UMED

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GMP

TESTING SERVICES

The contract testing laboratory (pharma & biologics) services were established in 2021 at the Medical Device Park, Hyderabad.

The facility is spread across 2 acres and has been constructed in full compliance with applicable regulatory requirements. It is supported by a well-trained, competent, and qualified team with extensive functional experience and deep domain expertise.

The team has successfully managed and supported multiple regulatory & customer audits, reflecting a strong commitment to quality, compliance, and operational excellence.

- **Chemical Testing**
- **Particle Characterization**
- **Microbiological Testing**
- **Medical Devices**
- **Packaging Material**
- **Raw & Bore well water testing USEPA/WHO/ IS10500**
- **Stability Studies**

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Plot No. G30/2, General Park, Sultanpur(V), Ameenpur(M), Sangareddy Dist, Telangana State -502319

Quality Management System

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

Instumentation

- HPLC – UV, PDA, RI
- UPLC UV-VIS PDA
- GC – FID, ALS
- GC –HS
- GC –MS/MS
- GC -MS
- UV-Vis Spectrometer
- Water activity analyzer
- LC –MS/MS
- pXRD
- PSD
- Particle counter(LBPC)
- Visometer
- TOC analyzer
- FTIR, Near IR
- qPCR
- DNA sequencer
  3500 thermoscientifics
- Particulate matter tester
- ICP MS
- AAS with flame
- Dissolution I, II
- Microplates Reader

Chemical Testing

- Exatrctables & Leachables
- Method Development & Validation
- Impurity Profiling Studies
- Dissolution Profiling
- Genotoxic Impurities
- Elemental Analysis
- Physical Characterization(XRD, PSD)
- Raw Material & Finished Products Testing as per Pharma copoeia (IP/USP/BP/EP/JP/chP)

Microbiology Testing

- MLT, BET, AET, DET, Sterility development and validations
- Microbial Limit Test (product, water and Packing material)
- Bioburden Test
- Bacterial endotoxin test (Gel clot and Kinetic method)
- Sterility (closed Method)
- Environmental Monitoring
- Preservative Efficacy testing
- Microbial Antibiotic Assays
- Liquid Born Particle count (LBPC)
- Dilution studies
- IN use Studies
- Microbial Ingress studies
- Water System Qualification
- Clean Room Qualifications (Viable and Non-viable)
- Microbial Identification using by 16S RNA (Bacteria)
- Fungal Identification by 18S RNA

Packaging Material Testing

as per USP 661,661.1 & 661.2

- Water Vapor Transmission Rate (WVTR)
- Bursting Strength test
- Heavy Metal Content
- Seal & Closure Integrity Tests
- Dimension & Visual Test
- Penetability Test

Specific tests that should be performed on empty syringes include:

- Glide force testing to evaluate syringe lubrication (ISO 11040-4)
- Pull-off force testing of the tip cap or the needle shield (ISO 11040-4)
- Flange break resistance testing (ISO 11040-4)
- Luer cone breakage resistance testing (ISO 11040-4)
- Needle penetration testing (ISO 11040-4, ISO 7864, ISO 9626, and DIN 13097-4)
- Needle pull-out force testing (ISO 11040-4)
- Luer lock adapter collar pull-off force testing (ISO 11040-4)
- Luer lock adaptor collar torque resistance testing (ISO 11040-4)
- Luer lock rigid tip cap unscrewing torque testing (ISO 11040-4).

Stability Studies

- Forced Degradation(FD)
- Photostability studies
- Incubation & testing as per ICH-QI
- Freeze thaw cycling stability studies

Particle Characterization Analysis

Integrated Technologies for Comprehensive Analysis

Inverted Fluorescence Microscopy :

Enables rapid detection of microscopic contaminants on transparent surfaces such as filters and slides. Fluorescent tagging enhances visibility of organic and biological particles, supporting precise identification

UV Fluorescence Imaging :

Utilizes ultraviolet excitation to reveal particles that are otherwise invisible under standard lighting, ideal for detecting trace residues like oils, polymers, and biological matter.

EDXRF (Energy Dispersive X-ray Fluorescence) :

Provides non-destructive elemental analysis of particles, allowing us to determine their chemical composition & trace their origin —essential for root-cause investigations and corrective actions.

Integrated Technologies for Comprehensive Analysis

Stereo Microscopy (Extended Analysis) :

Utilizes ultraviolet excitation to reveal particles that are otherwise invisible under standard lighting, ideal for detecting trace residues like oils, polymers, and biological matter.

Scanning Electron Microscopy (SEM) with EDX :

Provides non-destructive elemental analysis of particles, allowing us to determine their chemical composition & trace their origin —essential for root-cause investigations and corrective actions.

Medical Device Testing Services

★ Specialization

- Sterility testing and sterility validation
- Endotoxin testing
- Bio burden testing
- Pathogen testing
- Bio compatibility studies
- Stability studies

★ Routine

- Gloves
- Blood bags
- Male/Female condoms
- Sanitary Napkins
- Intra uterine devices- copper T
- Intra uterine devices- Tubal ring
- Surgical sutures
- Rubber stoppers
- Blood transfusion set
- Handloom cotton Gauze
- Peal strength
- Seal/closure integrity
- Package intergrity
- Pouch burst strength
- Label legibility strength
- Dye penetration test
- Vibration test
- Drop test
- Product sterile barriers
- Shipping configuration validaion

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

Bore well & Raw Water Testing

Raw water / Bore well water testing : USEPA,WHO and IS10500:2012

USEPA PARAMETERS

- Organic chemicals –53
- Inorganic chemicals –16
- Contaminants -14
- Disinfectants/by products -7
- Radioactive analysis –4

PARASITOLOGY

- Giardia lamblia
- Cryptosporidium

VIROLOGY

- Entero virus
- Hepatitis A virus

MICRO ORGANISMS

- Legionella Bacteria
- Salmonella Species
- Staphylococcus aureus
- Pseudomonas aeruginosa
- Heterotropic plate count
- Total coliform bacteria
- Escherichia coli
- Faecal coliforms

WHO PARAMETERS

- Inorganic chemicals – 19
- Disinfectants/by products - 6
- Physical parameters – 18
- Organic chemicals – 61
- Trihalomethanes – 5
- Radioactive analysis – 2

MICROBIOLOGY

- Total Coliform bacteria
- E.coli/Thermotolerant coliform bacteria
- Microcystin-LR

IS10500:2012

- Physical parameters – 6
- General parameters – 23
- Toxic substances -8
- Pesticides – 18
- Trihalomethanes – 5
- Radioactive analysis – 2

MICROBIOLOGY

- Total Coliform bacteria
- E.coli

VIROLOGY

- Entero virus
- Hepatitis A virus
- MS2 Phage

MICROBIAL IDENTIFICATION OF BACTERIA & FUNGI BY DNA SEQUENCING (3500 GENETIC ANALYZER)

Pharmaceutical Gases Validation

- Compressed Air(ISO 8573-1 /IP/BP/EP/USP)
- Nitrogen Gas Testing
- Breathing Air(ISO 8573-1 /IP/BP/EP/USP)
- Pure Steam Quality
- TestHTM2010, EN285
- Filter Integrity Test[Bubble Point Test]

UMED PHARMA ★★★★★ FDA APPROVED

UMED PHARMA ★★★★★ NABL ISO 17025 ACCREDITED

UMED PHARMA ★★★★★ DCA APPROVED

UMED PHARMA ★★★★★ GLP CERTIFIED

UMED PHARMA ★★★★★ ISO9001 CERTIFIED

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Pharma GMP Testing

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