Rubicon™
RESEARCH

INNOVATION | QUALITY | CARE

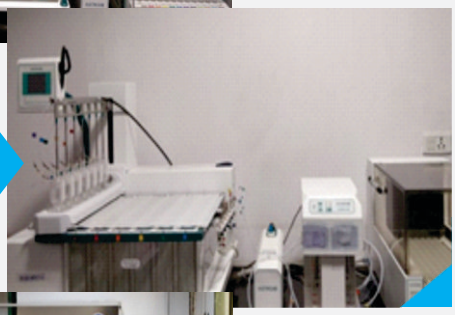
Happy to provide Analytical services of high Quality

- Raw Material Testing
- Packaging Material Testing
- Analytical Method Development
- Analytical Method Validation
- Stability Study

Quality Policy

"Rubicon is committed to provide analytical services of Highest Quality Standards, in compliance to the applicable regulatory requirements and to the satisfaction to customer with timely manner"

Dissolution apparatus 1 & 2



Dissolution Apparatu s 3

Diffraction Scanning Calorimeter

Ion Exchange Chromaotography

Rubicon

- US-FDA, MHRA audited and accepted testing laboratory provide the complete support to pharma analytical world.
- Analytical Solutions comprises of dynamic and qualified Analysts holding skills and vast experiences in different techniques of analytical services.
- We base our approach on your particular requirements and providing comprehensive range of tests.

Technology

- HPLC with UV/PDA/RI/FLR Detector
- HS and Auto injector GC with FID Detector
- Ion Exchange Chromatography
- UV-Spectrophotometer
- FTIR Spectrometer
- Dissolution apparatus 1 (Basket) & apparatus 2 (Paddle) with 1L & 2L capacity
- Dissolution apparatus 3 (Reciprocating Cylinder)
- MalvernParticle Size 3000
- Water activity meterTotal Organic Carbon Analyzer (TOC)
- Diffraction Scanning Calorimeter
- All instruments are aligning with 21-CFR-Part11.

Analysis Facility

- Raw material analysis
- Packaging Material analysis
- Method Development
- Method Validations
- Dissolution Profile study
- Stability study
- Water activity analysis
- Particle Size analysis
- Microbial analysis

Analytical Services

Quality Control Raw Material Testing

Before manufacturing begins, all raw materials must be tested for purity, identity and quality. We offer wide range of analytical service for raw material are excipient, colour, flavor as per USP/BP/Ph.Eur along with different analytical techniques as single window solution

Quality Control Packaging Material Testing

Packaging of materials is an integral part of any pharmaceutical industry. Packaging affects the quality and identification of drug product. We offer wide range of analytical service for packaging materials are Container, Closure, Carton or Outer and Box USP/BP/Ph. Eur along with different analytical techniques like DSC, TOC, FTIR, UV.

Analytical Method Validation

Rubicon designs the method-validation protocols depending on the regulatory body to which the submission is to be made and the nature of the Analytical method. However, some of the key parameters are:

- **Specificity**
- **Accuracy**
- **Precision**
- **LOD, LOQ**
- **Linearity**
- **Range**
- **Robustness**
- **Response Factor**

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Why Choose Forced Degradation For Drug Product

- Identify the likely degradation products
- Establish degradation pathways and the intrinsic stability of the molecule
- Validate the stability indicating power of the analytical procedures used
- Characterize product-related impurities

Analytical Method Development

We offer a comprehensive range of services for the Analytical development and validation of stability indicating assays, helping to monitor degradation of Pharmaceutical products upon storage that will guarantee safety and quality.

We offer state-of-the-art laboratory and expert methodologies for forced degradation studies during early product development – performed according to ICH in a cGMP compliant laboratory.

Our forced **degradation studies** can help you assess the effects of:

- Agitation
- Exposure to ICH light conditions
- High and low pH
- Temperature excursions
- Freeze and thaw stress
- Oxidation

Our expert staff is trained to the highest standards and has an in-depth knowledge of their fields and your business needs.

We provide experience in meeting both international and local regulations for a wide range of industries.

Stability Study Testing Services

We provide a complete range of storage conditions in numerous climatic walk-in chambers and climatic cabinets.

All storage chambers are fully controlled with 24/7 monitoring and alert systems (21 CFR part 11 compliant). For your reassurance, we operate back-up chambers for complete sample retrieval.

Long-term, intermediate and accelerated storage

- 25°C / 60% RH
- 30°C / 65% RH
- 30°C / 75% RH
- 40°C / 75% RH
- 2-8°C
- Photostability
- Transport Stability (freeze and thaw, cycle test)
- In-use stability

We Provide

- Support in designing studies for real-time, stress tests and photostability studies
- Development and validation of stability indicating methods
- Storage and management of stability samples
- Interim reports for every testing period
- Comprehensive final report

Total Organic Carbon

High Performance Chromatography
with UV/PDA/RI/FLR Detector

Our subject matter experts

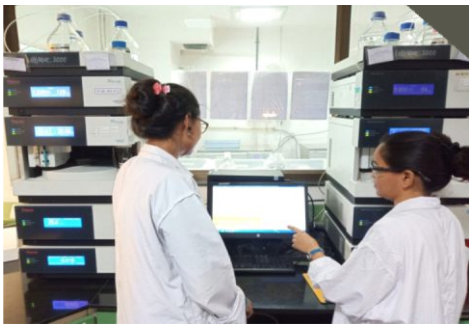
are available to provide technical information regarding testing, whether you need full-time support or extra capacity during times of heavy workload.

Our focus

is always on getting accurate results to help inform broader quality control decisions.

Malvern PS 3000

HS + Auto injector Gas Chromatography



Actual Lab Image with Our Analysts

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