MICRON HVAC PVT. LTD.

More Than Commitment...

WHAT WE OFFER

- HVAC / Cleanroom Validation Services
- Compressed Air Validation
- Thermal Validation & Calibration
- GMP / Pharma / HVAC Consultancy
- Biopharmaceuticals Consultancy
- PLC / CSV Validation
- Media Fill Videography

CC-3492

ISO 9001:2015

OHSAS 45001:2018

VISIT : www.micronhvac.com

KEY FACTS OF
MICRON HVAC

DIRECTOR

Mr. Arun Wangekar is founder & director of MICRON HVAC. He is A **Strategic Leader** enriched with **Mechanical Engineering** background and extensive experience in **Pharmaceutical HVAC, Cleanroom, Cleanroom design, Maintenance, Projects Management with execution, HVAC operation, Water systems, Pharma utility, Regulatory audit documentation, National & international audits & compliance, he had worked with India's top Pharmaceutical Companies**, like **Cipla, Sun Pharma, Emcure**, etc in the capacity of mid-level management with high caliber and excellence. He is having **23 Years'** experience. He has also been involved & participating in Training, Seminars, and others Pharma program during his tenure. From **Dec. 2010. Arun** has started his venture as **Proprietory Firm** & then converted in to **PVT. LTD. Firm** on **Sep 2016** as **Micron HVAC Private Limited**, to capture the top clients from the market like **Healthcare, Automobiles, Infrastructure, Foods, Medical devices, Agriculture** and **Hospitals** while main focus remains on **Pharmaceutical sector**. He is an expert in formulating strategic business plans, brand building, marketing plans, promotional plans, sales strategies.

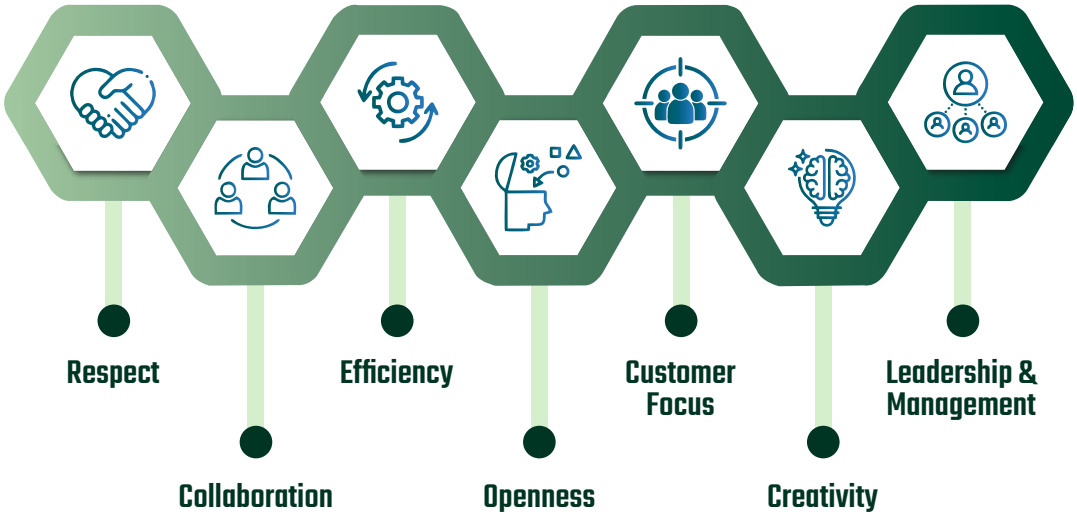
Currently, **Arun** is focusing to develop a professional and highly experienced pharmaceutical techno marketing field at Micron. Besides he is **engaged in business development in GMP, PHARMA & HVAC, CQV, IT Consultancy services filed**, for **national** & **international level** as a consulting company.

Arun has been serving as a **Director** in the Board of **Micron Air filters & Equipment's Pvt. Ltd.** Micron Air Filters is basically engaged in manufacturing of cleanroom & HVAC Air filters for Pharma, Health, Research & Automobiles areas.

He is also engaged in construction work, company named "**MIRACLE ENTERPRISES**". construction includes - in sector of pharmaceuticals projects, hospitals, medical college, residential, airport and many commercial and industrial projects.

Arun Wangekar
Founder & Director

Our
VALUES & BEHAVIOURS FRAME



Micron Cleanrooms | Micron HVAC | Micron GMP, Pharma, HVAC, Design, CQV & IT CSV

We Are PRIDE

MICRON

P — PEOPLE FOCUSED
Supportive | Welcoming | Kind

R — RESPECT
Listening | Appreciative | Protect Dignity

I — INTEGRITY
Professional | Communicate | Open

D — DEDICATION
Teamwork | Positive | Helpful

E — EXCELLENCE
Safe | Effective | Improving

OUR JOURNEY

MICRON

2023
Started calibration services
Started GMP & HVAC Consultancy

2022
Registered under NABL, Got NABL accreditation for thermal calibration.

2019
New corporate office set up at Thergaon, Pune.

2017
Expand validation services at Indore, Pithampur and Dewas

2016
Company was incorporated on 28 September 2016 as Pvt. Ltd. company.

2015
Validation expands at Aurangabad & Nashik site.

2009-2011
Proprietor firm started. Micron cleanroom services stablished in 2009.
1st validation started from Pondicherry & Ahmedabad.

Mr. Vikas Hari Sathe, brings **unique experience** in **management of formulation manufacturing operations** and **project management** for new manufacturing facilities with over **35 Years.**

He has **core experience** in **Designing & qualification of formulation manufacturing facilities**, **manufacturing operations** of wide spectrum formulations, GMP compliance and regulatory audits.

He is **SME** (Subject Matter Expert) in **Designing and Operations of Isolator based manufacturing facility for Cytotoxic / high potency injectable formulations, including Lyophilized formulations, Manufacturing facility for Aseptic terminally sterilized or sterilized Injectable formulations, Manufacturing facility for Oral Solid dosage forms - Tablets and capsules, Manufacturing facility for External Preparations (Ointments and Creams).**

He worked as **Plant Head** with reputed Indian Pharmaceutical Organizations.

Mr. Vikas Hari Sathe - M. Pharm, MAM.
Pharma Consultant, Micron HVAC Private Limited.

DID YOU KNOW?

He earned Master degree in Applied Management and has do the upgradation of existing facilities for GMP Compliance and Process, Productivity improvements. He is an expert in designing, developing equipment cleaning processes, cleaning validation & process validation, clean room qualification & designing facility monitoring program.

Dr. Nand Kishor Khandelwal, has been part of our **high potent GMP Consultant** Team & comes with a strong **Quality Assurance, Quality Control, Microbiology, Technology Transfer, Audit & Compliance, Qualification & Validations** background with over **32 Years** of experience across the **Sterile Parenterals**, **Cytotoxic Non-Sterile**, **Oral Solid**, **finished Pharmaceuticals**, **API** (Active Pharmaceutical Ingredient), and **Medical Devices** industries.

He is **SME** (Subject Matter Expert) in **aseptic processing**, **sterility assurance**, **microbiology**, **QMS** (Quality Management Systems), **risk assessment**, **investigations** & having vast experience in responding to **inspectional observations** of regulatory agencies.

He worked as **Head Quality** with reputed Indian Pharmaceutical Organizations such as, **Lupin Limited**, **Orchid Chemicals & Pharmaceuticals Ltd.**, **Wockhardt Limited**, **Emcure Pharmaceuticals Ltd.**, **Sri Krishna Pharmaceuticals Ltd**, he has faced several health authority inspections, **WHO**, **US FDA**, **UK-MHRA**, **Health Canada**, **European Union (EU)**, **TGA**, **SHAPRA**, **GCC**, **ANVISA**, **ISO** etc.

Dr. Nand Kishore Khandelwal - Ph.D.
GMP Consultant, Micron HVAC Private Limited.

DID YOU KNOW?

He earned a Ph.D. in Microbiology and was a Member of various professional bodies including PDA (Parenteral Drug Association), USA.
He has travelled to USA, China, Asia, Europe, Korea, and Oman on various Project assignments.

LEADERSHIP TEAM

Mr. Bipin Patil, is a **HVAC Consultant** and he has **39 Years** of experience in **HVAC & contamination controls.** He is running a **Aerience** (Institute of Air science & contamination Control) a unique **Training Institutes** located in Pune (India).

He is **SME** (Subject Matter Expert) in **Designing HVAC, design of cleanroom, special purpose laboratories, BSL -1, BSL-2, BSL-3, BSL-4, HVAC, Cleanroom performance, Optimization** and **Indoor Air Quality.**

He has successfully handled **MEP, CFD Analysis, Cleanroom designing, Building modelling projects** & **Cleanroom performance audits.**

He has **Designed** & Successfully Completed many **Pharmaceuticals, Automobiles & Engineering Projects** in **India** as well as **abroad.**

Mr. Bipin Patil - B.E.
HVAC Consultant, Micron HVAC Private Limited.

DID YOU KNOW?

He has trained professionals over 15 years in sustainable building design and fulfilled the growing need for skilled manpower across India to narrow down the gap between demand & supply.

Mr. Dnyanesh Motewar is a HVAC Consultant, he has 28 years of experience in HVAC, Clean room HVAC, Lab Airconditioning, Precision Air Conditioning and Comfort HVAC Systems, He is founder &Director of its own Sagra HVAC Pvt.Ltd., Firm was established in the year 2018.

He is SME (Subject Matter Expert) in designing Manufacturing, Engineering, Pharmaceuticals, FMCG And Construction gives us the insights in the industry specific business processes and improves our understanding of the client requirements. This has led us to undertake Turnkey Projects of Comfort Air Conditioning, Precision Air Conditioning, Ventilation and Clean Rooms Applications for Commercial, Industrial, Data centres & Hospitals.

He has designed & successfully delivered many Pharmaceutical, Hospitals, Data centres & IT Projects.

Mr. Dnyanesh Motewar- B.E. (Mechanical)

HVAC Consultant, Micron HVAC private Limited

DID YOU KNOW?

He is expert in HVAC Design & Engineering, Specialist in Optimizingcomfort, Efficiency & Performance.

LEADERSHIP TEAM

Mr. Kumar Kurle is a **GMP Consultant** and has over 23 years of experience in pharmaceuticals and biopharmaceuticals API and finished products.

He has core experience in research and development, technology transfer and scale up, facility design, Recombinant cell line development & characterization, Toxicological GLP studies. Process validation, cleaning validation, Analytical method development and validation and Quality management in the areas of Biosimilars, Recombinant vaccines, monoclonal antibodies and plasma proteins.

He has worked with reputed pharma/biopharmaceutical companies such as Cipla, Wockhardt, Gennova, Piramal and Dr. Reddy's.
He has headed quality assurance department over 15 years. He is adept in statistical process controls, GMP trainings, investigations, Risk assessment and CAPA management.

He has Strong subjective background of Chemistry, Biochemistry, Molecular Biology and Microbiology.

Mr. Kumar Kurle – MSc Microbiology

GMP Consultant

DID YOU KNOW?

He has played key role in two green field projects for erecting biopharma facilities.
He is a Certified Six-Sigma black belt (CSSBB) and Certified GMP professional (CPGP) from American Society for Quality (ASQ). He has extensive project management experience & QMS implementation for R&D labs as well as commercial manufacturing plants from scratch.
He has travelled across the globe in USA, Europe, Singapore, China & Japan on various project assignments

Mr. Prakash Deshmukh is a **Pharma Consultant** in the company. He has 32 years of experience in Pharmaceutical Manufacturing of liquid injectables, lyophilized products, Oral Solid Dosages, Liquid Orals.

He is expert in QMS, GMP Training, regulatory compliance, GMP auditing, Pharmaceutical Manufacturing, Qualification, Validation.He has worked with reputed Emcure Pharmaceuticals Ltd. / Gennova Biopharmaceuticals Ltd., Pfizer Ltd., M. J. Biopharmaceuticals Ltd.,Tata Pharma / Merind Ltd., Alembic Ltd.

He has perfect planning and execution of GMP audits, Handling of Investigations, Deviations, Change Controls, SOPs, Qualification and Validation documentation, Regulatory audits (USFDA, MHRA, TGA): Regulatory compliance, remediation. Successfully leading of Manufacturing team handling day-to-day production operations of pharmaceutical formulations, Preparation and critical review of SOPs, BMR, BPR, MFR, Qualification Protocols, Qualification Reports, APQRS, SMF, VMP, audit responses.

Mr. Prakash Deshmukh - M. Pharm

Pharma Consultant

DID YOU KNOW?

He is expert in Quality Management System (QMS), Manufacturing Operations and Project Management.

LEADERSHIP TEAM

AUDITING / GMP CONSULTANCY / MICROBIOLOGY / TRAINING

GMP AUDITING

- ✔ Conduct the mock audit of client's site to determine readiness for FDA inspection.
- ✔ Due diligence audit.
- ✔ Third Party Audit on behalf of procurement companies.
- ✔ GAP assessment audit.

ASEPTIC PROCESSING

- ✔ Provide support in development of Aseptic Process Simulation.
- ✔ Qualification of Equipment.
- ✔ Process Validation (Terminal Sterilization & Aseptic Processing)
- ✔ Equipment Procurement.
- ✔ Qualification of Utilities.

GMP TRAINING

- ✔ We can develop & deliver a comprehensive & meaningful in-house training program that is tailored to, & appropriate for client specific needs.
- ✔ Inhouse training is the most cost effective means to improve the skills & capabilities of employees.
- ✔ It is helpful because of convenience & less disruption, value for the money, save time, provide freedom of expression & maintain the confidentiality, provide freedom to discuss client's own case, studies, better interaction, and effective learning.

MICROBIOLOGY

- ✔ Review of Microbial testing methods/procedures viz. Growth Promotion testing, Microbial Limit Test, Sterility testing, Bacterial Endotoxins testing, water testing, antimicrobial and preservative effectiveness.
- ✔ Development of Environmental Monitoring Program (EM).
- ✔ Development of Contamination Control Program (CCP).
- ✔ Development of admixture studies.
- ✔ Development of Microbiology method validation protocols.

AUDITING / GMP CONSULTANCY / MICROBIOLOGY / TRAINING

VETERINARY INDUSTRIES

- Pharmaceuticals Finished Dosage.
- Active Pharmaceuticals Ingredients.
- Drug excipients.
- Medical Devices.

FACED NATIONAL & INTERNATIONAL REGULATORY INSPECTIONS

- Central Drugs Standard Control Org. (CDSCO)
- Indian FDA Inspections.
- U.S. Food & Drug Administration (USFDA)
- U.K Medicines & Healthcare Product Regulatory Agency (UK-MHRA)
- Agency for Medical Products & Medical Devices of the republic of Slovenia.
- Malta Medicines Authority, Malta and so on.....

SETTING UP FACILITIES

- Setting-Up Quality Control and Quality Assurance department.
- Setting-Up the Microbiology Laboratory.
- Setting-Up the Injectable Facility.
- Review of Layout for Finished dosage form manufacturing facility.
- Review of Validation protocols and reports.
- Development of QMS & Pharmaceutical Quality System.

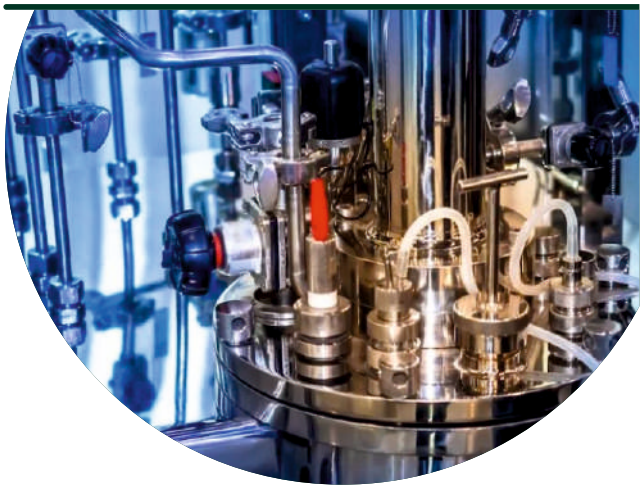
REGULATORY SERVICES

- Review of Abbreviated New Drug Application (ANDA) submissions.
- Review of Drug Master File (DMF) submissions.
- Guidance for preparation of ANDA and DMFs.
- Support in preparation of Remedial Action Plan (RAP) post FDA inspection.
- Provide support in drafting response to regulatory audit observations.

BIO PHARMACEUTICAL : AUDITING / CONSULTANCY / BIO PROCESS CONTROLS

DESIGN & IMPLEMENTATION OF BIO-PHARMACEUTICALS R&D LAB & MANUFACTURING PLANT

- R&D Laboratories - Molecular biology, Biosafety, Fermentation, Protein purification, formulation development, Microbiology, Biochemistry, Cell based bioassays, Chemistry, and plasma fractionation.
- Large scale commercial plants - Seed development, fermentation, Protein purification, Sterile injectable formulation plants, warehouse and quality control laboratory.



CELL LINE DEVELOPMENT & VALIDATION

- Recombinant cell line development
- GMP Cell bank manufacturing
- Cell Bank characterization and biosafety assessment.

ELECTRONIC DOCUMENT MANAGEMENT & PROCESS DIGITALIZATION

- Development and implementation digital solutions for R&D labs, and commercial manufacturing plants
- Process flow mapping, digitalization for R&D, Manufacturing process, quality control, material management, information management, dashboard creation, instrument integration, data trending and analysis, batch manufacturing records, SOPs, protocols and report management.

ANALYTICAL METHODS

- Analytical method development,
- Analytical method validation
- Continuous method performance verification
- Life cycle management of analytical methods, critical quality attributes and critical process parameters
- Chemical, Biochemical, Microbiology, cell-based bioassays

BIOPROCESS CONTROLS

- Identification of CTP and CQAs. Process capabilities studies, control charting
- Viral validation studies
- Process assessment, Assessment of critical quality attributes and critical process parameters
- Cleaning Validation in Biopharmaceutical process
- Technology transfer, Process validation and Continuous process performance verification
- PDA, FDA, EU, ICH compliance

BIOPROCESS EQUIPMENT QUALIFICATION

- URS, DQ, IQ, OQ, PQ and life cycle management
- Risk assessment
- Identification of System boundaries

CHARACTERIZATION OF DRUG SUBSTANCE AND DRUG PRODUCT

- Charactrization of drug substance and drug products
- Risk assessment and structure-function relationships
- Impurity profiling and stability studies
- Protocol preparation and report review

QUALITY MANAGEMENT SYSTEM

- Implementation of QMS in developmental phases of products viz. research and development, technology studies, pre-clinical, clinical phases and commercial manufacturing as per PDA and ICH expectations.
- QMS gap assessment and implementation of phase-appropriate GMP
- Risk Assessment and evaluation of effectiveness of CAPA

ENGINEERING • TURNKEY'S AND GREEN FILED SOLUTIONS

Offers services compliant to ISPE Engineering Guidelines in Pharmaceutical industries

DESIGN & DEVELOPMENT

- ✔ Feasibility Study.
- ✔ Conceptual Design.
- ✔ GMP Risk Assessment.
- ✔ Master Planning.
- ✔ Technology Selection.
- ✔ Equipment Study.
- ✔ Expansion.

CONCEPTUAL ENGINEERING

- ✔ Detailed Building.
- ✔ Architectural.
- ✔ Water System.
- ✔ MEP Designing.
- ✔ Water System.
- ✔ Electrical Load Sanctioning.
- ✔ Plumbing & Utilities.
- ✔ Civil.
- ✔ Structural.
- ✔ Process.
- ✔ HVAC.
- ✔ MEP Designing.
- ✔ Mechanical & Piping.

PROCUREMENT ASSISTANT

- ✔ Preparation of Detailed Vendor List.
- ✔ Floating of Equipment Enquiry.
- ✔ Follow up for Offers.
- ✔ Techno Commercial Evaluation of Offers.
- ✔ Approval of GA Drawings.

SEMI CONDUCTOR | ELECTRONICS

- ✔ Initial Design & Simulation
- ✔ Building Construction
- ✔ Cleanroom Construction
- ✔ Master Planning
- ✔ Regulatory Compliance

FMCG | HOSPITALS | DATA CENTERS

- ✔ FMCG Construction
- ✔ Hospitals / Operation Theaters
- ✔ Data Centre Air Conditioning
- ✔ Precision Air Conditioning
- ✔ Comfort Air Conditioning
- ✔ Large Ventilation System

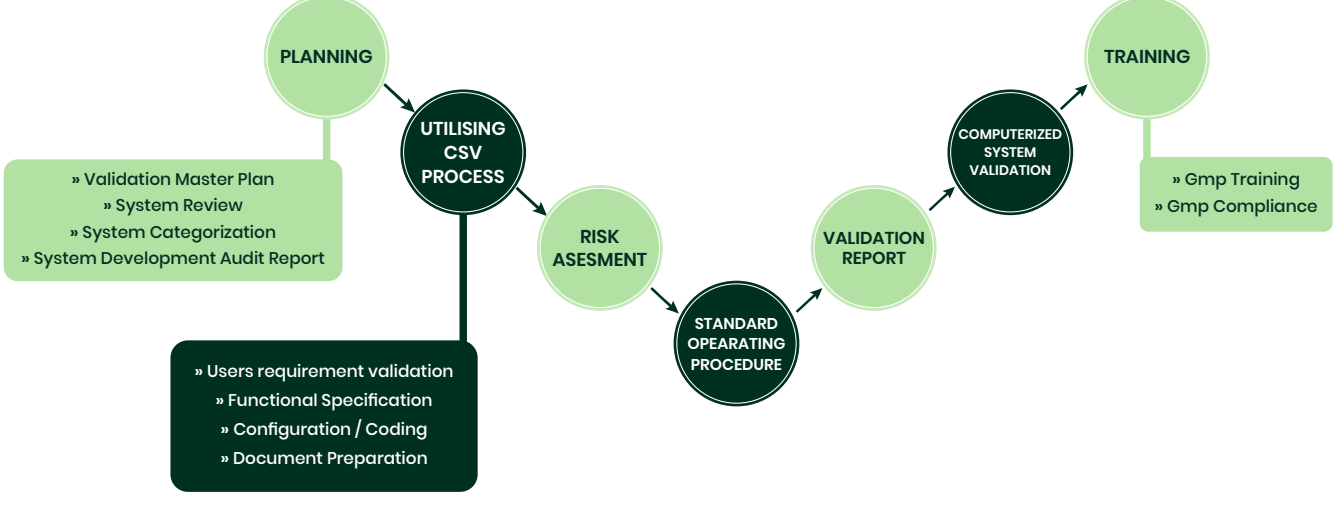
VALIDATION & TECHNICAL DOCUMENTATION• INTEGRATED CQV & CSV/CSA

WHO, Schedule-M, ISPE, US-FDA, UK-MHRA, Africa-SHAPRA, Brazil-ANVISA, Australia-TGA, EU-EMEA,

Integrated Commissioning Qualification and Validation- Verification

are integral steps in building quality into any Product, Process & facility, Equipment, System etc. with help of Master CQV Planning. **Micron HVAC** Leaders with an experience of over **35+ Years of Professional Expertise** provides an efficient and effective documentation system that meets the requirements of National & International Regulatory authorities.

MICRON with its team of experts can manage development & implementation of entire Validation program for its clients. We undertake complete validation tasks from basic to detailed on PLC/HMI/SCADA validation & computerized system validation (CSV) complying as per GAMP-5 Guideline and regulatory expectations. We provide quality validation services to our client ensure compliance with local health authorities, FDA and EMEA approval with no or minimal remarks.

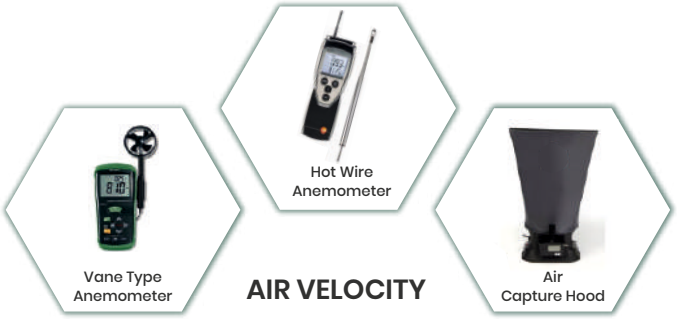


VALIDATION TESTING:
HVAC, CLEANROOM, COMPRESSED AIR

ISO14644-1,2- 2015(E) & ISO14644-3 - 2019(E). EU-GMP Annex-1, WHO, CGMP, ISO 8573 etc.

MICRON performs **Validation Testing of HVAC, Cleanrooms, Compressed Air** as per above regulations.

- ✔ Filter Face Velocity
- ✔ Duct Velocity, CFM
- ✔ Fresh Air Velocity
- ✔ Air Velocity
- ✔ CFM & ACPH Measurement
- ✔ HEPA Filter Leak Test for Plenum, Terminal, LAF, Isolator, Hot Air Unit by PAO oil



- ✔ Non-Viable Particle Count
- ✔ Recovery Test
- ✔ Power Failure & Induction Test
- ✔ Air Flow Visualization Test
- ✔ Media Fill Videography
- ✔ Sound Level & Lux Meter Test
- ✔ Dew Point & Moisture Content Test

Particle Counter

RECOVERY TEST

Validation Assets

Sr. No.	Instrument	Make/Model	Nos.
1	Air Capture Hood	TSI	11
2	Photometer	ATI	10
3	Particle Counter	PMS	22
4	Aerosol/Cold/Hot Generator	ATI	12
5	Water / Glycerol Fogger	Airtech / Concept	10
6	Data Logger	174 Testo	850

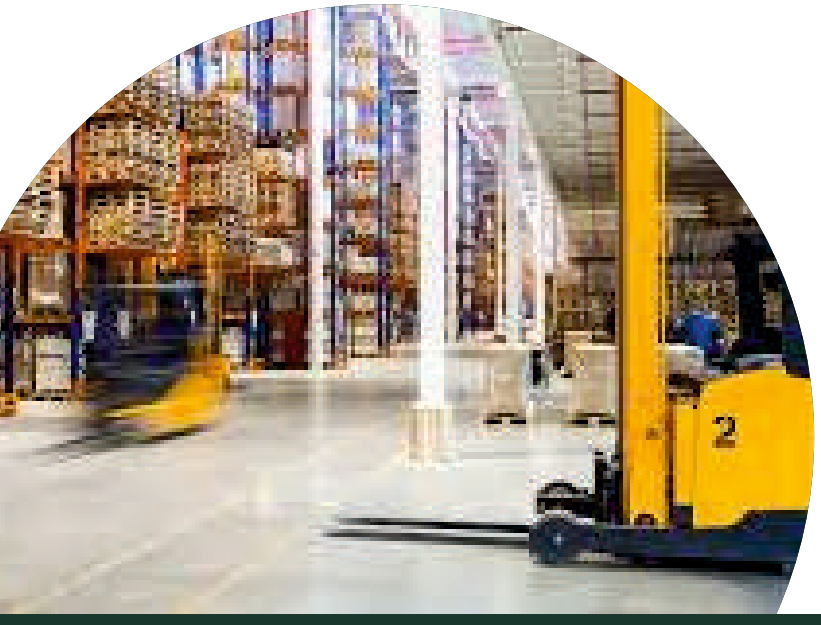
- ✔ Oil / Mist/Hydrocarbon Test
- ✔ Particle Size Concentration
- ✔ Bubble Point Test
- ✔ Viable & Non Viable Count Test
- ✔ Gases Test (CO2, CO, HC, Ho2, 02, H2S)

THERMAL VALIDATION AND CALIBRATION

ISO/IEC 17025 NABL Accreditations Lab, WHO TRS 961, WHO TRS 937 & ISO/IEC60068.

MICRON performs **Thermal Validation Testing & Callibration** for below system/areas as per above rules & norms

- ✔ Autoclave or Steam Sterilizer
- ✔ Cold Room
- ✔ Warehouses
- ✔ Cleanroom Mapping
- ✔ BOD
- ✔ Deep & Walking Freezer



- ✔ Incubators
- ✔ Stability Cabinet
- ✔ Depyrogenation Tunnel
- ✔ Dry Heat Sterilizer (DHS)
- ✔ Washer Disinfector
- ✔ Potable Data Logger
- ✔ Hygrometer
- ✔ Wireless Data Logger

COMPUTER SYSTEM VALIDATION & COMPUTER SOFTWARE ASSURANCE

21 CFR Part 11, EU Annex 11, PIC'S, ANVISA and GAMP 5/ISO 14971 / ISO 27001 / ISO12207/ASTM E 2500

MICRON performs validation of **Process Control System, Manufacturing Execution System, Laboratory Application System / Quality Management System** as per above rules, regulation, and reference standard.

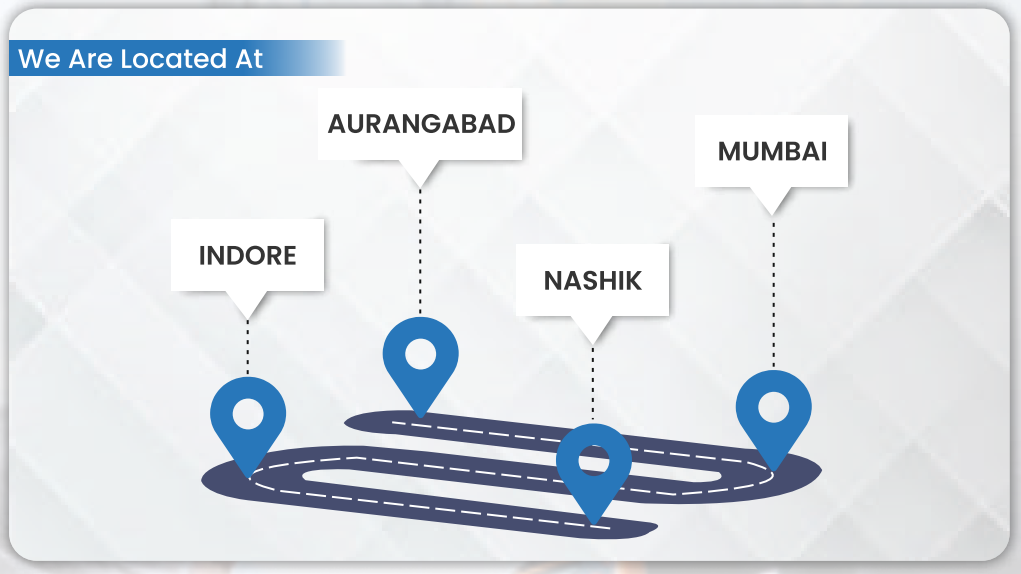
- ✔ HPLC
- ✔ Gas Chromatography
- ✔ FTIR / IR
- ✔ TOC
- ✔ Stability Chamber
- ✔ Muffle Furnace
- ✔ Humidity Chamber
- ✔ Polarimeter
- ✔ Dissolution Tester
- ✔ Sonicator / Refrigerator

- ✔ BMS/EMS
- ✔ Water System / WFI / PW / EDI
- ✔ Blender
- ✔ FBP / FBD
- ✔ Compression Machine
- ✔ Compactor
- ✔ Rapid Mixer Granulator
- ✔ Blister Packing Machine / Strip Machine
- ✔ Vail Washing Machine
- ✔ Depyrogenation Tunnel
- ✔ Vial Filing Machine
- ✔ Vial Sealing Machine
- ✔ Manufacturing & Vessel
- ✔ Integrity Apparatus
- ✔ Isolator / Lyophilizer
- ✔ ORABS

Our Esteemed Clients

THANK YOU

OUR GOAL IS CUSTOMER'S SATISFACTION



MICRON HVAC PVT. LTD.
More Than Commitment...

Corporate Office : Greens Centre, O-309/310, S. No. 26, CTS No. 5401, Thergaon, Pune - 411033, MH, India

Contact : 020 29529739 / +91 9552764776

Email : arun@micronhvac.com / info@micronhvac.com enq@micronhvac.com

Web : www.micronhvac.com

CIN No. : U74999PN2016PTC166600

VISIT US