ARCHERCHEM

CALIBRATION & VALIDATION

Master in Measurement, Partner in Performance

ARCHERCHEM CALIBRATIONS PVT LTD

www.archercal.com

HISTORY

20

Years in trading of bulk drugs, chemicals and intermediates, Herbal Extracts, Oils and Cosmetic ingredients

Since 2000

4

Years in instruments sales and servicing

Market Leadership

Leader in offering

"Total Solutions"

Integrity

ISO /IEC :
17025: 2017
Accredited Cal Lab
at Mumbai &
Vadodara

NABL Accredited

HEALTHCARE,
INSTRUMENTS,
CALIBRATION

Group of Companies

Professional Management & leadership team

Strong Management

ARCHERCHEM CALIBRATIONS PVT LTD

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OFFERING

We offer complete end to end Calibration, Validation and Mapping services.

CALIBRATION

- Electro – Technical
- Dimension
- Pressure
- Mass & Volume
- Torque
- Force & Hardness
- Speed/ Acceleration
- Density
- Sound & Vibration
- Temp. & Humidity
- Flow (Gas & Liquid)

VALIDATION

- Temperature Mapping
- Relative Humidity Mapping

HVAC VALIDATION

- Clean Room Validation
- Isolator Validation
- Biosafety, LAF validation
- PLC validation

We also provide consultancy for Lab set up, ISO/IEC 17025 accreditation and conduct seminars & training programs related to calibration/ testing/inspection activities.

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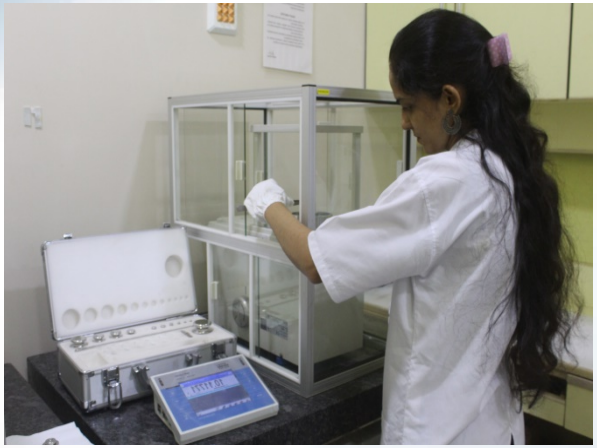
INFRASTRUCTURE



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CALIBRATION - ELECTROTECHNICAL

Sr.	Instrument	Range
1	Multimeter up to 4 ½ DMM	V,I,R,C, Hz, °C
2	Portable Process calibrators/ Universal Calibrators	V,I,R, Temp.
3	AC/DC Voltmeter/Ammeter	0 to 1000 V , 0 to 10 A
4	Energy Meter	1 -ph/3 - ph Energy meters
5	Stop watch/ Time interval meter/Timer	Up to 24 hrs
6	Clamp on meter/Tong Testers	V,I,R,C,
7	Temperature Indicator/Controller -- By Electrical Simulation	RTD/TC type
8	Temperature Loggers -- By Electrical Simulation	RTD/TC type

CALIBRATION - THERMAL

Sr.	Instrument	Range
1	RTD/ Thermocouple sensor with or without Indicator	(-) 196 °C to 1200 °C
2	Temperature Transmitter with or without Indicator	(-) 80 °C to 300°C
3	Temperature Switch	0 °C to 300°C
4	Temperature Chart Recorder	(-) 80 °C to 1200 °C
5	Glass / Digital Thermometers & Temperature Gauge	(-) 80 °C to 300 °C
6	Deep freezer/ Refrigerator/ Cold Chambers (Using Single Point calibration)	(-) 80 to Amb °C
7	BOD Incubator (Using Single Point calibration)	Amb to 600 °C
8	Water Bath	Amb to 100 °C
9	HPLC,/GC-MS Temperature Ovens / Shaker Bath/ Liquid Bath	Amb to 600 °C
10	Muffle furnace OR Temperature Ovens/ Dry Block Calibrator/ Heating Block	Amb to 1200°C

CALIBRATION - THERMAL

Sr.	Instrument	Range
11	Thermo Hygrometer (Table Top)/ Relative Humidity Probe or Transmitter with sensor	10 % Rh to 95 % RH @ 25 °C & 10 °C to 50 °C @ 50 % RH
12	Data Logger	10 % Rh to 95 % RH @ 25 °C &10°C to 50 °C @ 50 % RH
13	Humidity Calibrator/Generator & Environmental Chamber (Single Point Sensor calibration)	10 % RH to 95 % RH
14	IR Thermometer/ Thermal Imagers/ Pyrometers	50°C to 1200°C
15	Validation of Autoclave (Temperature / Pressure Mapping)	9/ 16 sensor method for various temp/ humidity points
16	Validation of Stability Chamber/ walking Chamber/ Environmental chamber -- Mapping	9/ 16 sensor method for various temp/ humidity points
17	Validation of Deep freezer/ Refrigerator/ Cold Chamber/ BOD Incubator/ Oven/ Muffle Furnace	9/ 16 sensor method for various temp/ humidity points
18	Area Mapping (Temperature & Relative Humidity)	As per customer protocol - Data loggers Used.

CALIBRATION – MECHANICAL - PRESSURE

Sr.	Instrument	Range
1	Analogue/ Digital Vacuum Gauge	0 to (-) 0.98 bar
2	Analogue/ Digital Pressure Gauge	Up to 1000 bar
3	Pressure Transmitter / Switch/ Recorder	- 0.98 bar to 1000 bar
4	Compound Gauges	- 0.98 bar to 100 bar
5	Magnehelic Gauges	Up to 2000 mmWC
6	Differential Pressure Transmitter/ Switch	Up to 2000 mmWC
7	Barometer	0.06 to 1 bar (abs)
8	Absolute pressure Indicator/ Gauge/ Transmitter/ Switch	1 to 35 bar (abs)

CALIBRATION – MECHANICAL – MASS & VOLUME

Sr.	Instrument	Range
1	Weight Set (Class E1 and courser)	1 mg to 200 g
2	Loose weights (Class E2 and courser)	500 g to 5 kg
3	Loose weights (Class F1 and courser)	500 g to 20 kg
4	Ultra Micro - Balance (d = 0.1 µg)	1 mg to 20 g
5	Micro Balance (d= 1µg)	1 mg to 200 g
6	Analytical Balnce (d=0.01 mg / 0.1 mg)	1 mg to 200 g
7	Precision Balance (d = 1 mg / 10 mg)	Capacity 600 kg
8	Industrial Balance / Ordinary Balance (d = 50 mg & above)	Capacity up to 600 kg
Sr.	**Instrument**	**Range**
1	Micropipette (Fixed/ Multichannel Volume)	1 µl to 10000 µl
2	Glass Wares - Pipette/ burette/ Flask/ Cylinder/ Bottle/ Jar/ Can etc. (Fixed/ Variable Volume)	1ml to 500 ml

CALIBRATION – MECHANICAL - DIMENSIONAL

Sr.No.	Instrument	Range
1	Vernier Caliper	Upto 1000mm / 0.01 mm
2	Vernier Depth Gauge	Upto 300/ 0.02 mm
3	Vernier Height Gauge	upto 600 / 0.02 mm
4	External Micrometer	up to 1000 mm/ 0.001 mm
5	Micrometer Setting Standard	up to 500 mm
6	Inside Micrometer	Up to 1000 mm/ 0,01 mm
7	Depth Micrometer	Upto 300/ 0.001 mm
8	Lever Dial	Upto 1 mm / 0.002 mm
9	Plunger Dial	up to 50 / 0.001 mm
10	Bore Gauge	up to 500 mm
11	Pistol Caliper	0 - 50 mm
12	Bevel Protractor / Combination Set	150 / 300 mm and Angle
13	Dial Thickness Gauge	up to 30 mm / 0.001 mm
14	Feeler Gauge	Short / Long
15	Pin Gauge	0.1 to 20 mm
16	Thickness Foil	Up to 2 mm
17	Dial Snap Gauge	Up to 250 mm
18	Cylindrical Setting Master	Up to 100 mm
19	Three Point Micrometer	Up to 150 mm
20	Coating Thickness Gauge	Up to 1.50 mm

CALIBRATION – MECHANICAL - DIMENSIONAL

Sr.No.	Instrument	Range
21	Ultrasonic Thickness Gauge	Upto 200 mm
22	Radius Gauge	Up to 25 mm
23	Thread Pitch Gauge	0.17 to 6.35 mm
24	Taper Scale	Upto 15 mm
25	Test Sieves	0.032 to 125 mm
26	Measuring Tape	Up to 30 Mtr
27	Pie Tape	Upto 1500 mm
28	Measuring Scale	Upto 1000 mm
29	Spirit Level	0 ± 0.20 / 0.010 mm/m
30	Slip Gauge / Length Bar (for 0 , I, II)	Up to 100 mm
31	Plug Gauge	Up to 300 mm
32	Snap Gauge	Up to 300 mm
33	Ring Gauge	Up to 300 mm
34	Thread Plug Gauge (GO & NO GO)	Up to 100 mm
35	Thread Ring Gauge (GO or NOGO)	Up to 100 mm
36	Taper Thread Plug Gauge	Up to 100 mm
37	Rubber Hardness Tester (Durometer)	0 to 100 Shore A & D
38	Wobble Meter	--
39	Torque Wrench	Up to 2000 Nm

CALIBRATION – MECHANICAL – OTHER

Sr. No.	Instrument	Range
1	pH Meter	1 to 14 pH
2	Conductivity Meter	1 µs to 100 µs
3	ORP Meter	1 mv to 1000 mV
4	TDS Meter	upto 999 ppm

CALIBRATION – FLOW

Sr. No.	Instrument	Range
1	Digital Flow Meter (Gas Flow)	0.1 ml/min to 1000 ml/min
1	Rotameter (Gas Flow)	1 ml/min to 2400 ltr/min
2	Liquid Flow meter	1 ml/min to 25 ml/min
2	Liquid Flow meter	1 ml/min to 450 lit/hrs

TEMPERATURE MAPPING

Scope of Work -

- Temperature and Humidity Room Qualifications
- Temperature and Humidity Warehouse Qualifications

We execute validation of following equipment's and facilities by keeping in mind about the critical requirements of various regulatory authorities and Latest GMP, GLP requirements in the industry

- Autoclaves
- Freezers
- Ovens
- Vacuum Ovens
- Coolers
- Cryogenic Freezers
- Dehydrogenation Ovens
- Incubators
- Refrigerators
- Ultra Low Temperature (ULT) Freezers
- Dry Heat Ovens
- Stability Chambers

From the smallest bench top oven, to the largest sterilizer, we can conduct the mapping as per your requirements.

If you already have a validation protocol in place, then we can execute as per it. However if necessary, we can help to draw up a protocol which suits your specific application.

TEMPERATURE MAPPING

Why do temperature mapping?

There's increased emphasis by regulators on compliance with GMP requirements for controlled temperature storage requirements

Clause 3.19 of the PIC/S GMP guide states:

"Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored."

A temperature mapping exercise comprises four broad activities:

- Protocol development
- Temperature mapping
- Data analysis
- Reporting

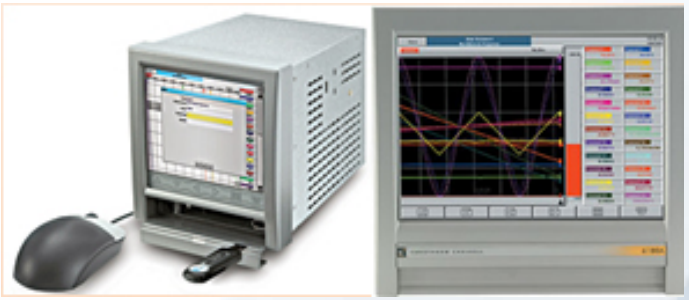
Compliance

- Traceability to national and international standards such as HTM 2010
- CFR21 Part 11 compliant software
- Robust quality system including ISO 9001:2015

TEMPERATURE MAPPING

Master Instruments used for Temperature Mapping

Sr. No.	Instrument Name	Make/Model	Range	Accuracy
1	30-CH Paperless data Logger With RTD Pt-100 sensors & T Type TC sensors	Yokogawa/GP-10	PT 100 (-200 to 850°C) T Type TC: -200 to 400 °C	Class : 1/10 DIN ± 0.5 °C
2	Mini Data Logger	TESTO/174H	-20 to +70 °C 2 to 98 % RH	± 0.5 °C ±3 %RH



VALIDATION

- **Clean Room / HAVC Validation**
- **Isolator Validation**
- **Biosafety, LAF validation**
- **PLC validation**

Clean Room / HAVC Validation:

Archerchem provide the Clean Room/ HVAC validations as per ISO 14644, EU cGMP, US Federal Standard 209E, USFDA ,Schedule M (National Regulatory Body), WHO Geneva, TGA (Australia), European (EMEA), MHRA (European Countries) guidelines for all room classifications.

We provide extensive range of services pertaining to clean room validation by our panel of expert professionals.

VALIDATION - Clean Room / HAVC Validation

ARCHERCHEM carries out following tests to validate clean rooms/clean zones.

a. Air Velocity Measurement

To determine the average filter face velocity and uniformity, average room airflow velocity and uniformity within a clean room.

b. DOP/PAO HEPA Filter Integrity Test

We conduct complete HEPA/ULPA filter integrity testing services for both the Pharmaceutical and Microelectronics industries. All filter integrity tests are executed in accordance with IES-RP-CC-001-86 & ISO 14644. HEPA Filter Integrity Test conducted with both Di–Octal Phthalate (DOP) and Poly Alpha Olefin (PAO. The tests assure that filters are in conformance with various standards and/or governing agency requirements. Apart from certification, we also helps to predict potential performance issues if any.

c. **Particle Count Test**

Our Particle Count Test provides complete airborne particle count cleanliness classification. The test is performed to determine the actual particle count level within the facility. The test identifies particle count on basis of As-Built, At-Rest, or Operational as per ISO 14644 , EU GMP .

VALIDATION - Clean Room / HAVC Validation:

d. Room Pressurization Test

We conduct Room Pressurization Test for industrial clean rooms. As a part of the validation process, this test verifies that a pressure differential meet the specified requirements.

e. Airflow Visualization Test

Visualization is carried out by using water fogger and taking Video Graph. The purpose of the airflow visualization test is to show the actual airflow pattern throughout the unidirectional clean room. The test can also be used to demonstrate the effects on airflow caused by equipment. It is best to perform this test after all airflow velocity and uniformity tests and room pressurization tests have been performed. The test determining the airflow patterns within a room using ISO 14644 guides. This visual monitoring service is important in clean room laminar flow tests and it covers;

- Airflow balancing
- Fuming Hoods
- Point Exhaust tests
- Personnel safety exhausts verification
- Pressure balancing between rooms and spaces
- Leak detection in ducts

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VALIDATION - Clean Room / HAVC Validation:

f. Light Intensity Test

The purpose of the lighting level tests is to verify that the installed light levels and uniformity meet the specified requirements.

g. Noise Level Test

We perform noise level test that measure the sound pressure. The measurements will vary based on the occupancy state-of-the-art clean room.

h. Air Exchange Rate

Air Exchange Rate tests determine the total air volume within a clean room. We use Air Capture Hoods and its measures air volume flowing through registers, diffusers and grills.

i. Containment Test

The test is carried to demonstrate that airborne contamination does not enter from a higher pressure area adjacent to the clean room by means of leaks in the construction materials..

VALIDATION - Clean Room / HAVC Validation:

j. Recovery Test

These tests demonstrate the ability of the clean room to remove particulate by purging the area with filtered air. It also testifies if the room can change from a "dirty" to "clean" state within the specified time.

K. Temperature and Humidity Test

Two levels of temperature and humidity tests are used by us depending on the requirement.
In the first level, general temperature and humidity uniformity are tested. The general level test is used to ensure that the clean room's HVAC system maintains the specified levels of temperature and humidity required for occupant comfort.

The second level or the comprehensive level test identified that the clean room HVAC systems needs to maintain the specified levels of temperature and humidity required for both occupant comfort and process temperature control.

VALIDATION – Isolator Validator

Flexible film and rigid isolators are becoming the preferred method for the manufacturing of sterile pharmaceuticals. They provide a physical barrier to protect both the product and the operator. Unless containment is required isolators are kept at positive pressure to ensure only filtered air enters the chamber and maintains a high air quality.

We are able to assist in the qualification of all types of isolators. We can provide operational resources and assistance with the generation of;
User Requirement Specifications (URS),
Factory acceptance test (FAT),
Site acceptance test (SAT),
Installation Qualification (IQ),
Operational Qualification (OQ) and
Performance Qualification (PQ)

VALIDATION –Biosafety cabinet , LAF Validation

We provide complete validation services for cabinets ranging single to bunch of quantities. Some of the equipment we can test for you;
Class I or Class II Biological Safety Cabinet (BSC),
Laminar Air Flow (LAF) units ,
UDAF (Unidirectional Air Flow) systems and
Fume Cupboards

At ARCHERCHEM , we deliver :
Traceability to national and international standards
Biological Safety Cabinets are tested in compliance with EN12469:2000
Fume Cupboards tested in compliance with EN14175:2004
HEPA filter testing (using the aerosol penetration method) .
All results are clearly reported with a pass/fail section visible at a glance.

VALIDATION –PLC Validation

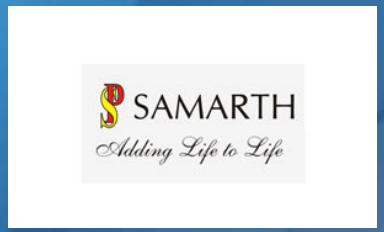
GAMP 5: A Risk-Based Approach to Compliant GxP computerized systems was launched on 28th February 2008. The release of GAMP 5 aims to provide guidance on regulatory compliance through cost and time effective methods and signifies a period of transition of new ideas with a more innovative approach to compliant systems.

GAMP 5 relies heavily on Risk Assessments and to put it in to context based on ICH Q8, ICH Q9 and ICH Q10 and ASTM 2500.

ARCHERCHEM staff are experienced in the validation of PLC and SCADA systems, of various industrial facilities.
We can provide operational resources and assistance in ;
Generation of User Requirement Specifications (URS),
through Commissioning and Installation Qualification (IQ),
Operational Qualification (OQ) and
Performance Qualification (PQ).

We are able to assist in the Development of the VALIDATION MASTER PLAN and executing it accordingly

CUSTOMERS



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OUR KEY STRENGTH

- Well established solution provider in calibration
- Automated web based software
- Best in Class Quality in operations
- Technically sound and experienced Team
- Compliance to global standards
- Preferred partner to our customers

Thank you for your attention

Please send enquires at

sales@archercal.com