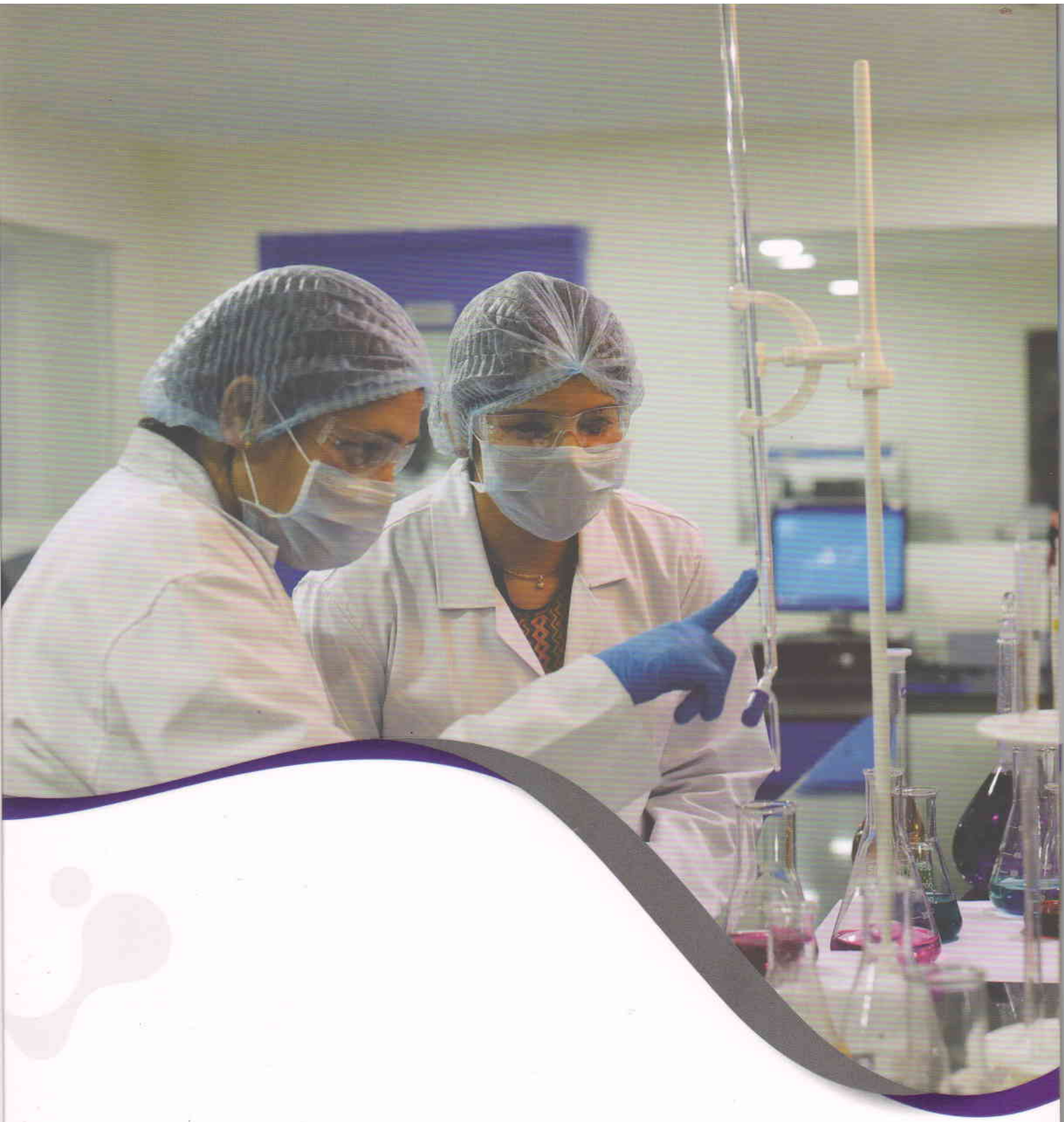


MEGSAN

Robust. Precise. Reliable.

FDA Inspected Facility

Megsan is an industry-leading, global provider of laboratory testing services. We perform wide range of analytical laboratory tests across the pharmaceutical and packaging industries. Our purpose to make certain that, all materials and products we test and certify for our clients are consistent, marketable quality; are compliant with all relevant industry standards & regulations and are ultimately fit for purpose.

We are an organization committed to provide affordable and quality services, in around the country and world clients are benefited from our services.

Our state of the art analytical laboratory situated in Hyderabad, India with built up area of 30,000 sq ft. We use a combination of instruments, analytical techniques and methods to meet service needs.

What we do

We deliver our services through a set quick turnaround time that we make to our clients.

1. **Elemental Impurity Studies**
   Elemental impurity services are performed as per USP General Chapter <232> Elemental Impurities-Limits, <233> Elemental Impurities-Procedures, ICH Q3D, EMEA Guideline and/or customer requirements.

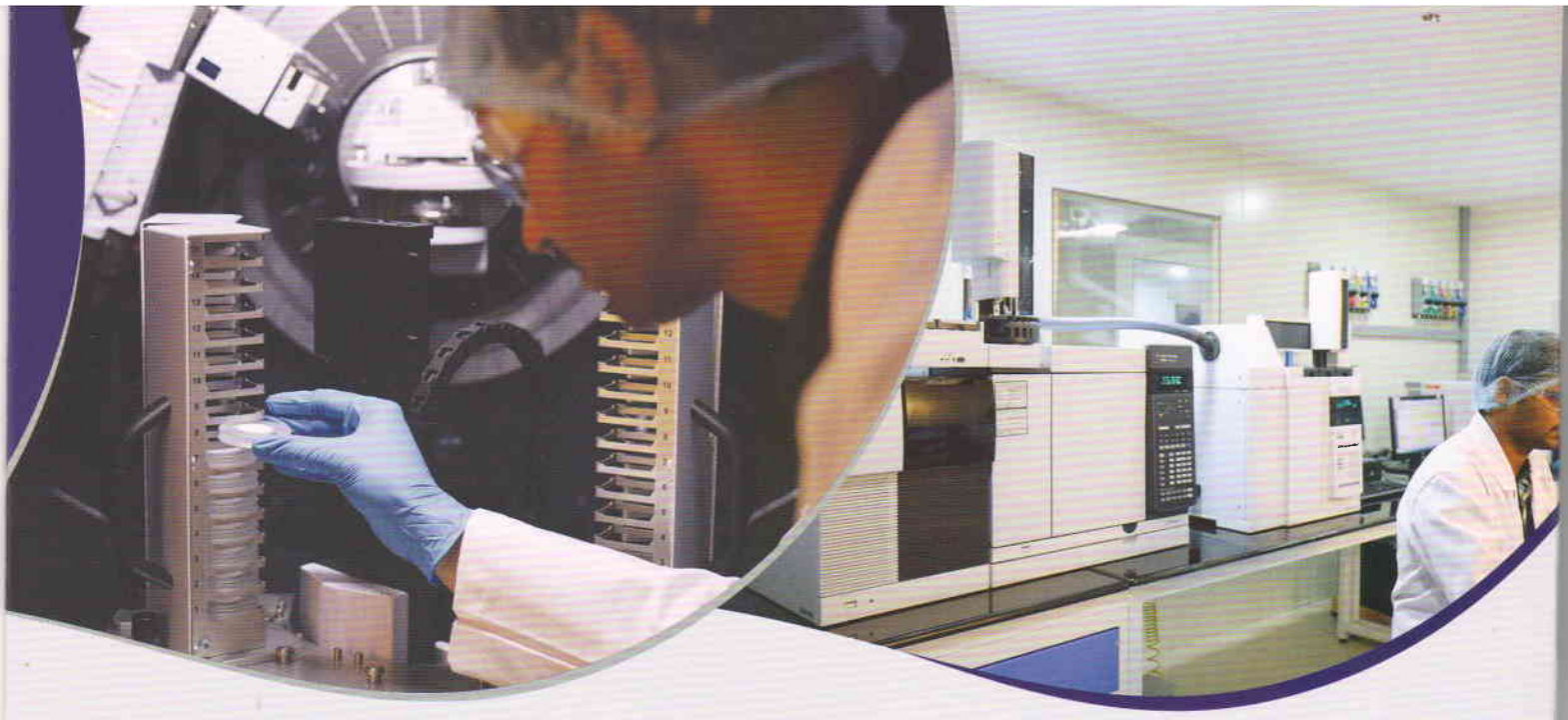
2. **Extractables and Leachables Studies**
   Extractables and leachables services are performed as per latest industry best practices, United States Pharmacopeia (USP) requirements (including USP chapters <1663>, <1664>, and <1664.1>), PQRI recommendation and/or customer requirements.

3. **Genotoxic Impurity Studies**
   Genotoxic impurity services are performed as per ICH M7 (R1) and/or customer requirements for identification and quantification of mutagenic & carcinogenic impurities.

4. **Method Development and Validation**
   Analytical method development and validation services are performed as per ICH Q2, USP <1225>, method verifications as per <1226>, and/or customer requirements. We provide identification, related substance, assay, dissolution, content uniformity, residual solvents, and elemental / genotoxic impurity determinations etc.

5. **Dissolution Studies**
   Dissolution study services are performed as per USP, EP, BP and/or customer requirements.

6. **Raw Material and Excipient Testing**
   Raw material and excipient testing services are performed as per USP/IP/BP/EP/JP and/or customer requirements. We offer chemical and biological tests like assay, identification, residual solvents etc.



7. Packaging Material Testing

Packaging material testing services are performed as per USP 660, 661.1 & 661.2 and/or customer requirements. We offer tests like hydrolytic resistance, glass grains test, surface glass test, surface etching test, chemical and physicochemical tests, and delamination studies by using Scanning Electron Microscope (SEM), Inverted Microscope etc.

8. Pharmacopeia Compendial Testing

Pharmacopeia compendial testing services are performed as per USP/IP/BP/EP/JP and/or customer requirements. We provide chemical and biological tests like assay, identification, residual solvents, calculating surface area by nitrogen adsorption through BET surface area analyzer, and impurity etc.

9. Solid State Characterization

Characterization testing services are screening and quantification of polymorphic forms/impurity by pXRD; identification of melting point, eutectic point, glass transition temperature, heat of fusion and reaction, amorphous content, oxidative and thermal stability by DSC; particle size distribution by using laser diffraction technology and other aspects of characterization as per customer requirements.

10. Stability Studies

Stability studies (storage and testing) are performed as per ICH Q1A and photo stability testing as per ICH Q1B. We offer conditions like 25°c/60%RH; 30°c/65%RH; 30°c/75%RH; 40°c/75%RH; 2-8 °c and/or customer requirements.

11. Microbiological Testing

Microbiological services include development and validation of Microbial enumeration test and test for specified microorganisms (MLT), Antimicrobial Effectiveness Test (AET/PET), Sterility, Bacterial Endotoxin Test (BET by Gel clot & Kinetic methods), Microbiological Assays; testing's like MLT, AET/ PET, Water System Validations; Disinfectant Efficacy Test; Hand Sanitizer Efficacy Evaluation; Environmental Monitoring. We offer services as per various compendia and/or customer requirements.

12. In-vitro microbial kill rate study

In-vitro microbial kill rate study is most appropriate tool to determine bactericidal or fungicidal effect, to understand the dynamic interaction between antimicrobial agent and microbial strain. Estimation of antimicrobial effect is concentration and time dependent. Study majorly carried out for antibiotics routinely administered in ophthalmic category.

How we do

MEGSAN
Robust. Precise. Reliable.

We have world class sophisticated equipment's with cGMP compliance.
Our experienced scientist's and advance equipment support to cater all testing activities.

- **pXRD** (1 No's)
- **DSC** (1 No's)
- **LCMS/MS** (2 No's-with PDA Detector connected to Lab solution server)
- **GC MS/MS** (3 No's -with FID Detector connected to Lab solution server)
- **ICPMS** (4 No's)
- **ICP-OES** (1 No's)
- **AAS** (1 No's- with Flame, Graphite, VGA techniques)
- **HPLC** (15 No's- with UV,PDA,FLR,RI detectors connected to Empower 3 and Lab solution servers)
- **UPLC** (2 No's- with PDA,TUV Detectors connected to Empower 3 server)
- **IC** (2 No's- with conductivity and cyanide detector)
- **GC** HS (04 No's- with ECD,TCD,FID detector connected to Lab solution server and Open Lab Software)
- **Scanning Electron Microscope** (SEM) -(1 No's)
- **Inverted Microscope** (1 No's)
- **Friability Tester** (1 No's)
- **Hardness Tester** (1 No's)
- **Melting Range Apparatus** (1 No's)
- **Disintegration Tester** (1 No's)
- **Viscometer** (1 No's)
- **Microwave digester** (3 No's)
- **TLC** (1 No's)
- **UV Vis** (2 No's)
- **FTIR** (1 No's)
- **Torque Tester** (1 No's)
- **Particle Size Analyzer** (1 No's)
- **Surface Area Analyzer** (1 No's)
- **Walk-in Stability Chambers** (50,000L capacity, complies to ICH conditions)
- **Walk-in Cold Rooms** (30,000L)
- **Photo Stability Chamber** (1 No's)
- **Dissolution Apparatus** (2 No's)
- **Auto Polarimeter** (1 No's)
- **Karl Fisher Titrator** (1 No's)
- **Auto Titrator** (1 No's)
- **Kjeldahl Unit** (1 No's)
- **Flame Photometer** (1 No's)
- **TOC** (1 No's)
- **Buchi Soxhlet Extractor** (2 No's)
- **Tap Density Apparatus** (1 No's)
- **Milli Q Water System with elix** (2 No's)
- **Analytical Balance** (15 No's)
- **Double-door Autoclave** (1 No's)
- **Vertical Autoclave** (2 No's)
- **Endo Safe Portable Test System** (PTS) -(1 No's)
- **Laminar Air Flow Unit** (3 No's)
- **Bio Safety Cabinet** (2 No's)
- **Incubators** (11 No's)
- **CO2 Incubator** (1 No's)

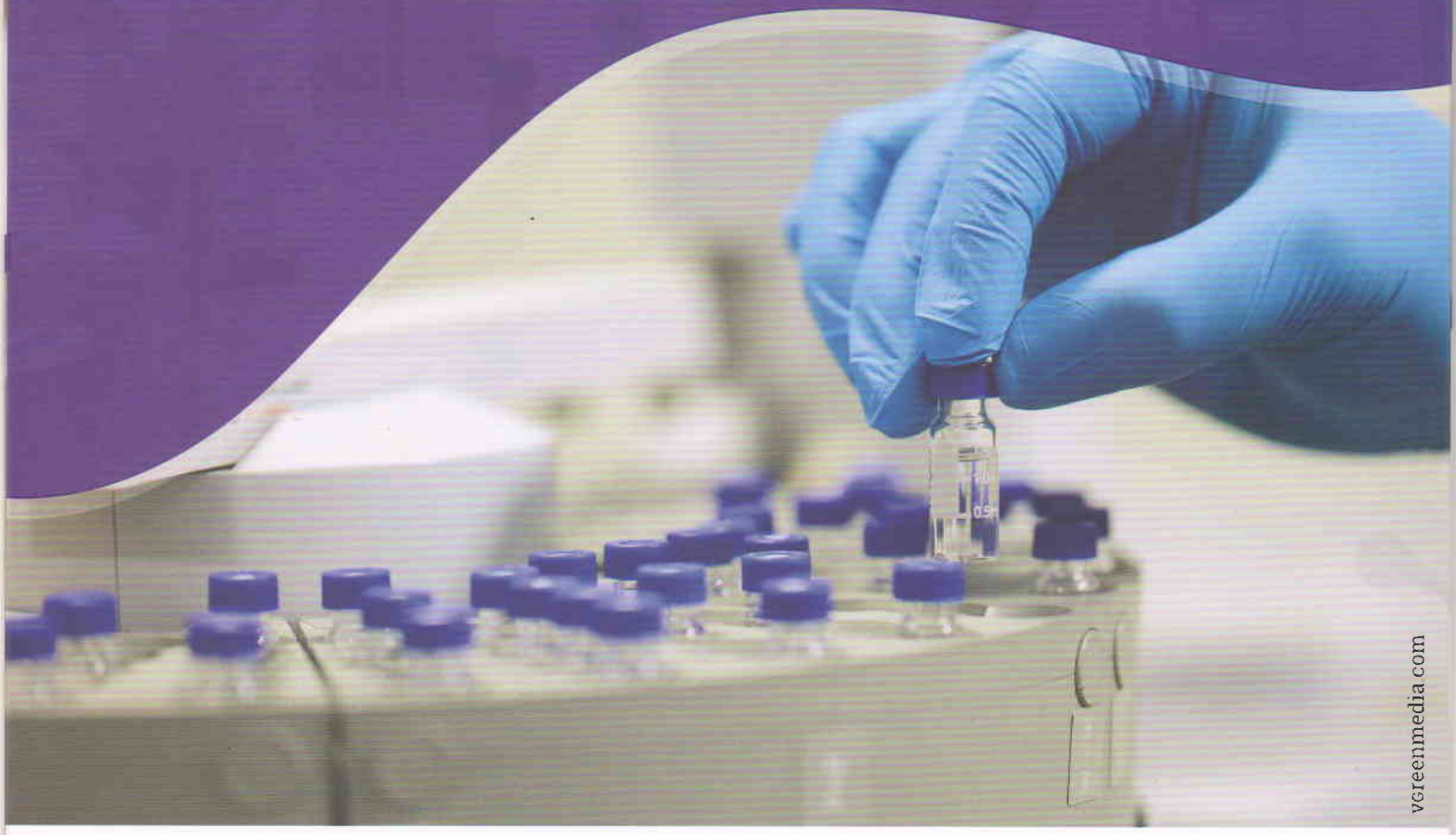
What we have

We operate in accordance with applicable National and International Standards.

USFDA | NABL | ISO 9001 | DCA

what we test

- Active Pharmaceutical Ingredients (APIs) / Drug Substance
- Finished Drug Products (Tablets, Capsules, Injectables, Ointments, Lotions, Syrups, Suspensions, Gels, Inhalations, Creams & Emulsion Transdermal Patches etc)
- Raw materials
- Key starting materials (KSM)
- Intermediates
- Excipients
- Facility Qualifications (water and area)
- Packaging materials and closures (Primary/Secondary)
- Manufacturing Aids (Filters, Tubing's, SS vessels etc)
- Water for pharmaceutical purposes



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