



# SINGLE WINDOW cGMP TESTING SERVICES



**Method Development & Validation**



**Extractables & Leachables**



**Microbiological Testing**



**Stability Studies**



**Packaging Material**



**Physical Characterization**



**Impurity Qualification Studies**



**Bioassays**



Pharma



Biologics



Medical Devices



New Chemical Entities



Speciality Chemicals

# Our Services

## Specializations

- ▶ Extractables & leachables
- ▶ Method development & validation
- ▶ Impurity profiling studies
- ▶ Dissolution profiling
- ▶ Genotoxic impurities
- ▶ Elemental Analysis
- ▶ Physical characterization (XRD, PSD)
- ▶ Disinfectant efficacy studies
- ▶ Human serum albumin studies
- ▶ Batch release assays for recombinant Proteins & peptides
- ▶ Microbial Identification by sanger sequencing



## Routine Services

- ▶ Pharmacopoeia testing (IP/USP/BP/EP/JP/chP)
- ▶ Release testing, COA
- ▶ Water testing as per USP /BP/EP/IP/CT
- ▶ Raw material analysis
- ▶ Excipient analysis
- ▶ Elemental analysis by AAS
- ▶ Microbiology: MLT, BET, AET, DET, environmental monitoring, water testing as per regulatory requirement, method development & validation
- ▶ Liquid particle count
- ▶ SOR
- ▶ TOC

## Stability Studies

- ▶ Developmental stability studies
- ▶ Follow-up stability studies
- ▶ Freeze thaw cycling stability studies
- ▶ Photo stability studies



Client Specific Lab

- ⊕ An exclusive of customer's own facility
- ⊕ Devoted lab space, equipment, manpower
- ⊕ Round the clock operations
- ⊕ FTE model ; full time equipment
- ⊕ RRS Model ; fee for Service

# Facilities & Technologies

- ▶ Spacious Analytical Laboratory Meets all Regulatory bodies
- ▶ LIMS & QMS for sample tracking and results reporting.
- ▶ QMS, DMS & LMS integration.
- ▶ Facility meets 5s Concept

# Instrumentation

- ▶ HPLC – UV, PDA, RI
- ▶ UPLC UV-VIS PDA
- ▶ GC – FID, ALS
- ▶ GC –HS
- ▶ GC –MS/MS
- ▶ GC –MS
- ▶ UV-Vis Spectrophotometer
- ▶ Water activity analyzer
- ▶ LC –MS/MS
- ▶ DSC
- ▶ TGA
- ▶ pXRD
- ▶ PSD
- ▶ Particle counter(LBPC)
- ▶ Visometer
- ▶ TOC analyzer
- ▶ FTIR, Near IR
- ▶ DNA sequencer  
3500 thermoscientifics
- ▶ qPCR
- ▶ Particulate matter Measuring Device
- ▶ ICP-MS
- ▶ AAS
- ▶ Dissolution I, II, III, IV
- ▶ Microplate Reader

# Quality Management System

M/S UMED PHARMA LAB PVT. LTD. is committed to provide accurate, reliable, impartial, confident, cost effective, consistent and timely test results to the customer by following effective professional practices with the involvement of competent personnel. Laboratory is also committed to comply with ISO/IEC 17025:2017 and continually improve effectiveness of laboratory management system. All personnel are familiarized with laboratory management system for implementing policies and procedure with irrespective of duties.

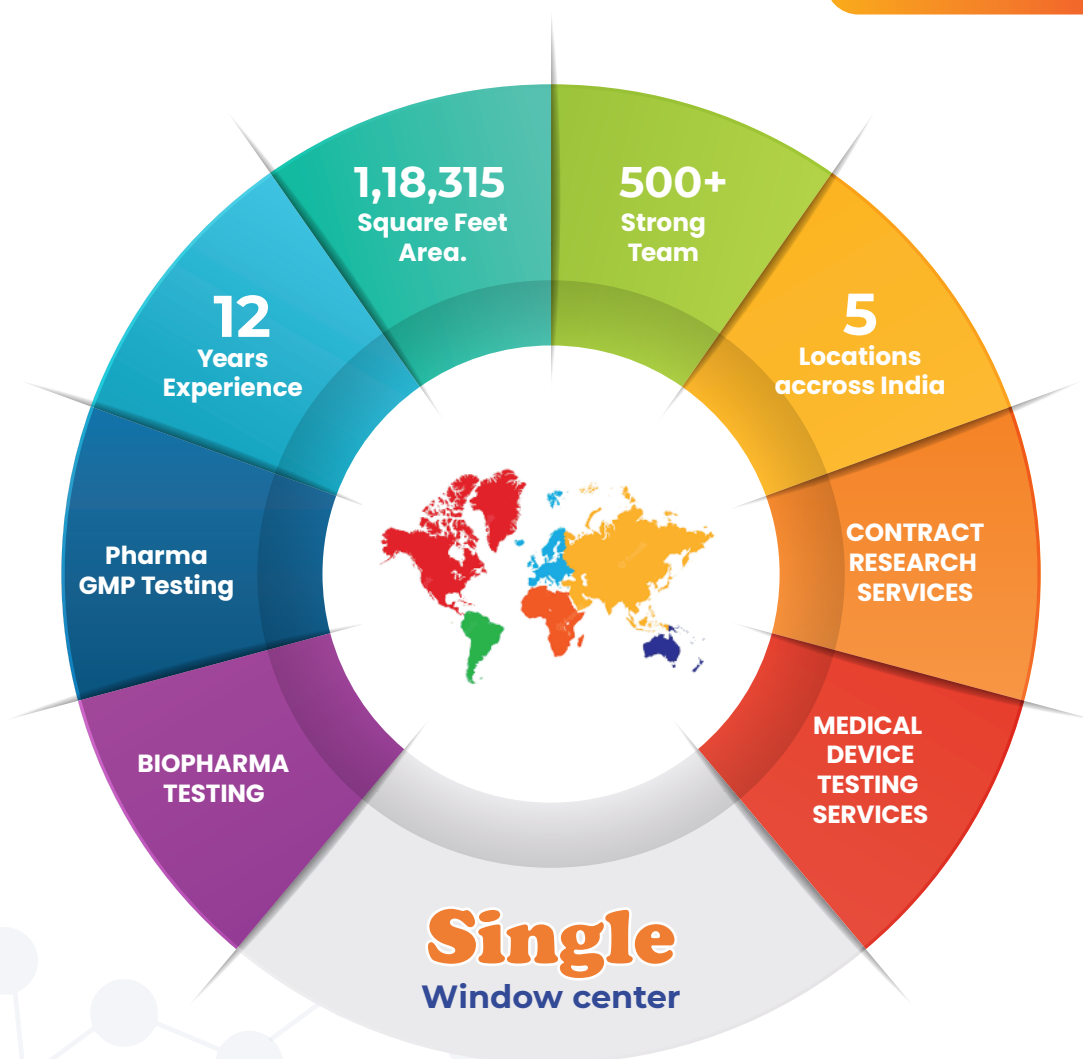
# Accreditations, Licenses & Approvals

Umed is routinely and successfully inspected by regulatory and accreditation authorities. Umed is also audited by several customers every year. As a part of its commitment to continuous improvement external audits are actively encouraged by Umed.



# About Umed Pharma

Umed pharma Lab Pvt. Ltd., was established in the year 2011 and the facility unit-II is established in 2021 at Sultanpur location. Unit-II is established with highly state of art equipment that serves all pharma testing needs like analytical, microbial, biopharmaceutical, medical device and also the contract research services including research and development. Contract testing activities comply with GXP and Regulatory standards. The facility is housed in an area of 2 acres of space, which is built in compliance with regulatory requirements. Unit-II is under the maintenance of adequately trained, talented and qualified group of people having functional experience over years with a deep domain knowledge. The team has successfully managed regulatory and customer audits in the professional journey.



## Get in touch

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