Formula Weight	Molarity / Normality		mL of Conc. Chemical/Water
		M	N	
Acetic Acid, Glacial	60.053	17.4	17.4	57.5/942.5
Formic Acid	46.026	23.6	23.6	42.5/957.5
Hydrochloric Acid	36.461	12.1	12.1	82.5/917.5
Nitric Acid	63.013	15.9	15.9	63.0/937.0
Phosphoric Acid	97.995	14.8	44.4	22.5/977.5
Sulfuric Acid	98.079	18.0	36.0	28.0/972.0
Ammonium Hydroxide	35.046	14.5	14.5	69.0/931.0
Sodium Hydroxide	39.997	19.4	19.4	51.5/948.5
Potassium Hydroxide	56.105	11.7	11.7	85.5/914.5

Contact Us at:

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Sipka Labs

Service-Focused Labs
Innovative Solutions
Personal Attention
Key Performance Advantages
Accuracy



*Striving to Provide
Outstanding
Analytical Services
at Competitive Prices*

ABOUT SIPKA LABS

Sipka Labs at Monmouth Junction, NJ provide a comprehensive range of services and valuable solutions to the pharmaceutical, nutraceutical, biotechnology, generic drug, medical device, and food industries. Dedication to our clients is at the heart of all our endeavors. We offer comprehensive, state-of-the-art assay development, transfer, validation and sample analysis technologies. We have expertise in many proven validated methods to quantitatively measure many types of compounds using LC/MS/MS, HPLC, FTIR and GC.

WHY CHOOSE SIPKA LABS?

- ◆ Service-Focused Labs
- ◆ Innovative and Intelligent Solutions
- ◆ Personal Attention
- ◆ Key Advantages:
 - ◇ Quality execution
 - ◇ Flexible
 - ◇ Responsive
 - ◇ On-time report deliveries
 - ◇ Competitive prices
- ◆ Accuracy

EXPERT STAFF

To ensure our laboratories continue to provide the highest quality of services to sponsors, our staff members frequently update their analytical skills by participating in seminars and scientific conferences. Our proven laboratory systems deliver accurate, high-quality results in a good laboratory practice (GLP)-compliant setting.

WE OFFER:

- ◆ State-of-the-art facilities
- ◆ Experienced, well-trained staff
- ◆ Expertise in a variety of methods
- ◆ Flexible and responsive project managers
- ◆ Ability to meet tight timelines and remain within limited budget

SCIENTIFIC EXCELLENCE, PROVEN SYSTEMS

Each member of our laboratory management team has a PhD and more than 15 years of analytical experience. Our ability to meet and exceed the expectations of our clients is directly tied to the responsiveness of our staff. Our dedicated scientists have the experience and expertise for robust method development and are trained in the use of the latest equipment to execute these methods. The scientists at Sipka effectively meet client's requirement for accurate, high-quality results with:

- ◆ Efficient resolution of complex analytical problems
- ◆ Recommendations on procedures to obtain the needed data
- ◆ Refined analytical standard operating procedures (SOPs) and laboratory procedures

Our scientists have expertise in more than 100 proven, validated methods to quantitatively measure various types of compounds from small molecules and conventional drugs to peptides. We use state-of-the-art equipment including:

ANALYTICAL LABORATORY EQUIPMENTS

- ◆ Waters HPLC systems equipped with empower[®]2 software and PDA, UV, RI, conductivity, ELSD, MS and fluorescence detectors
- ◆ Waters Micromass LC/MS/MS, Masslynx 4.1
- ◆ HP GC with FID, TCD (Direct/Headspace)/Empower 2
- ◆ HP UV/Vis Spectrometers/Auto sampler/Chemstation
- ◆ Dissolution Apparatus/Auto Samplers
- ◆ Metrohm Karl-Fischer and Potentiometric titrators/Brinkmann workcell
- ◆ Nicolet Avator FTIR
- ◆ Jasco Polarimeter
- ◆ Brookfield Viscometer and more...

OPERATIONS

Strict confidentiality policies and procedures are applied to all analytical work generated at Sipka Labs to ensure that each client receives services of the highest integrity and quality. Sipka Labs' features include the following:

- ◆ Fully secured facilities monitored by analog/digital systems with access controls
- ◆ Uninterrupted Power Supply (UPS)-protected laboratory instrumentation
- ◆ Licensed to handle Schedule II-V controlled substances
- ◆ Backup, archiving, cataloging, and storing of raw and processed laboratory data
- ◆ Streamlined, and strictly GLP-compliant SOPs.

VALUE-ADDED SERVICES

Quality Assurance

Sipka Labs ensure accurate, high-quality results the sponsors need through:

- ◆ Thorough review of study data and reports
- ◆ Strict compliance with SOPs and analytical methods

Project Management

The Project Managers are professionals with scientific training, experience, and effective project management and communication skills. We provide customized service to the individual needs of the client and data of the highest quality.

Client Services

Client satisfaction is a high priority at Sipka Labs. We guarantee that each client will have direct access to a single point of contact who is most intimately involved with the client's project from 7:30 AM to 9 PM everyday.