



**QUALITY TECHNICAL
SOLUTIONS (QTS)
NABL ACCREDITED
LAB (17025: 2005) &
ISO 9001:2015**



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Introduction....

Young technocrats came together and in partnership formed Quality Technical Solutions (QTS). QTS is an ISO certified 9001:2015 & NABL Accredited ISO/IEC 17025: 2005 company established in 2015. We are known for prompt, economical and reliable Calibration, Validation (HVAC & Thermal) & Mensuration services catering in all type of industries.

Keeping in mind our motto of achieving continually better levels of customer satisfaction, QTS maintains a very professional approach in its working and complies with applicable National / International codes and standards. Above all, QTS upgrades the knowledge and skills of its personnel through training to ensure continuous human resources development.

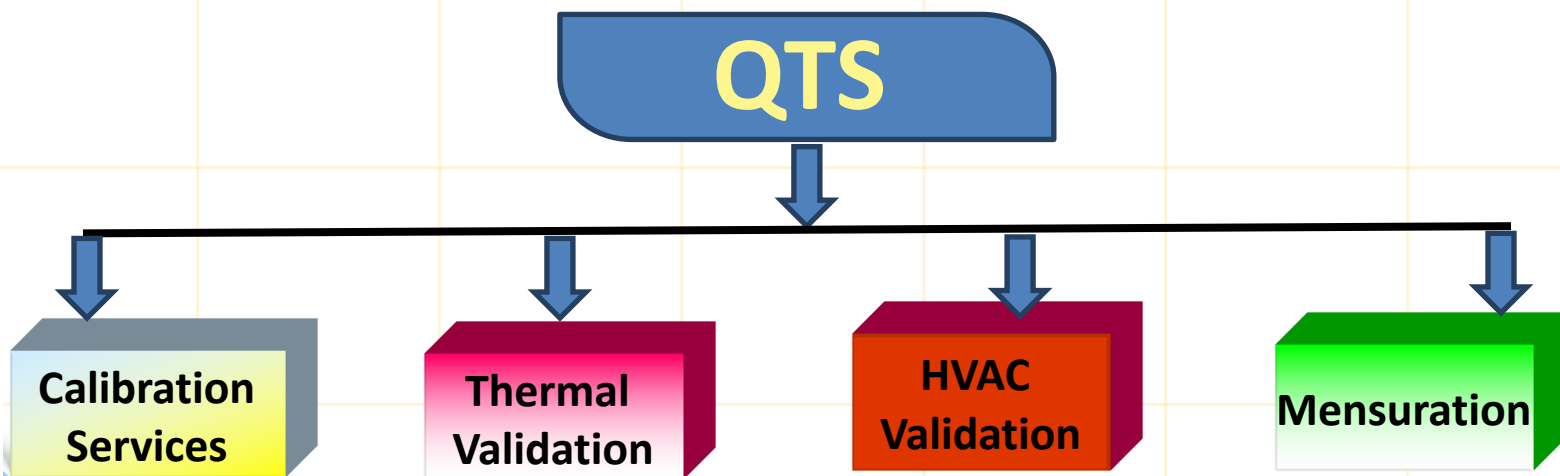




Why QTS?

QTS is highly skilled and experienced in providing Excellent services, High degree potential and excellent commitment for services.

Our aim is to provide best in class calibration and Validation services with best price and on time to our customers. We keep ourselves ahead of competition with our facilities and services by updating our Primary Master instruments and by providing timely training to our personnel. Today we have sophisticated instruments of reputed companies like Yokogawa, Druck, Mikronix, Eurotherm, Fluke, WIKA, Crystal, Huber, Rotronic, Ebro, TSI, Testo, Isotherm etc.





LEGAL STATUS

Name of the company : QTS (QUALITY TECHNICAL SOLUTIONS)

Legal Status : Partnership Company registered under the company act

Partnership : Mr. Bhagoji Kokare,

Registered Office : D-2, Ramdas Niwas, Vinayak Chowk, Kolsewadi,
Kalyan (E). Dist:Thane – 421 306.

Head Office : PAP-R-289, Near Golden Garage,
Rabale MIDC, Navi-Mumbai.

Mob : +91 77569 25492

E-mail : admin@qualitytechnical.com

Bankers : Bank of Baroda

Pan No : AAFAQ5118K

CST No : 27451134261C

Service tax No : AAFAQ5118KSD001

VAT TIN No : 27451134261V.

GST No: 27AAFAQ5118K1Z6

MSME No : UDYAM-MH-33-0006311

Shop & Establishment Reg. No : 1710200311426422.

Key Personal Contacts: Mr. Bhagoji Kokare - +91 7756925492





QUALITY POLICY

QTS is pioneer in calibration and validation since 2015. It uses techniques that have high degree of reliability and follows generally recognized Good laboratory, site calibration and validation practice.

It is our policy to provide highest quality services attainable to customer with the aim of achieving total customer satisfaction.

It is our policy to comply with all applicable statutory and legal requirements.

The lab will maintain best in class service. We are committed to continual improvement of our quality management system by following professional practices as detailed in Quality Manual in line with ISO/IEC – 17025:2017 and ISO 9001 :2015 with consistent operation of the laboratory.

QTS is committed towards maintaining impartiality in performing all of its activities and thereby ensuring that the implementation of all of the requirements of ISO/IEC 17025 : 2017 and ISO 9001 : 2015 is done without any bias.

This responsibility and commitment for the quality management system is practiced and communicated by the management through establishing, documenting, implementing and maintaining quality management system. All the personnel connected with calibration activities are Qualified, Competent, Experienced and familiarize themselves through communication, training and relevant experience regarding the quality management system.





QUALITY OBJECTIVE

- ❖ Rise in customer base.
- ❖ Reduction in customer complaints.
- ❖ Timely Calibration / Validation Service to Customer.
- ❖ Reduction in Non-conforming work incidences.
- ❖ Increase customer satisfaction.
- ❖ Enhancement in scope.
- ❖ Improvement in CMC.
- ❖ Rise in Turnover.



CALIBRATION CAPABILITIES

- ❖ **ELECTRO TECHNICAL.**
- ❖ **THERMAL.**
- ❖ **MECHANICAL (PRESSURE & VACUUM, SPEED).**
- ❖ **MECHANICAL (MASS & VOLUMETRIC).**
- ❖ **MECHANICAL (DIMENSION).**
- ❖ **FLOW.**



WE PROVIDE CALIBRATION FACILITIES FOR

Mechanical	Thermal	Electro Technical
Pressure/Vacuum Gauges	RTD	Digital Multimeter
Manometer, Magnehelic Gauge	Thermocouple	Temperature Indicator / Controller
Pressure/D.P. Switches	Temperature Furnaces	Universal Calibrator
Pressure/D.P. Transmitter	Temperature Gauge	Clamp meter
Pressure Calibrator	Temperature Transmitter	Megger
Tonnage Gauge	Glass Thermometer	Timer
Standard Weights	Infrared Thermometer	Hour meter / Clock
Weighing Balance	Temperature Switch	Stopwatch
Tachometer	Wet & Dry Thermometer	Capacitance meter
Safety Valve	Temperature Ind. With Sensor	Amp. Meter
Conveyor Belt	Thermostat	Volt meter
I to P convertor	Digital Thermo hygrometer	Decade Resistance Box
Strip chart recorder	Baking oven/furnace	RTD Simulator
RPM Meter	Portable electro drying oven	Label counter
Digital Stroboscope	Humidity chamber	TDS meter
Rate & Totalizing indicator	BOD incubator / freezer	

CONTD...





Mass & Volumetric	Dimension	Flow
Digital analytical balance	Dial/ Digital Vernier Caliper	Gas flow meter
Weights box	Plain/Dial/Digital Gauge	Liquid flow meter
Loose Weights	Vernier Depth Gauge	
Pipette	Outside Micrometer	Other
Micropipette	Depth Micrometer	Tap Density tester
Burettes	Inside Micrometer	Velocity sensor
Measuring conical flask	Bevel Protector / Combination Set	Sound level meter
Measuring cylinder	Plunger Dial	ORP controller
Beaker	Lever Dial	Spirit level bottle
Jar	Feeler Gauge	B.P. Apparatus
	slip gauge	TPK Instrument
PH/Conductivity	Dial Thickness Gauge	Dew point meter
PH meter/sensor	Measuring Tape	Dig. Vibration meter
Conductivity meter/sensor	Steel Scale	Spring level bottle
PH/Conductivity Transmitter	Dial Snap Gauge	Dulco meter
	Ultrasonic thickness gauge	Electronic anemometer
Intensity	Tablet Hardness Tester	CFM indicator / transmitter
Lux meter	Standard Length Bar	Bag broken counter
U.V. meter	Pin Gauge box	Control Valve





WE SUPPLY INSTRUMENTS LIKE

- ❖ **ALL TYPES OF GAUGES.**
- ❖ **Glass Thermometer, Digital Thermometer, Min – Max Thermometer, Stem Thermometer, Digital & Analog Hygrometer, Humidity Chamber.**
- ❖ **Standard Weight Box, Loose Weights (E1, E2, F1, F2, M1, M2)**
- ❖ **All Types of RTD & Thermocouple Sensors.**
- ❖ **RTD & Thermocouple Calibrator.**
- ❖ **Tachometer.**
- ❖ **Temperature Calibrator.**



- ❖ **Digital Stop Watch.**
- ❖ **Digital Multimeter & Clampmeter.**
- ❖ **V / I Loop Calibrator .**
- ❖ **Vernier Caliper, Micrometer.**
- ❖ **Slip Gauge / Block Gauge.**
- ❖ **Sound Level Meter / DB Meter.**
- ❖ **LUX Meter.**
- ❖ **Conductivity & Buffer Solution.**
- ❖ **Anemometer.**



THERMAL VALIDATION

We are specializing in Thermal Validation in the various fields like Pharmaceutical, Biotechnology, Medical Devices industries, Beverages etc.

Equipment Validation :

Equipment Validation ensures that an instrument is appropriate for its intended use. Typical validation phases are:

- ✓ **Double door / Vertical Autoclave.**
- ✓ **Oven.**
- ✓ **Dry heat Sterilizer.**
- ✓ **Tray dryer / Vacuum Tray Dryer.**
- ✓ **Tunnel Sterilizer.**
- ✓ **Cold room BOD Incubator.**
- ✓ **Room Study (Temp. & RH)**
- ✓ **Water / Dry Bath.**
- ✓ **Manufacturing vessel.**
- ✓ **Refrigerator / Deep Freezer.**
- ✓ **Muffle / Bunsen Furnace .**

CONTD...



QTS is well equipped with 600+ portable loggers, 400 + sensors, 8 chartless Data loggers (12 To 50 channels).

The data logged from the mapping of the above equipment is further processed to give analysis reports like FO values, lethal rate, standard deviation, lag time in case of autoclaves and, Hot spot and cold spot identification in case of other equipments and rooms.

This process can be certified by 21 CFR Part 11.





CERTIFICATE FORMAT USING 21 CFR Part 11 SOFTWARE

Instrument	Serial	37295830
Data state	Original	
MEGAFINE PHARMA (P) LTD AIR LOCK		
Reason for logging		



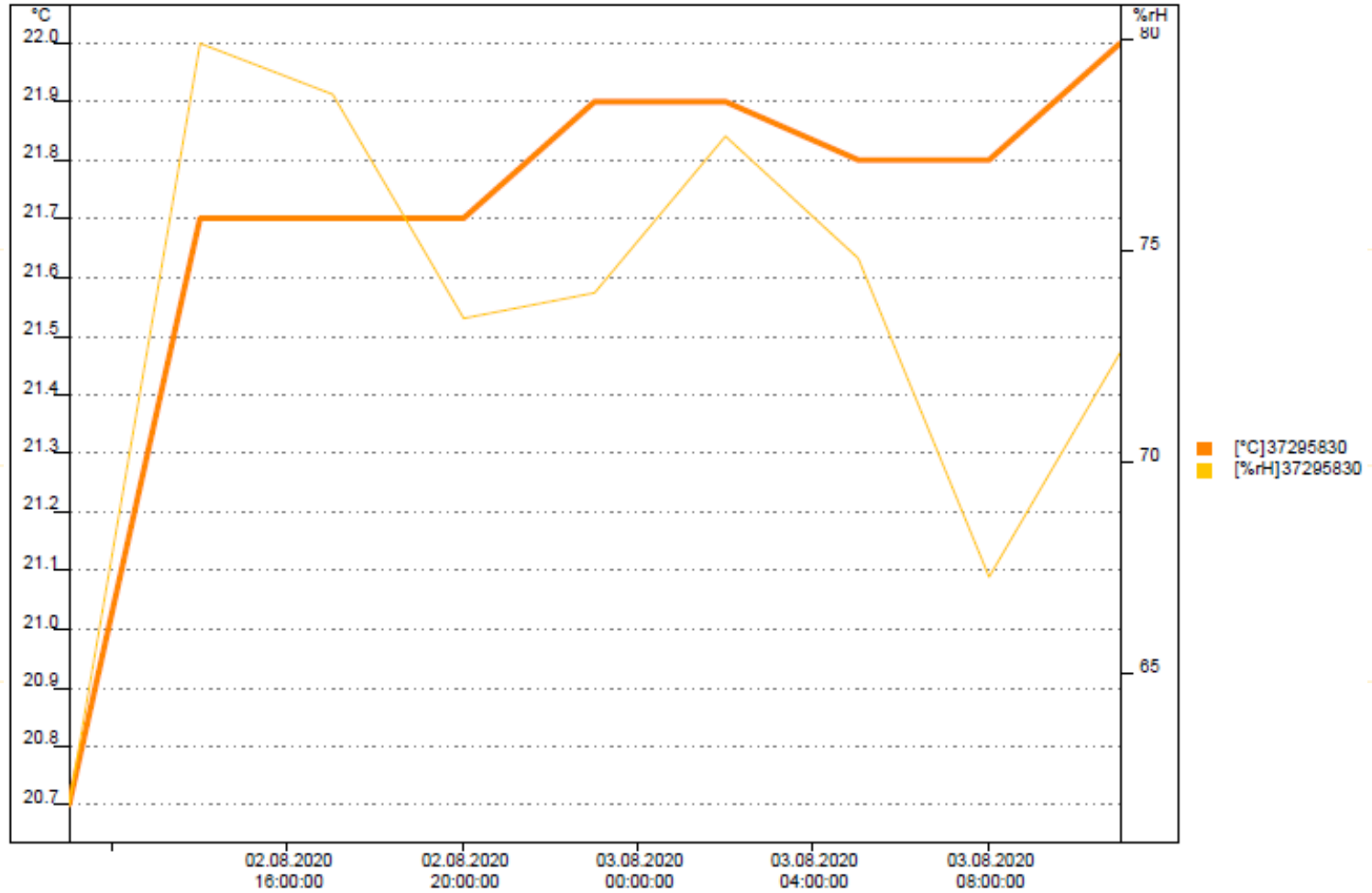
Date	14.01.2021 18:50:42
Timezone	India Standard Time
User	Sudeep Shelar
Name	
Signature	

C:\Users\Sudeep Shelar\Desktop\AIR LOCK.vi2			
	Min:	Max:	Mean:
C:1 [°C]37295830	20.7	22.0	21.7
C:2 [%rH]37295830	61.9	79.9	73.4



CERTIFICATE FORMAT USING 21 CFR Part 11 SOFTWARE

C:\Users\Sudeep Shelar\Desktop\AIR LOCK.vi2





Master	Make	Accuracy
Portable Temp. & Rh data loggers 21 CFR Part 11	Ebro / Testo	±0.5 °C, ±3 %RH
Portable Temp. data loggers 21 CFR Part 11	Testo	±0.5 °C
3 wire RTD	Radix & Plaschem	Class A
Thermocouples	Tempens / Plaschem	Class A
Temperature Data Logger	SIMEX	-100 to 400 °C (RTD,PT 100) 0 to 1200 °C (K TYPE TC) -50 to 400 °C (T TYPE TC)
Temperature Data Logger	G-TEK	-100 to 400 °C (RTD,PT 100) 0 to 1200 °C (K TYPE TC) -50 to 400 °C (T TYPE TC)
Temperature Data Logger	YOKOGAWA (12 Channel)	± 0.15% rdg + 0.3 °C (RTD,PT 100) ± 0.15% rdg + 0.7 °C (K type T/C) ± 0.15% rdg + 0.5 °C (T type T/C)
Temperature Data Logger 21 CFR Part 11	YOKOGAWA (40 & 50 Channel)	± 0.2% rdg + 0.2 °C (RTD,PT 100) ± 0.01% rdg + 0.2 °C (K type T/C) ±(0.10 % rdg + 0.2 °C) (T type T/C)
Temperature Data Logger 21 CFR Part 11	EUROTHERM 40 Channel	0.042%I/P + 0.065% range (PT 100 RTD), 0.084% I/P + 0.039% range (K Type TC), ± 0.2°C for 0 to 400 °C & 0.084% I/P + 0.039% range (T Type))





HVAC VALIDATION

HVAC (Heating, Ventilation, & Air Conditioning) validation continues to be a source of anxiety for many manufacturers of pharmaceutical & biologic products. HVAC validation is likely to be successful when good strategy and planning are involved in the process. QTS guides you in the right direction.

There are many factors to consider in HVAC validation and it is best to take on a realistic approach based on good science, business and compliance sense. We are familiar with HVAC validation requirements and industry standard validation practices for your product forms, what documented evidence is needed for your HVAC Systems (e.g. drawings, specifications, balancing reports), and we know if your control systems are strong enough to be validated.



We then develop a general strategy consisting of the following factors:

- Classification of HVAC systems as GMP or non GMP systems.
- Determination of what documentation you have and what documentation you need to create before validation begins.
- Development of targets for differential pressure, room air changes, temperature and humidity.
- Concentration of validation efforts on the areas where there is a direct product impact.
- Validation of Building monitoring system that are connected to HVAC systems.





CLEAN ROOM VALIDATION

- Filter Integrity Leak Test (using PAO).
- Recovery period study.
- Calculation of air changes / hour in room.
- Filter face air velocity measurement.
- Air velocity / CFM measurement in Duct.
- Air flow visualization test.
- Air borne particulate matter monitoring.
- Room temperature / RH monitoring.
- Air velocity / CFM measurement across Relief/Bleed air filter.
- Air velocity / CFM measurement across fresh air filter.



ISOLATOR VALIDATION

- Noise level.
- Particle count test.
- Light intensity.
- Recovery time determination.
- Air Flow velocity.
- Smoke Pattern.
- Gauntlet breach air velocity Filter Leak.





DOCUMENTATION OF HVAC VALIDATION

- We have latest & upgraded systems to overcome the conflict of integrity.
- We provide wet prints of
 - a) Air Velocity Measurement Study
 - b) Filter Integrity Leak Test (PAO Test)
 - c) Non Viable Air borne particulate matter monitoring Test
- In Smoke patten test continuous display of Date & Time is visible.



WET Print of Non Viable Particle Count

Non viable Particle Count test is done using TSI make 50 LPM Particle Counter & Particle Measuring Systems make 100 LPM Particle Counter

- Air borne particulate matter monitoring at Rest
- Air borne particulate matter monitoring in Operation
- Recovery Study



Inst Model 9350-03
Serial # 93501712001
Cal Date 14/05/2020

Sample 1 of 1
Sample # 491
Start Time 06/10/2020, 13:15:23
End Time 06/10/2020, 13:16:23
Zone AIR LOCK
Location Location01
Recipe
Sample Time 00:01:00
Volume 50.0 L
Instrument Status: OK

Particles / m3:	Cumul Alarm
0.5	147420
1.0	69440
5.0	8100

Inst Model 9350-03
Serial # 93501712001
Cal Date 14/05/2020

Sample 1 of 1
Sample # 492
Start Time 06/10/2020, 13:17:12
End Time 06/10/2020, 13:18:12
Zone AIR LOCK
Location Location02
Recipe
Sample Time 00:01:00
Volume 50.0 L
Instrument Status: OK

Particles / m3:	Cumul Alarm
0.5	142800
1.0	73980
5.0	8360



WET Print of Air Velocity Measurement Test

Air Velocity Measurement test is done using TSI make Air Capture Hood & for equipment's Matrix / Hot Wire Anemometer is used.

- Calculation of air changes / hour in room.
- Filter face air velocity measurement.
- Air velocity / CFM measurement in Duct
- Air velocity / CFM measurement across Relief/Bleed air filter.
- Air velocity / CFM measurement across fresh air filter



MODEL: 8715
SERIAL: T87151952003
REV: 1.11.1
TEST ID: HAU01SG1
Sample 1 Date: 06/10/20
Sample 1 Time: 09:41:32

Temperature
Avg 20.6 °C
Min 20.6 °C
Max 20.6 °C
Samples 1

Baro Press
Avg 376.9 in.H2O bp
Min 376.9 in.H2O bp
Max 376.9 in.H2O bp
Samples 1

Standard Flow (Hood)
Cf = 1.350
Avg 257 CFM
Min 257 CFM
Max 257 CFM
Sum 257 CFM
Samples 1

Samples
06/10/20
09:41:32 20.6 °C
09:41:32 376.9 in.H2O bp
09:41:32 257 CFM



WET Print of Filter Integrity Leak Test

This Test is done using TEC services make
PH4 & PH5 Aerosol Photometer

- Terminal HEPA Filter integrity Test using PAO oil
- Plenum HEPA Filter integrity Test using PAO oil



Test Report
Print Date: 06 OCT 20

Certification Company

Co: QTS NAVI MUMBAI

Operator: SURESH KOKARE

Witnessed By: AJIT MHASKE

Client Information

Co:

Location: CHANGE ROOM

Filter ID: HAHU-001/HF/0.3/02

Instrument

TEC Model: PH4

FW Ver: 1.52U

Serial #: 02379

Cal Due: 04 MAY 21

Instrument Configuration

Reagent: PAO

Upstream Conc: 28ug/L

Alarm Set Point: .010%

Scan Data

Scan #1

Max Penetration: 0.0005%

Test Date & Time

Date: 06 OCT 20

Start: 11:01

End: 11:07

Scan: 4 min 28 sec

Test Result: PASS

NOTES:



Compressed Air, Nitrogen & Oxygen Validation

- Non-Viable Particulate Count Monitoring
- Dew Point Measurement
- Oil Mist Measurement
- Water Vapour / Moisture Measurement
- Carbon Dioxide Measurement
- Oxygen Measurement
- Sulphur Dioxide Measurement
- Carbon Monoxide Measurement
- Carbon Dioxide Measurement
- Carbon Monoxide Measurement
- Nitrogen Oxide Measurement
- Nitrogen Dioxide Measurement
- Hydrocarbons Measurement
- Hydrogen Sulphide Measurement



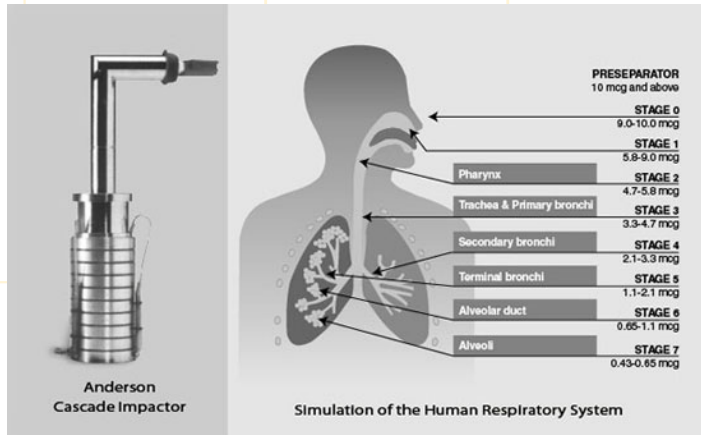
PURE STEAM QUALITY TEST

TEST PERFORMED AS PER EN285 / HTM 2010

- Super Heat Value Test.
- Non-Condensable Gases Test.
- Dryness Value Test.



Cascade Impactor Mensuration



QTS has been providing Stage Mensuration services for Cascade Impactors & Next Generation Impactors in India.

The Quick Vision Measuring instrument is highly accurate and capable of Mensurating many stages automatically.

The methods for Mensuration have been developed by a group of experienced people from pharma industries.

QTS continuously updates its methods for Mensuration as per the requirements of pharma industry & hence has become a unique service provider for Mensuration in India.



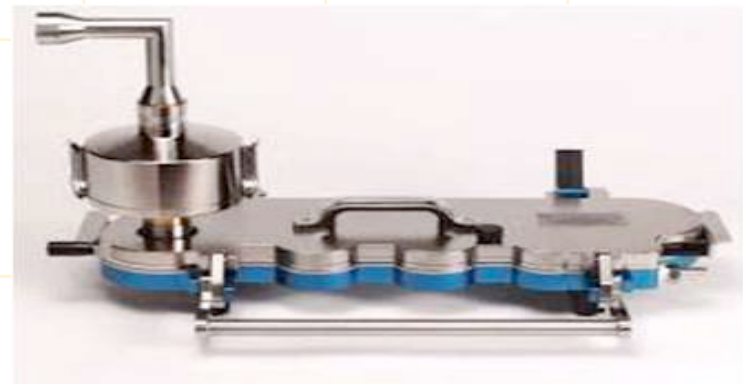
Cascade Impactor Mensuration

The Process of measuring nozzle diameters of the jets and other critical dimensions of Cascade Impactor & Next Generation Impactor is called as Mensuration.

In use, some occlusion and wear of holes will occur for cascade impactors. So in order to validate/evaluate the performance of Cascade & NGI Impactor Mensuration is necessary.

Both European and US Pharmacopoeia recommends periodically Stage Mensuration of Cascade Impactors prior to use.

Dimensions of the jets of all stages should be measured and documented for compliance with USP and EP.





TURNKEY PROJECTS

- We also undertake Turnkey Projects for Pharma & Healthcare.
- Installation of AHU along with qualification documents.
- Modular Partition installation.
- Cooling Tower installation.
- Chiller Installation.
- Qualification Documentation.



LIST OF CUSTOMERS

PHARMACEUTICALS

- BEC CHEMICALS PVT LTD – ROHA, MUMBAI
- CIPLA LTD - VIKHROLI
- D.K. PHARAMA CHEM PVT. LTD. – BADLAPUR
- EVONIK DEGUSSA INDIA PVT.LTD. – MUMBAI
- EMBASSY – PUNE
- FULLIFE - KHOPOLI
- GLENMARK – TALOJA, MAHAPE, ANDHERI
- GANGWAL CHEMICALS - BOISAR
- JAYPRECISION – KANDIVALI, VASAI
- KREMOINT - AMBERNATH
- LINDE – TALOJA, ANKLESHWAR, PUNE
- LUPIN - PUNE
- MACLEODS PHARMA. – MUMBAI
- JHONSON & JHONSON – MULUND
- MEGAFINE PHARMA PVT LTD – NASHIK
- miBEC (A Division of BEC Chemicals Pvt Ltd) – NAVI MUMBAI
- MEDITAB. – SATARA



LIST OF CUSTOMERS



PHARMACEUTICALS

- MEDISPRAY – SATARA
- SERUM INSTITUTE OF INDIA – PUNE
- SITEC LABS PVT. LTD. – MUMBAI
- SOHAN HEALTH CARE – PUNE
- TATA COMMUNICATIONS LTD – PUNE
- TAIYO NIPPON K – AIR PVT LTD – PUNE
- WATSON – NAVI MUMBAI
- WELSPUN INDIA LTD - ANJAR



HOSPITALS

- Dr. LH HIRANANDANI HOSPITAL – POWAI
- GOVT. HOSPITAL – AURANGABAD
- KARUNA HOSPITAL – BORIVALI
- SUSHRUT HOSPITAL - KURLA



LIST OF CUSTOMERS



COLD CHAIN

- MAHESH CARGO – MUMBAI
- TRANSAIR – SAHAR
- VERITAS LOGISTICS – PANVEL
- SAINATH ROADWAYS – BHIWANDI
- ASHAPURA ROADWAYS – MAROL
- KOOL-EX - BHIWANDI

GLOBAL

- CIPLA QCIL – UGANDA
- HOSPICE – UGANDA
- GALTECH – DUBAI
- WOCKHARDT – DUBAI
- ETHIOPIA

Thank You!

