



SWAN BIOTEC PVT. LTD.
QUALITY SOLUTIONS

Quality Solutions for Pharma Process

OUR GLOBAL PARTNERS



Shimadzu TOC Analyzer – The Brand for Total Organic Carbon Analysis



- 680°C catalytic combustion oxidation with NDIR detector

Highlights:

- **Global Regulation:** Meets the requirements of USP, EP and JP for PW and WFI.
- **USP 643 and USP 661.1/661.2 Compliance:** PW /WFI and pharmaceutical packaging systems
- **Application Versatility:** Purification Plant validation, Cleaning Validation, and the measurement of Total Nitrogen (TN) in Proteins
- **21 CFR Part 11 Compliance:** ER and ES, ensuring data integrity and regulatory compliance.

“USP 643 : For PW & WFI water.”

“Validation of purification system”

“Cleaning Validation”

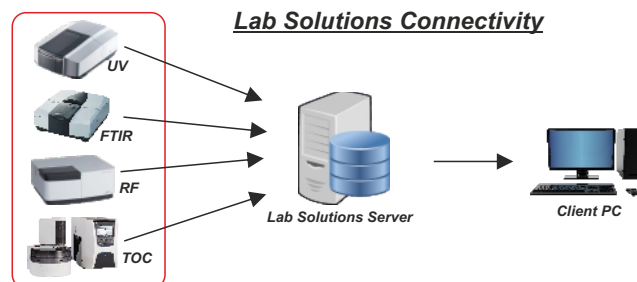
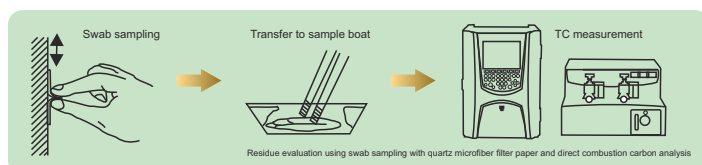
“Measurement of TN in Protein”

“USP 661.1 : Plastic materials for construction”

“USP 661.2 : Plastic Packaging Systems for Pharmaceutical Use”



Swab Sampling/Direct Combustion



Shimadzu eTOC Analyzer – Ultra-Low TOC Measurement for PW & WFI Water Systems



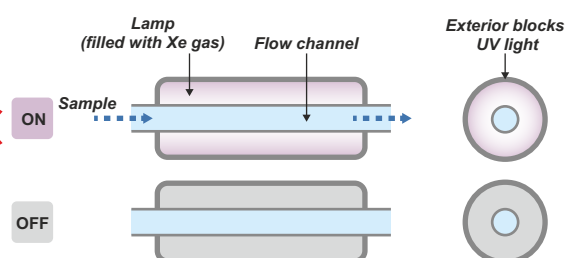
First TOC analyzer in the world to use a mercury-free excimer lamp.
New “Active-Path” technology for transferring energy from the lamp to the sample



The Shimadzu eTOC Analyzer offers **exceptional sensitivity** with a detection limit as low as **0.1 ppb**.

Key Features:

- **Innovative & Advanced Excimer Mercury-Free UV Lamp**
- **Active-Path Technology:** A breakthrough method that enhances energy transfer from the excimer lamp directly to the sample, ensuring faster and more reliable oxidation for accurate TOC measurements.
- **On-Line & Off-Line measurements**
- **Pharmacopeia Compliance:** USP, EP, IP, and JP.
- **World Smallest Compact Size**
- **Onsite Calibration & Validation**
- **Fully 21 CFR Part 11 compliance**
- **Output :** 4-20mA, USB, Printer, LAN, Modbus (TCP/IP)



Sterility Test Isolator with Built-In Bio-Decontamination System



- **6-log Sporocidal Reduction**
- Meets **GAMP5, cGMP, PDA, FDA** standards
- **ISO 5/Grade A Aseptic Environment**
- **Fastest Bio-decon cycle** in the market
- Built-in **Environmental Monitoring System**
- Ideal for **Sterility Test, Cell Therapy, Milling / Compounding** etc.
- **21 CFR Part 11 Compliant**
- Equipped with **RTP port**

Different Configurations:



M-1



M-2



M-11

Dimensions (Single Chamber):

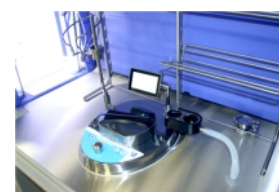
QUBE: External Dimensions			
Type	Width (mm)	Depth (mm)	Height (mm)
QHPV	1360	843	2335
QMTD	660	800	1750
QUBE: Internal Dimensions			
Type	Width (mm)	Depth (mm)	Height (mm)
QHPV	1100	540	750
QMTD	440	365	495



Sterility Test Isolator



Environmental Monitoring



Sterility Test Pump



Glove Tester



Racking



RTP Port

Hydrogen Peroxide Vapour (HPV) Bio-Decontamination Generators



- **High Efficacy:** Achieves 6-log sporicidal reduction.
- **Versatile Configurations:** Available in fixed, mobile, or semi-permanent setups for enclosures and rooms up to 400 m³.
- **Rapid Cycles:** Quick and validatable bio-decontamination processes.
- **Material Compatibility:** Excellent sensitive compatible for electronics boards, panels etc.
- **Broad Spectrum:** Eradication of wide range of microorganisms.
- **Regulatory Compliant:** Adheres to cGLP, cGMP standards and 21 CFR part 11, GAMP5, Annex 1 EU GMP.



ProteQ



L4

Biological, Chemical Indicators & H₂O₂ Solution: BQ Triple-Lock Assurance



- **Optimized Compatibility:** Designed for seamless integration with BQ equipment.
- **Effective Cycles:** Achieves rapid, reliable, and optimal bio-decontamination.
- **Single Source Support:** Comprehensive customer service from one provider.
- **Simplified Supply Chain:** Easy and efficient procurement.



BI

H₂O₂

CI

Filter Integrity Tester



- Bubble Point /Forward flow/Water intrusion/Pressure attenuation
- FDA 21 CFR Part 11 ER & ES
- Compliance to EUGMP, FDA, CN GMP
- Meets offline and Online Integrity Testing
- Supply Air 4 -8bar
- Range 0-7000mbar

Applications

- Liquid and gas sterilization filters
- Ultrafiltration membrane packages and hollow fiber membrane columns
- Virus removal filters
- Pressure holding test of stainless steel filtration system



Glove Integrity Tester



- Compliance: ISO 14644-7, EU GMP Annex1, FDA 21 CFR Part 11
- Pressure Range: 500-2,000 Pa
- Minimum Detectable Pore Size < 100µm
- Upto 24 tests can be done simultaneously
- Fully automated with WiFi Glove Integrity Testing
- Flange Size: 7, 8, 10 inch or Customized
- Weight 4.5kg



Portable Particle Counters



- Compact Stainless steel enclosure particle counters with flow rates of 100/50/28.3L/min.
- Measures 6 channel particle sizes: 0.3, 0.5, 1.0, 3.0, 5.0, 10.0 (µm).
- Measures Particle count, Air velocity, Temp., RH, DP..
- Built-in printer, stores up to 10million data points.
- Large touch screen.



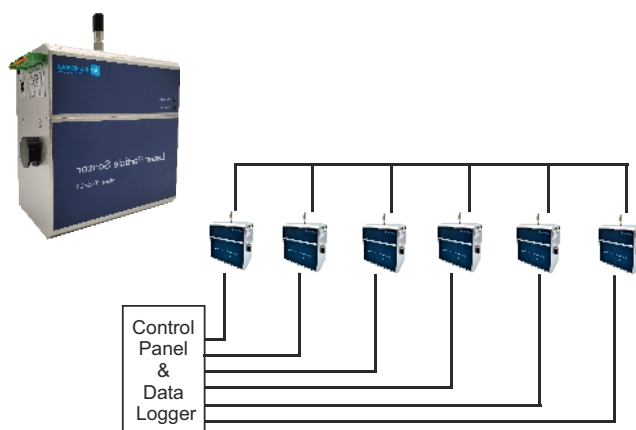
Online Particle Counter



- 28.3 L/min (1.0 CFM) SS sensors are fully compliant with ISO 21501-4.
- Standard sizes: 0.5 and 5.0 (µm).
- Optional sizes: 0.3, 0.5, 0.7, 1.0, 3.0, 5.0, 10.0 (µm)
- Built-in pump with HEPA filter.
- Process or building automation system.
- Data Storage: 5,000 records.

AUTOMATION:

- Control Panel, Ethernet switch, POE support, Cabling (Ethernet, copper).
- SCADA system with PLC integration & Validation Documentation.
- Individual NVPC Control, Historical Data Storage, Tower lights with buzzers for real-time alerts, 21 CFR Part 11 Compliance, Customizable Reporting.



Microbial Air Sampler - Clean Room



- Environmental Monitoring in Cleanrooms.
- Available Flow rates: 100LPM, 180LPM, 200LPM
- Easy Clip type Aspirating heads
- Available with multi-heads
- Dedicated samplers for Bio-safety cabinets / LAF
- Autoclavable SS Aspirating heads
- Compliant with ISO 14698-1, EN 17141, EU GMP, Annex 1 etc.
- Data integrity 21 CFR Part 11 and GAMP5
- Data transfer via Bluetooth network



Microbial Air Sampler - Isolator



- Environmental Monitoring in Isolators
- Available Flow rates: 25LPM, 100LPM, 180LPM, 200LPM
- Easy Clip type Aspirating heads
- Available with multi-heads
- Dedicated samplers for Isolators / RABS
- Autoclavable SS Aspirating heads
- Compliant with ISO 14698-1, EN 17141, EU GMP, Annex 1 etc.
- Data integrity 21 CFR Part 11 and GAMP5
- Data transfer via Bluetooth network



Microbial Air Sampler - Continuous Monitoring



- **Continuous Monitoring** – unlike traditional sieve samplers with limited sampling times. With flow rate of 15 LPM / 25 LPM.
- **Integrated Pump** – GENIUS Satellite combines the sampling head (10 × 10 × 10 cm) with a built-in pump display.
- **Scalable Monitoring** – single operator can manage multiple (≤ 24) GENIUS Satellites simultaneously.
- **Flexible Integration** – GENIUS Satellites can be placed in both tight-space isolators and larger RABS, ensuring maximum versatility for different cleanroom configurations.
- **Simple Installation** – quick setup reduces both time and costs.
- **Space Optimization** – compact design with no external pumps or command units, saving space and minimizing clutter.
- **Sampling Cost Savings** – continuous sampling for up to 4 hours reduces the number of media plates required.
- **Standards Compliance** – ensures a smooth transition from traditional sampling methods to advanced monitoring.



Microbial Air Sampler - Compressed Air / Gas



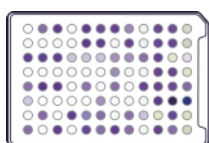
- 100 LPM flow rate with stainless steel calibrated valve.
- Autoclavable components.
- FLUGAS - Samples the compressed air / gas
- VERIGAS - Samples the compressed air / gas / clean room
- AGC - Samples the compressed air / gas / air check
- TRIOGAS - Samples the compressed air / gas
- Compliant with ISO 14698-1, ISO 8573-7, EU GMP, Annex 1 etc.
- Data integrity 21 CFR Part 11 and GAMP5



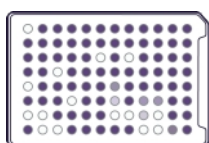
Microbial Identification and Microarray



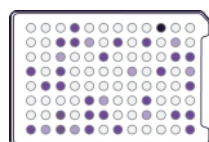
- Total solution for Microbial Analysis
- Identification of Aerobic Bacteria, Anaerobes, Yeast and Fungi
- No need of Gram's Staining/ Catalase/Oxidase
- Extensive database of over 3,000 organisms.
- Fungal database with microscopic and macroscopic images
- 21 CFR Part 11 package with Electronic signature.
- Fully Automated Odin with built-in incubator of 8 Plates / 50 Plates
- Semi-Automated ID system - Plate reader and Odin software.
- Phenotypic characterization with 1920 assays in a controlled environment.
- Cellular Metabolic characterization, Growth kinetics, and Identification.
 - Characterize microbial phenotypes,
 - Monitor growth and Measure cell respiration
 - Identify unknown microbes



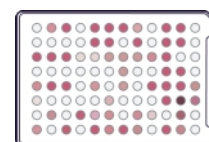
GEN III (Aerobes)



YT (Yeasts)



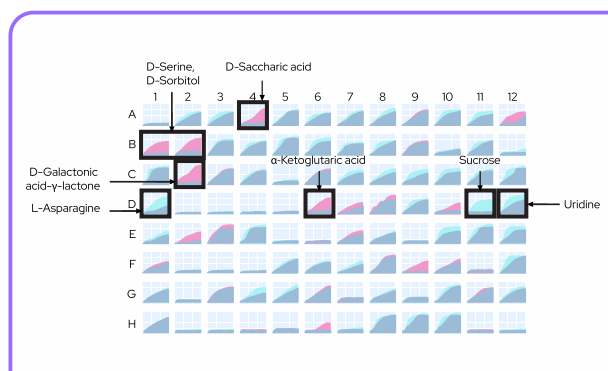
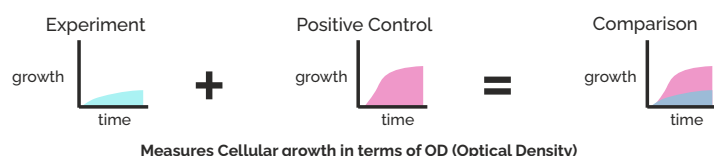
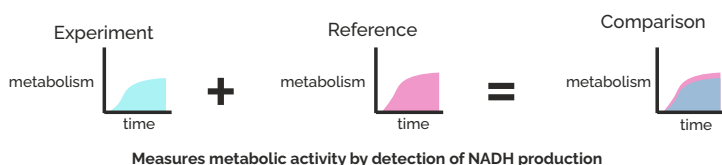
AN (Anaerobes)



FF (Filamentous Fungi)

- Biolog's Microplates are available for : Microbial Identification, Metabolic Characterization, Community Analysis
- Characterize Microbial Phenotype: With 4,800 conditions to measure thousands of cellular phenotypes in a single experiment.
- Characterize Mammalian Phenotype: To investigate up to 1,400 metabolic and chemical sensitivity phenotypes.
- EcoPlates for Community-Level Physiological Profiling (CLPP)
- PreBioM plate for Gut-Microbiome Analysis

See What is Happening in Two Ways



Anaerobic Chambers and Media



- InstaSleeve™ Technology
- Built-in Incubator (150/500 plate capacity)
- Modular Expansion for small equipment
- Vacuum less passbox with automatic oxygen removal
- Hypoxia option (0.1-10%) for microaerophilic
- Palladium catalyst with built-in heater
- HEPA filter, H₂S and Odor removal



TruPRAS Anaerobic Media



- Pre-reduced Oxygen-free culture media
- Fully manufactured and packed under anaerobic condition
- Zero oxygen exposure during preparation and transfer
- Custom formulations for GMP-Ready manufacturing
- Anaerobic Media matcher for selection of suitable anaerobic media



Water Activity (ERH) Meter



- Meets or exceeds the requirements of USP-NF 1112, <922>, <1115>.
- Digital Sensor Technology. Non-destructive measurement.
- International certified calibration standards available.
- Absolutely no maintenance and no recurring cost.
- Suitable for Lab. & Production site/on-site monitoring applications.
- Sorption Isotherm can be made for measurement of moisture.
- 21 CFR Part 11 Compliant.



Handheld



Aw Easy



HC2-Aw-USB



HygroLab



Aw Therm

Nucleic Acid, Protein Estimation and ELISA



UV-Vis Nano Spectrophotometer

- Nano volume measurement for Nucleic acids and Proteins
- Range: 2 ng to 27500 ng/μL nucleic acid and 0.04 mg/mL protein
- Cuvette measurement across wide wavelength ranging 190-1000 nm
- Modes: Endpoint, Kinetic and Spectrum detection
- Fast measurement: 5 sec for nano / 2 sec for cuvette. USB backup and graphical results in PDF
- 10.1 inch touch LED with standalone android software. Flexible operation with dedicated software for Windows PC.



Microplate Spectrophotometer

- Monochromator based absorbance measurement for ELISA
- Xenon flash lamp and photo diode detector 200-999 nm range
- Supports 6 wells to 384 wells microplates. Optional microvolume plate 16 well with 2μL
- Endpoint, Kinetic, Spectrum well area scanning
- Shaking and incubation for controlled workflow



Luminometer

- PMT detector with the range of 1.0×10^{-18} moles of ATP
- Spectral range of 350-650nm
- Endpoint and Kinetic measurement modes
- Suitable for Gene expression studies with chemiluminescence/bioluminescence
- Supports 1.5 mL micro centrifuge tubes
- Microplate luminometer support 6-96 well plates



Compressed Air Quality Measurement System



- Based on color change gas detector tube method.
- Oil Mist, Water vapor, CO, CO₂, NO + NO₂, H₂S, SO₂
- Meets the requirement USP, IP, BP, EP etc.



Cleaning Validation Swabs



- Made up of with Polyester head material
- Chemical resistance & good sorbency
- Autoclavable for reuse
- Tested with Textile committee for lint free & non-abrasive



TX 714A



TX 761K

Negative Pressure Containment Isolator



- Rigid 316L Stainless Steel Isolator, 3 mm main chamberwall
- Ra 0.6 μm internal / 1.0 μm external, citric passivated
- 19 mm radiused corners, seamless welded construction
- H14 HEPA with safe-change.
- ISO 14644-7 leak rate 0.25 % vol/hr at 250 Pa
- ISO 8 cleanroom $\cdot \leq 25^{\circ}\text{C} \cdot \leq 60\% \text{ RH}$
- Sampling and dispensing of raw materials
- Meets OEB 3, OEB 4, OEM 5 containment requirements.



High Quality Water Purification System



- Generates Purified (Type II) water and Ultrapure (Type I) Water.
- Meets USP and ASTM standards.
- Displays Resistivity, Conductivity and Temperature of Water Inlet and outlet parameters.
- Continuous, Volume & Time control modes of water dispensing.
- In-built automated alarm.
- Equipment calibrated by certified standard.



Automated Dry Fog System



- Nocotech® is a dry fog system for Bio-decontamination.
- Portable airborne surface disinfection/insect extermination.
- Capacity for 10-1,000m³ area. A touch pad for selecting volume of room.
- Excellent material compatibility with fastest cycle time.
- Biodegradable, residue-free, non-corrosive.
- Certified according to EN 17272 (bactericide, fungicide, virucide and sporicide).



Liquid Particle Counter



- High resolution particle testing for Injections , Ophthalmics & Packaging material
- Compliance with USP <788>, USP <789>
- GMP / 21 CFR Part 11 software
- 1024 size channels Resolution upto 0.01 μm
- Micro-volume sampling from 50-1000 μL
- Photoresistive Method + Light Scattering Method Based on Single Particle Optical Sensor (SPOS) Technology
- Max. concentration : 10,000 particles / ml
- Particle size range : 0.5 - 400 μm



Steam Quality Detector



- 3 min Quick determination
- NCG detection limit : 0-20%
- Dryness detection limit : 0.80-1
- Super heat detection limit : 0-50 $^{\circ}\text{C}$
- Complies with EN 285 , 21 CFR Part 11 , GMP



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