

*Contract Research Laboratory  
Provides Analytical, Bioanalytical,  
Microbiology, Consulting and  
Regulatory, and Validation  
Services*

### **Highlight of Services**

1. Analytical Method Development and Validation Services
2. Product Testing, Chemical Analysis, Material Testing, Reverse Engineering
3. Microbiology: Bacterial Identification, Mold Testing, Air Sampling, Water Analysis
4. Bioanalytical Method Development and Validation Services
5. Regulatory Submission Services
6. Quality Assurance and Audit Services
7. Instrument Qualification and Validation and Qualification and
8. Instrument Preventative Maintenance and on-site Repairs.
9. Software Validation Services
10. Facility Design and Validation

**CALL (800) 421-5284**



### **Contract Research Laboratory**

**Toll: 800-421-5284**

**Address:**

**4080 Paradise Rd**

**Suite 15-125**

**Las Vegas, NV 89169**

**Email: [info@contractresearch.us](mailto:info@contractresearch.us)**

**[www.ContractResearch.us](http://www.ContractResearch.us)**



**Contract Research Laboratory**

## **Contract Research Laboratory**

*Development &  
Validation Services*

Contract Research Laboratory Provides:  
Microbiology Services,  
Analytical & Bioanalytical Development,  
Drug development, Product Development,  
Software Development, Software Validation,  
Equipment and Instrument Validation, Facility  
Design and Validation, Quality Control Audit,  
Regulatory Consulting Regulatory and

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## Chemical Analysis Services

- Finished pharmaceutical products:
  - Method development activities to support de-formulation studies and determination of active/excipient ratios
  - Method Validation Phase I, II, III
  - Release Testing
- Raw material and Excipients testing:
  - Proof of structure
  - Identification and quantitation
  - Establishment of purity as well as release
  - Specification development for excipient-masking transformations  
Packaging components Physico-chemical testing Moisture permeability Container-closure integrity evaluations
  - Extractable /leachable determinations

## HPLC, IC, LC/MS, GC, GC/MS

- Chromatographic Purity And Stability Indicating Assays
- Solid Oral - Assay, Impurities, Content Uniformity
- Liquid Oral - Assay, Impurities, Dose Uniformity
- Cleaning Verification Methods.
- Impurity Identification
- High Resolution Mass Spectrometry  
Liquid and Gas Chromatography
- HPLC , GC , Chiral HPLC And Chiral GC, and Capillary Electrophoresis
- Ion Chromatography

## Microbiology Services

- Microbiology Testing for: Pharmaceuticals, Cosmetics, and Food Industries
- Microbial Identification, Microbial Limits
- Water Testing, Air Sampling
- Bioburden Analysis
- Kinetic LAL
- Bacterial Endotoxin Test
- Minimum Lethal Concentration
- USP and ASTM Testing
- Aerobic and Anaerobic Plate Count
- Fungal Plate Count
- Mold Testing
- Contamination Determination

## Bioanalytical Development

- Bioanalytical Method Development and Validation
- Quantitation Of Metabolites and Drugs In Biological Matrices
- LC/MS And LC/MS/MS
- GC/MS And GC/MS/MS
- Liquid Chromatography
- Automated Solid Phase And Liquid-Liquid Extraction
- ELISA, Electrophoresis, Bioassays
- Affinity Chromatography
- Protein Assays
- Peptide Sequencing

## Regulatory & Audit Services

- Preparation of IND, NDA, ANAD and CMC , Setting Strategies With FDA for Successful Submissions
- Interacting Directly With FDA
- Consulting for Regulatory Submission
- System Audit (QA), Review, & Training
- GMP/GLP Site Audit, Audit Reports

## Computer Validation Services

- Project Planning
- Risk Assessment and Analysis
- Developing User Requirement Specification (URS) and Functional Requirement Specification (FRS)
- Validation Protocols
- Validation Reports
- Traceability Matrix, & Sop Development

## Instrument Qualification & Repair

- HPLC Installation, Operational And Performance Qualifications (IQ/OQ/PQ)
- HPLC Preventative Maintenance And Repair Services

## Facility Design and Validation

- Facility Validation and Designing:
  - HVAC System Validation
  - Water System Validation
  - Security System Validation

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