AUTOCAL®

Bringing Sharpness To The Quality Of Life Science

- Calibration
- Process Validation
- HVAC & Clean Room Validation
- PLC Validation
- Testing
- Education
- Compressed Air Validation
- Steam Quality Test

CALIBRATION

Are your critical standards and instruments calibrated with the highest degree of accuracy?

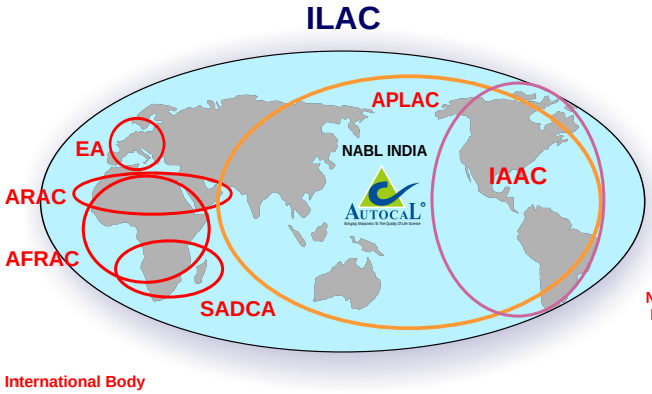
Accurately calibrated standards and instruments are critical for successful operation of regulated industries. All standards and instruments in your research laboratories and manufacturing plants should be correctly calibrated, which improves the overall virtue and quality of your production chain increasing consumer safety, product effectiveness and profitable operations.

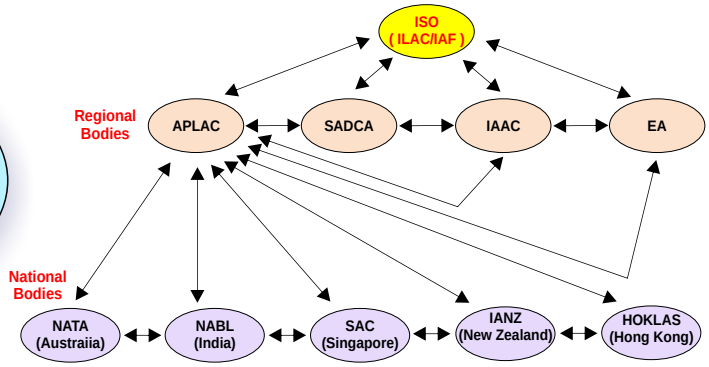
Autocal's services includes nationally & internationally traceable calibration, featuring all NABL accredited disciplines

Autocal being the pioneer in Calibration field can calibrate the full suite of standards and instruments used in laboratory manufacturing environments. Our top-of-the-line metrology laboratory offers National Accreditation Board for Testing and Calibration laboratories (NABL) accredited calibration traceable to the International Standards of Units (SI). All of our calibration services are accredited by National Accreditation Board for Testing and Calibration Laboratories.

Accurately calibrated equipment is the foundation for quality and success of your business

Accurate calibration of your equipments boosts technology investment, reduces downtime and helps ensure quality. **Autocal Solutions** offers both in-house as well as on-site calibration operation for various applications. Our highly qualified personnel caters to manage your calibration projects from scheduling through documentation delivery providing you performance of highest standards.





International Body

- EA - European Cooperation for Accreditation
- APLAC - Asia Pacific Laboratory Accreditation Cooperation
- ILAC - International Laboratory Accreditation Cooperation
- IAAC - Inter-American Accreditation Cooperation
- SADCA - Southern African Development Community Accreditation
- AFRAC - African Regional Accreditation Cooperation
- ARAC - Arab Accreditation Cooperation

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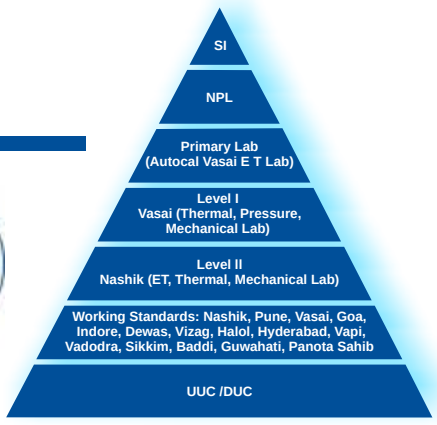


NABL

Pioneers in the Industry, Autocal Solutions meets the rigorous qualifications for National Accreditation Board for Testing and Calibration laboratories (NABL) accreditations as per ISO / IEC 17025. Our current NABL scope can be viewed at www.nabl-india.org.

Vasai Lab certificate No.: C-0915, C-0916 & C-1409
Nashik Lab certificate No.: C-1505, C-1506 & C-1507

Purpose of Calibration

There are three main reasons for having instruments calibrated:
1. To ensure readings from an instrument are consistent with other measurements.
2. To determine the accuracy of the instrument readings.
3. To establish the reliability of the instrument i.e. that it can be trusted.

Autocal's approach to Calibration

Our reference standards are traceable to the International System of Units (SI). In-house calibrations are performed in our state-of-the-art, environmentally-controlled metrology laboratory, which allows us to offer **minimal measurement uncertainty** for your sensitive standards and instruments.

The perfect ranges for your requirements

Our state of the art laboratory features the highest quality primary reference standards, allowing us to offer the ranges and capabilities our customers demand.

- Temperature : -196ºC (at fixed temp.) -95ºC to 1200ºC
- Relative Humidity : 10%RH to 95%RH
- Pressure : -1bar to 2000 bar
- Mass : 1 mg to 600 kg
- Volume : 10µl to 20 ltr
- Torque : 1 N-m to 1000 N-m
- Sound : 74dB, 84dB, 94dB, 104dB, 114dB@1kHz
- Gas Flow : 0.5 SLPM to 4000 SLPM
- Liquid Flow : 0.5m^3/hr to 240m^3/hr
- Length : 1µm to 1000mm
- Electro-Technical : DC Voltage, DC Current, AC Voltage, AC Current, DC Resistance, AC Resistance, Capacitance, Inductance, Frequency, DC Power, AC Power, Power Factor, Active Energy, Transformer Turns Ratio, etc.

All Parameters under one roof

With a broad range of calibration standards in Temperature, Pressure, Humidity, Mass, Electro-Technical parameters and more, **Autocal Solution's** Metrology Laboratory can calibrate hundreds of makes and models of standards and instruments.

Strict Quality review for all Calibrations

All **Autocal Solutions** services meet cGMP requirements. Our highly trained quality staff review and verify each and every calibration documentation, which provides the critical information you need to support the accuracy requirements of your standards and instruments.

Quick Turnaround which keeps your operations On-Schedule

We understand sending your instruments out for calibration can impact your activities. Our large suite of standards, qualified staff and automated workflow helps get your instruments back to you quickly with minimum disruption to your operation.

Autocal Solution's can calibrate

Electro Technical
Multifunction Calibrator
Multimeters – Digital / Analog
Clampmeter
Voltmeters – Digital/Analog – AC / DC
Ammeters – Digital / Analog – AC /DC
Voltage Source (Power Source)
H V Break Down Tester
HV probe
HV divider
Current source
Standard Shunt (AC/DC)
Earth Leakage Current Tester
Power Meter / Power Analyser
Power Factor Meter
V-A-W Meter
KVA Meter
KVAR Meter
PT/CT Burden
CT/PT Ratio / Phase Error
4-20 mA -10V Transducer
Decade Box – Resistance / Capacitance / Inductance
Megger / Insulation Tester
Million-Mega Ohmmeter / Micro Ohmmeter
Resistivity Meter
Safety Ohmmeter
Hi Voltage Testers / Hi Pot Testers

Capacitance Comparator
LCR meters
Function Generator / meter
Earth Testers
Frequency Counters
F to V & V to F Meter
F to I & I to F Meter
Stopwatch
Timer/Counter
Time Totalizer
CRO / Oscilloscope
PH Meter
Conductivity Meter
Waveform Generators (Frequency)

Spectrum Analyser
Oil Tester
Wheatstone bridge
RCD Testers
Multifunction Installation Testers
Electrical Safety Testers
Safety Analysers
Appliance Testers
Transformer Turns Ratio meter
Transformer Turns Ratio standards
Winding Resistance Meters

Thermal
Temperature sensors (RTD, PT-100, PRT, SPRT, Thermocouples)
Temperature Indicator / Controller
Temperature Transmitters
Temperature Recorders
T+RH sensors
Data loggers
Hygrometers
Humidity Transmitters
Temperature
Oven
Bath
Furnace
Environmental Chambers
IR Thermometers
Pyrometers
Thermal Imagers

Pressure
Pressure Gauges / Indicators
Vaccum Gauges / Indicators
Pressure Switches / Transmitters
Vaccum Switches / Transmitters
Differential pressure gauges / Indicators / Transmitters
Differential Vaccum Gauges / Indicators / Transmitters
Pressure Recorders
Dead Weight Testers

Speed
RPM Meter
Tachometer
Centrifuge m/c

Torque
Torque Wrench

Mass
Weighing Balance
Weights

Volume
Micropipette
Pipette
Burette
Measuring cylinder
Volumetric Flask
Graduated Jar/Can

Dimension
Caliper (Vernier / Dial / Digital)
Depth Caliper (Vernier / Dial / Digital)
Height Gauge (Vernier / Dial / Digital)
External Micrometer
Internal Micrometer (Stick Type)
Head
Depth Micrometer (Traverse)
Setting Rod/Extension Rod
Dial Gauge (Plunger Type)
Dial Gauge (Lever Type)
Bore Gauge (Transmission Movement only)
Dial Thickness Gauge
Dial Caliper (External Measurement)
Dial Caliper (Internal Measurement)
Feeler Gauge
Standard Foils
Measuring Scale/Tape
Cylindrical Measuring Pin
Cylindrical Setting Master
Snap Gauge / Gap Gauge
Plain Plug Gauge / OD Gauge
Plain Ring Gauge / ID Gauge
Thread Plug Gauge
Thread Ring
Profile Projector
Centring device
Spirit levels
Force gauge
Load cells
Hardness testers

Acoustics
Sound Level Meter

Gas Flow
Gas Flow Meter / Controller
Gas Flow Transmitters
Rotameter

Liquid Flow
Liquid Flow Meter / Water Meter

Conductivity
Conductivity Sensor
Conductivity Transmitter

ORP
ORP Meter

Level
Level Transmitter

Lux
Lux Meters

COMPRESSED AIR VALIDATION

VALIDATION

Prompt and dependable customer service, quality assurance, training and engineering support contributes to the value our customers have come to expect from Autocal. Our employees are committed to implementing and maintaining the highest standards of quality to merit customer satisfaction. We aim for excellence in everything we do. Our engineers continue to refine manufacturing techniques and take full advantage of the newest machining innovations. Extensive commitment to research and development keeps our service on the leading edge of technology to benefit our customers.

Why Test Your Compressed Air?

Clean Dry Air is essential for many different types of applications. Air compressors draw in large volumes of air from the surrounding atmosphere containing contaminants. The air compressor itself can also add contaminants. Process air contamination found in automotive spray paint air lines, powder coating air lines, pharmaceutical processing air lines, food processing air lines, instrument air lines and in nuclear facilities can affect product quality. A major problem in compressed air systems is the presence of water, oil and solid contaminants which can affect air quality and lead to rust, scaling, instruments clogging, valves sticking and process contamination.

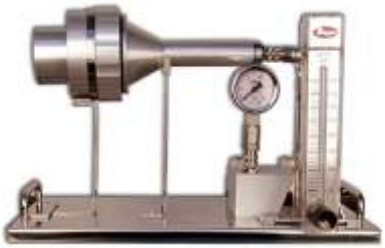
AIR QUALITY IS IMPORTANT

So have your compressed air tested periodically to assure:-

- Protection of equipment and processes
- Safety for your employees
- Energy efficiency of compressor
- Lower operating and maintenance costs
- Assure product quality
- Meet standards/regulations

Services Offered for Compressed Air

- Water vapour (Moisture Content)
- Total Viable Count
- Carbon Monoxide-CO
- Carbon Dioxide-CO_2
- Sulphur Dioxide-SO_2
- Hydro Carbon-HC
- Nitrogen Oxide-NOX
- Oxygen-O_2
- Dew Point
- Oil Mist
- Non-Viable Particle Count
- Hydrogen Sulfied-H_2S



HVAC & CLEAN ROOM VALIDATION

Autocal Solutions Pvt. Ltd. provides Clean Room and Area Validation services with complete set of latest equipments by experienced engineers. Our primary area of quality service is fulfilling validation, regulatory and compliance services from stand-alone automated equipment to start-up, commissioning and validation of new facilities.

Complying to Standards

- ISO-14644-1,2,3
- WHO-TRS-937
- Schedule M
- EU-GMP/ EC GMP
- WHO-TRS-961

Services Offered for Clean Room Validation

- Air flow Test & ACPH Calculations
- Installed Filter System Leakage Test (using PAO)
- Non-Viable Particle Count Test
- Recovery Test
- Air Flow Pattern Test (Using Water Fogger)
- Air Pressure Balancing
- Containment Test
- Temperature & RH Measurement
- Light Intensity Measurement
- Sound Level Measurement

HVAC system provides a specific set of environment condition which is required to make quality products so therefore it must be validated.
Autocal specializes in providing our customers in the Pharmaceutical, Biotechnology & Medical devices industries with cGMP validation services. We are aligned with our customer's compliance and validation needs.

VALIDATION PLAN

- Validation Master Plan
- User Requirement Specification
- Design Qualification
- Installation Qualification
- Operation Qualification
- Preformance Qualification
- Re - Qualification

PLC VALIDATION

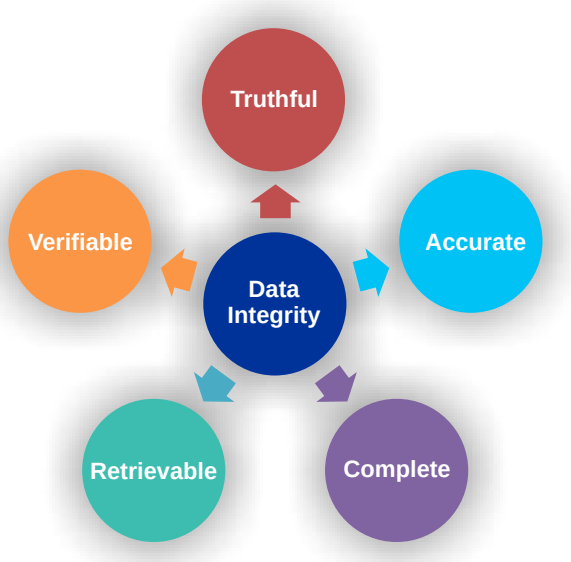
Offers Turnkey Validation services compliant to 21CFR part 11/Annex 11 regulations in pharmaceutical industry. We undertake complete turnkey Validation from basic to detailed on PLC and computerized systems based on GAMP guidelines.

Services Offered

- Programmable Logic Control (PLC)
- Supervisory Control & Data Acquisition (SCADA/DAS) Systems
- Computer System / PLC Validation
- Validate Building Management (BMS) & Environment Control Systems
- Human Machine Interface (HMI/MMI) System
- Distributed Control Systems (DCS)
- Computer Based Systems in Laboratory
- Data Acquisition Software for different Process/ Equipment's

Good CSV can help you reduce CAPA, change control, batch recall and give all people on earth good peace of mind including your shareholders. Data Integrity, Security, Patient safety and Product Quality is a key thing.

An Introduction to Data Integrity...

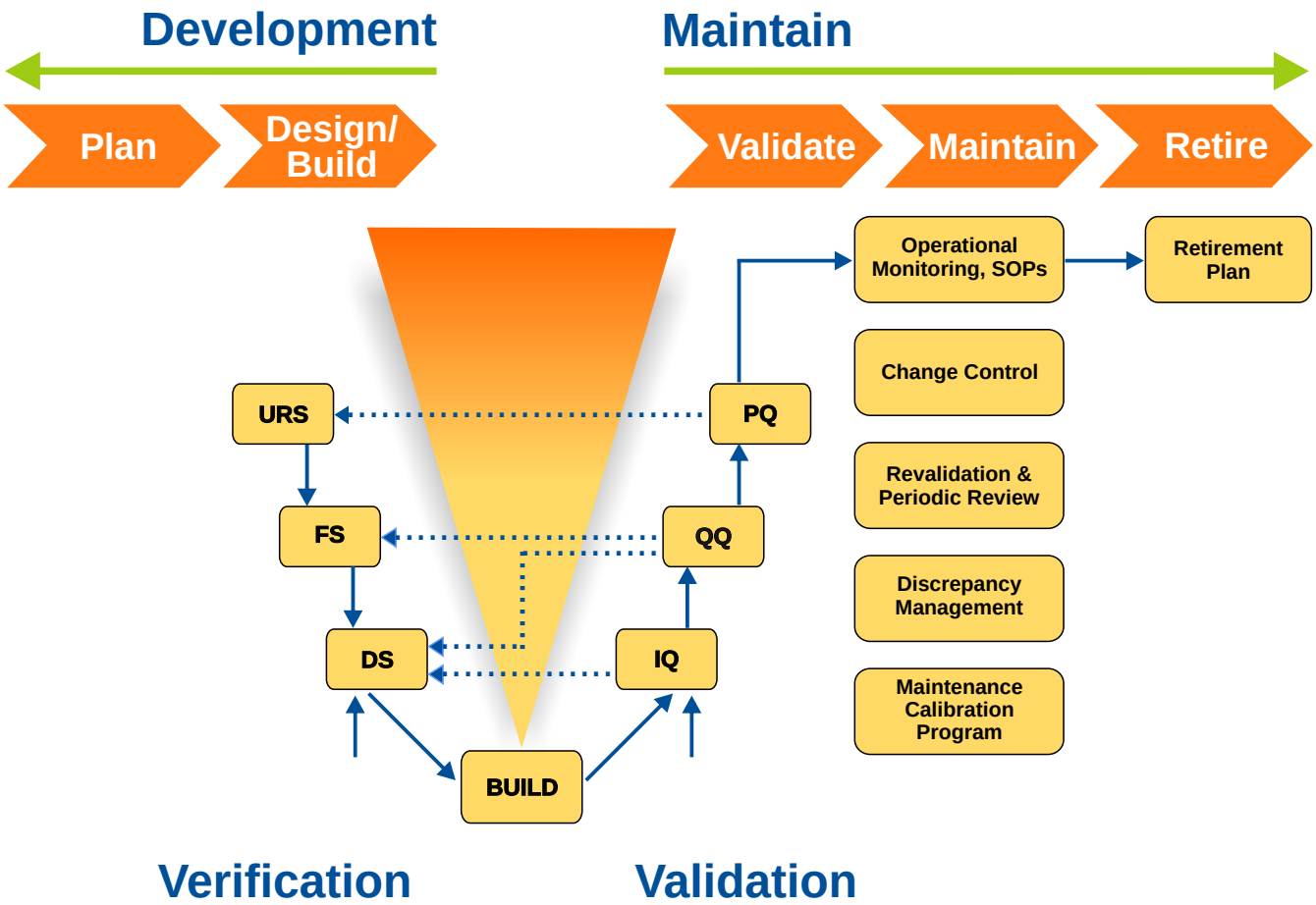


OUR SUPPORTS / HIGHLIGHTS

- Most appropriate & latest GAMP, PIC / S, 21 CFR Part 11, EU Annex 11 guideline based compliance services for your new / legacy systems
- Comprehensive GAP & RISK Analysis
- Organizing and executing activities at client's plants
- Preparation of Protocols & Validation related documentation as per regulatory & client's requirements
- Accountable for completing activities as per schedule, proper co-ordination with client
- Understanding clients requirement. Preparation for Vendor Audits requires a thorough knowledge / understanding of Validation principles and quality philosophies
- Co-ordination of QA and QC programs and functions
- Implementation of company's first self-directed work teams resulting in a flat organization
- Planning, development and direction of Quality programs

We have performed Computer System Validation of the following system in leading pharmaceuticals companies all over India. Most of these companies have cleared their local & international audits like USFDA, MHRA etc.

THE V - MODEL



THERMAL VALIDATION

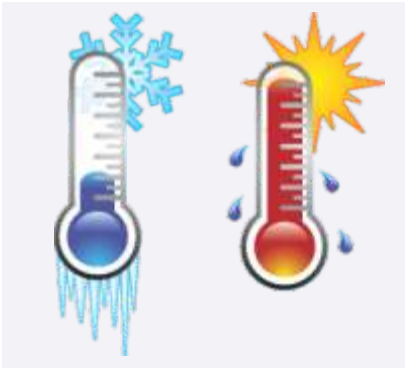
Autocal Solutions Pvt. Ltd. is a leading validation solutions provider to the pharmaceutical and healthcare industries. Our clients recognize us as the premier source for validation professionals for projects of all sizes. In order to ensure the highest level of safety and efficacy in manufactured products, all processes used throughout the manufacturing, packaging and storage facilities, are required to be validated.

Complying to Standards

- WHO TRS 961
- ISO/IEC: 60068

Specialises in the qualification of the following equipment

- Autoclave / Sterilizer Qualification
- Cold Rooms, Warehouse and Room Mapping
- Depyrogenation Ovens Qualification
- Lyophilizers Qualification
- Depyrogenation Tunnels
- BOD, Deep Freezers / Walk In Freezers
- Photostability Chamber Qualification
- Steam-in-Place Qualification
- Incubators
- Stability Cabinets
- Washer Disinfectors
- CIP Systems
- Dry Heat Ovens
- Furnaces



Autocal provides the facilities to measure and analyze and validate the isolated container / Cold Box to maintain the desired conditions for the different ambient profiles as per customer requirements.

Our primary area of quality service is fulfilling validation, regulatory and compliance services from stand-alone automated equipment to start-up, commissioning and validation of new facilities. **Autocal** achieves results through a comprehensive portfolio of services.

Results you can count on; reports you can trust

Validation and Qualification testing provides documented evidence that your chamber or equipment is installed correctly, operates accurately and performs reliably. At the conclusion of your project, **Autocal Solutions Pvt. Ltd.**, will provide a clear, comprehensive validation report, confirming that your systems are compliant to your standard operating procedures. Our validation reports contain all of the data necessary for you to have confidence in the operation of your equipment; each one is written to comply with your quality assurances practices, as well as cGMP and FDA requirements.

Autocal can perform accurate qualifications that meet or beat your targeted time frame. Our wide variety of data logging system options help us choose a custom solution to meet your unique protocol requirements.

Wireless High-Performance Data Loggers

- Real-time environmental chamber monitoring facility with high accuracy range from -80°C to 140°C
- Easily fits in all chambers, vessels, containers and appliances
- 21CFR Part 11 compliant software for reporting and analysis
- NIST- traceable calibrations certificate to meet regulatory requirements

Wired High-Performance Data Loggers

- Ultra-premium Type T PTFP coated wires for projects ranging from -200°C to 200°C
- Ultra-premium Type T Kapton coated wires for dry projects up to 350°C
- Speciality thermocouples for high temperature projects
- Custom thermocouple feed-throughs optimize mapping results
- NIST - traceable calibrations certificate to meet regulatory requirements

Protocol Development and Consultation

Autocal Solution Pvt. Ltd. can create Installation Qualification (IQ), Operational Qualification(OQ) and Performance Qualification (PQ) protocols for you or we can execute your own protocols. As a cost-saving measure, we apply our experience with instrumentation and controls recommending and implementing essential modifications to bring your equipment into compliance.

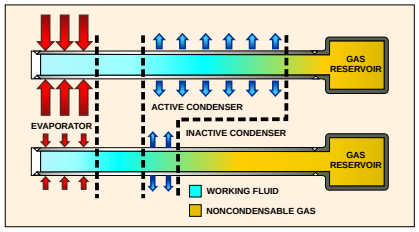
STEAM QUALITY TEST

The testing involved in facility utility pure steam validation requires a continuous supply of saturated steam; preferably sourced from the actual line that supplies your sterilization systems. Too high a level of non-condensable gases will prevent the attainment of sterilization and too little moisture carried in suspension may allow the steam to become super-heated during expansion into the chamber, while excess moisture may cause damp loads.

Why Steam Quality Test is require?

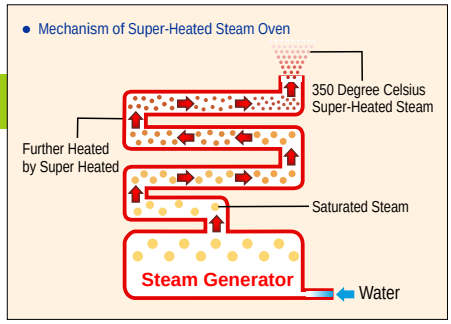
- To detect Non-condensable Gas, Dryness, Superheat.
- To qualify plant/utility/clean/pure steam generators, steam distribution systems and steam supplies to autoclaves in accordance with cGMP (Orange Guide), HTM 01, HTM 2010: 1994, HTM 2031: 1997, EN 285: 2006,AAMI ST79, ISO 14937:2000, ISPE Baseline guide for Steam and Water and PDA Technical Reports No. 1 & 48.
- To test your physical steam quality with assured and repeatable results in no time at all.
- To satisfy your Regulator/QA immediately.

Non-condensable Gases Test



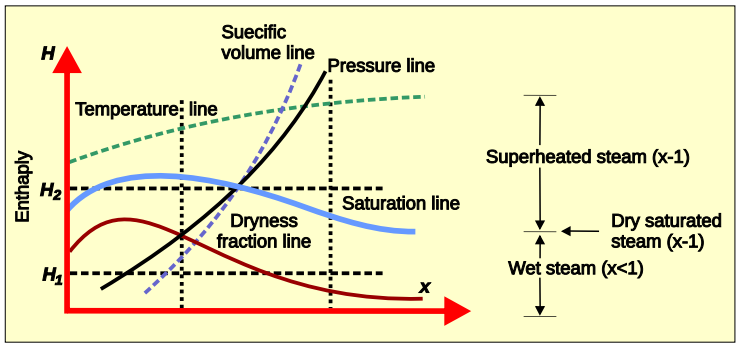
Non-condensable gases originate from the water that the steam is generated from. The effect of such gases being present in the steam supply to a sterilizer can be the same as air, none sterilization of the volume they occupy.

Super-heated Steam Test



Superheated steam is steam at a temperature above its boiling point for its pressure. Superheated steam acts as hot air and requires sustained high temperatures and long hold times before sterilization can occur. It is essential in facility utility pure steam validation to verify that the steam being tested is not superheated.

Dryness Value Test



Wet steam is undesirable as it has less energy than dry steam and more importantly can cause wet loads. The packaging used for sterile products prevents reinfection when dry, but its bacterial retentive properties will be adversely affected by the presence of moisture. Wet loads can be considered to be un-sterile. The dryness fraction describes how dry steam is, with a value of 1 representing steam that is 100% dry, and dry, and therefore free of entrained moisture. Steam with a dryness fraction of 0.99 consists of 99% steam and 1% water. If we measure the latent heat present in steam that has a dryness fraction of 0.99 we will find that it possesses 99% of the full quotient of latent heat.

Why Autocal?

- India's largest and best Accredited Calibration and Validation Laboratory
- NABL Accredited Lab as per ISO/IEC 17025: 2005
- Highly Qualified Personnel
- Modern, Sophisticated, Reliable Calibration Setup
- Equipment Traceability to National & International Standards
- Annual Agreements and Contracts for service
- 15 PAN India locations and still growing
- More than 3000 customers including 1700 pharma companies
- 4 Laboratories in India
- Almost all parameters under one roof
- RH done with European Masters
- Very competitive rates
- Quick and professional service
- Monthly Calibration due reminders
- More than 400 employees to cater urgent needs
- 100 USFDA, MHRAF & other audits through
- Audit Support
- More than 3000 wireless Temp + RH data loggers can be deployed at a time
- 15 setups of HVAC Equipments
- **Testing of :**
  - Water
  - Air
  - Microbiological
  - Food
- Continuous quality improvements on all SOPs

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Autocal Solutions Pvt. Ltd.

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