CLEAN ROOM

FILTOTECH AIR CONTROL SYSTEM PRIVATE LIMITED

#Above image of clean room is for representation purpose only

DESCRIPTION:

*A **clean room** is an environment, typically used in manufacturing, including of pharmaceutical products or scientific research, as well as aerospace semiconductor engineering applications with a low level of environmental pollutants such as dust, airborne microbes, aerosol particles, and chemical vapors. More accurately, a clean room has a **controlled** level of contamination that is specified by the number of particles per cubic meter at a specified particle size. To give perspective, the ambient air outside in a typical urban environment contains 35,000,000 particles per cubic meter in the size range 0.5 µm and larger in diameter, corresponding to an ISO 9 cleanroom, while an ISO 1 cleanroom allows no particles in that size range and only 12 particles per cubic meter of 0.3 µm and smaller.*

OVERVIEW:

Clean rooms are used in practically every industry where small particles can adversely affect the manufacturing process. They vary in size and complexity, and are used extensively in industries such as semiconductor manufacturing, pharmaceuticals, biotech, medical device and life sciences, as well as critical process manufacturing common in aerospace, optics, military and Department of Energy.

A cleanroom is any given contained space where provisions are made to reduce particulate contamination and control other environmental parameters such as temperature, humidity and pressure. The key component is the High Efficiency Particulate Air (HEPA) filter that is used to trap particles that are 0.3 micron and larger in size. All of the air delivered to a cleanroom passes through HEPA filters, and in some cases where stringent cleanliness performance is necessary, Ultra Low Particulate Air (ULPA) filters are used.

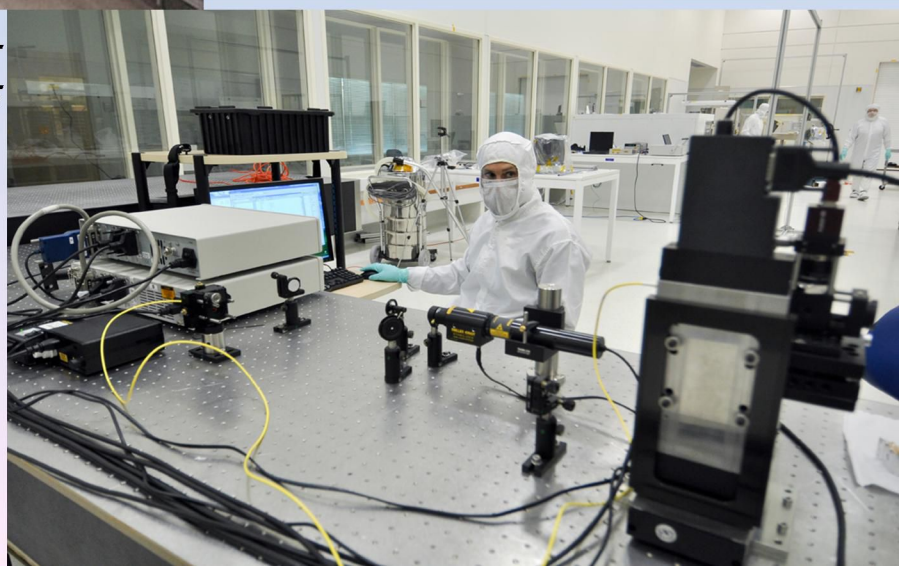
Personnel selected to work in cleanrooms undergo extensive training in contamination control theory. They enter and exit the cleanroom through airlocks, air showers and/or gowning rooms, and they must wear special clothing designed to trap contaminants that are naturally generated by skin and the body.

PHARMACEUTICAL CLEAN ROOMS

BIO-MEDICAL CLEAN ROOMS

INDUSTRIAL CLEAN ROOMS

SCIENTIFIC CLEAN ROOMS



TURNKEY CLEAN ROOM CONFIGURATION

Standard / Wipe Down

- *Modular PCGI,SS, glass or aluminum walls and ceilings.*
- *Vinyl ,epoxy or PU floors.*
- *Cleanroom HVAC system.*
- *Cleanroom light fixtures*
- *ISO5, ISO6, ISO7, ISO8, Class 100, Class 1000, Class 10k, Class 100k*

Applications: medical device, pharmacy, electronics, aerospace, & industrial

Aseptic / Wash Down

- *Washable stainless steel with Coved corners and ceiling joints.*
- *Chemical resistant epoxy, vinyl or PU floor with standard cove.*
- *Room side replaceable HEPA or ULPA filters*
- *ISO5, ISO6, ISO7, ISO8, Class 100, Class 1000, Class 10k, Class 100k*
- *Containment and Isolation.*
- *Room air pressure, temperature and humidity control.*

Applications: pharmaceutical, medical device, hospital, food and beverage

Traditional

- *Standard construction – epoxy or PU paint on drywall.*
- *Coved epoxy or vinyl floor*
- *Static HEPA filters at terminals with central air handler*

ISO5,ISO6, ISO7, ISO8, Class 100, Class 1000, Class 10k, Class 100k

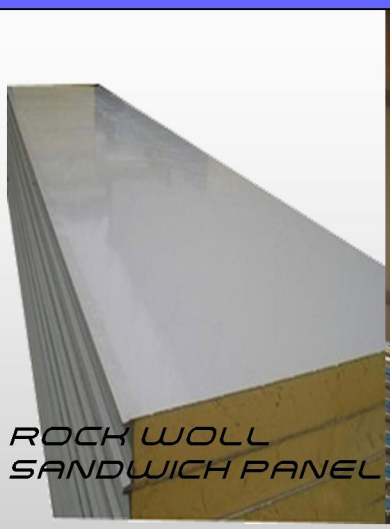
Special Systems

- *+/- precision temperature and humidity control*
- *Non combustible*
- *Negative pressure rooms*
- *Custom size equipment enclosures*
- *Contamination control BIBO HEPA systems*
- *LEED green building energy saver designs*
- *Mezzanines*

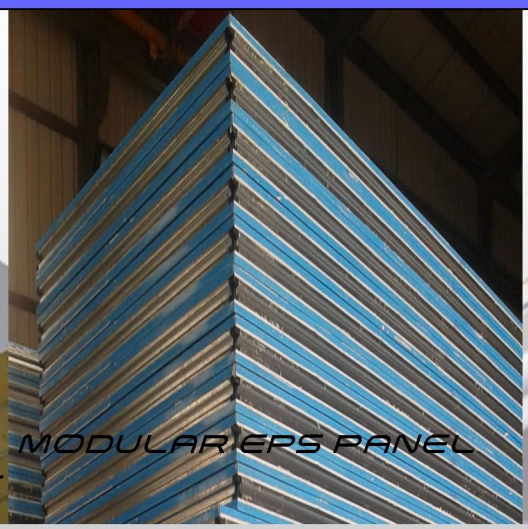
Extreme height and size combination modular and softwall construction

CLEAN ROOM PRODUCTS

CLEAN ROOM WALLS



ROCK WOLL SANDWICH PANEL



MODULAR EPS PANEL

MODULAR SS PANEL

CLEAN ROOM DOORS

CLEAN ROOM AUTOMATIC DOORS

CLEAN ROOM SS DOORS

CLEAN ROOM AIR-TIGHT PCGI DOORS

CLEAN ROOM PRODUCTS

CLEAN ROOM VIEW PANELS

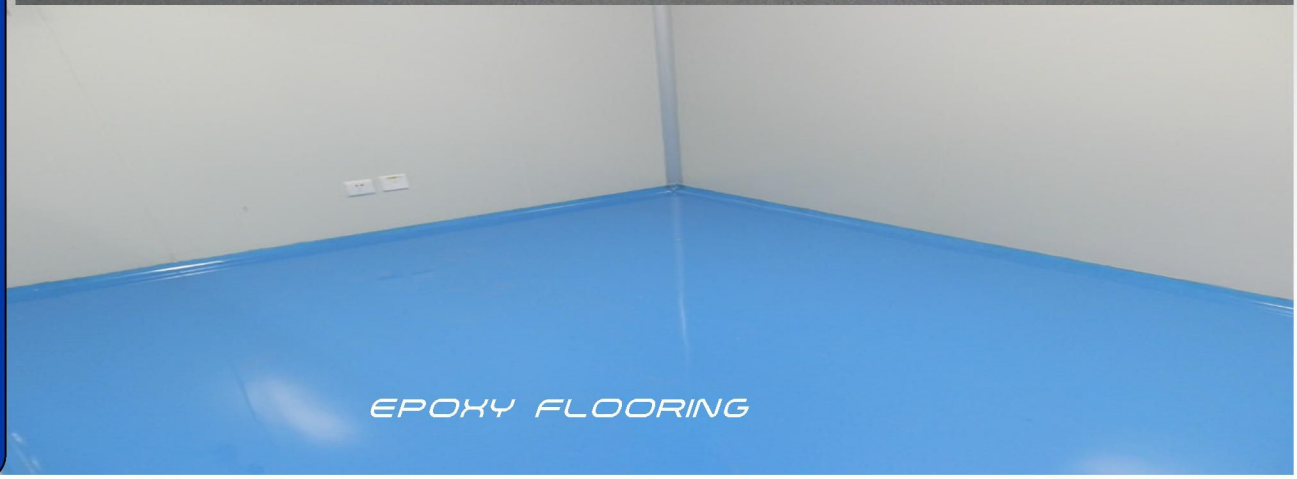
DOUBLE PANE TOUGHNED GLASS VIEW PANELS

CLEAN ROOM COVING

PVC /ALUMINIUM/ SS COVING

CLEAN ROOM FLOORING

VINYL FLOORING



EPOXY FLOORING

CLEAN ROOM PRODUCTS

CLEAN ROOM WASH STATION

HAND WASH STATION

- Made of Stainless steel , maintenance free , hygienic and sturdy design.
- Foot/Elbow/or sensor operated faucets.

LAMINAR AIR FLOW BENCH

HORIZONTAL LAMINAR AIR FLOW BENCH

- ***SS 304/MS Powder coated material of construction.***
- ***Tested and certified HEPA filters.***
- ***Differential Pressure gauges.***
- ***Fluorescent lamp.***
- ***UV Lamp with UV hour meter.***
- ***Solid state controller.***
- ***SS working table.***

VERTICAL LAMINAR AIR FLOW BENCH

- ***SS 304/MS Powder coated material of construction.***
- ***Tested and certified HEPA filters.***
- ***Differential Pressure gauges.***
- ***Fluorescent lamp.***
- ***UV Lamp with UV hour meter.***
- ***Solid state controller.***
- ***SS working table.***

CLEAN ROOM PRODUCTS

BIO SAFETY CABINET

BIO SAFETY CABINET

- *SS 304/MS Powder coated material of construction.*
- *Available in class I, II-A,II-B, & III.*
- *Tested and certified HEPA filters.*
- *Differential Pressure gauges.*
- *Fluorescent lamp.*
- *UV Lamp with UV hour meter.*
- *Solid state controller.*
- *Front Opening gloves port.*
- *HEPA Filter at exhaust.*

DISPENSING AND SAMPLING BOOTH

- *SS 304/MS Powder coated material of construction.*
- *Tested and certified HEPA filters.*
- *Differential Pressure gauges.*
- *Fluorescent lamp.*
- *Solid state controller.*
- *Power point for weighing machine.*
- *Perforated working table.*
- *Working level indicator.*

AIR SHOWER

- *SS 304/MS Powder coated material of construction.*
- *Tested and certified HEPA filters.*
- *Differential Pressure gauges.*
- *Fluorescent lamp.*
- *Solid state controller.*
- *Angle changing nozzles.*
- *Heavy duty dust collection system.*

CLEAN ROOM HVAC SYSTEM

CLEAN ROOM HVAC SYSTEM

Indoor air quality is of paramount importance for human comfort and health. Air, whether it is from outside or re-circulated within the area, acts as a vehicle for airborne contaminants brought in by the movement of people, material, etc. Since many of these air-borne contaminants are harmful either to products or people working in such environments their removal is necessary on medical, legal, social or financial grounds.

Cleanrooms are specially constructed, environmentally controlled enclosed spaces where the concentration of airborne particles (contaminants) is kept within specified limits. In industry, cleanrooms are used in the manufacturing of electronic hardware such as integrated circuits (ICs) and hard drives. In biotechnology and medicine, cleanrooms are used when it is necessary to ensure an environment free of bacteria, viruses, or other pathogens.

Four fundamental rules apply to cleanrooms.
1)First, contaminants must not be introduced into the controlled environment from the outside.
2)Second, the apparatus or equipment within the controlled environment must not generate or otherwise give rise to contaminants (for example as a result of friction, chemical reactions, or biological processes).
3)Third, contaminants must not be allowed to accumulate in the controlled environment.
4)Fourth, existing contaminants must be eliminated to the greatest extent possible, and as rapidly as possible.

These requirements are defined in Federal industry standard 209 and ISO 14644-1. It takes an incredible amount of technology toachieve and maintain these objectives. The HVAC system for cleanrooms is a specialized field requiring thorough understanding of cleanliness guidelines, airflow streams, room pressurization, temperature, humidity and filtration requirements, knowledge of codes and standards, specialty equipment, instrumentation and control, and many more details. This course will describe some basic requirements of HVAC design for cleanroom applications.

COMPONENTS OFCLEAN ROOM HVAC SYSTEM

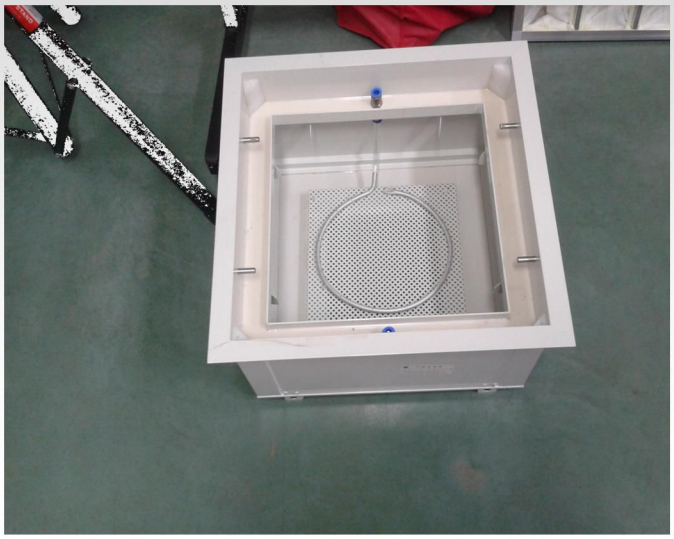
CLEAN ROOM AHU

AHU is the heart of HVAC system installed in the cleanroom.

- ***PCGI ,puff injected Panels.***
- ***Branded and certified motors.***
- ***High performance and efficient Blowers.***
- ***High efficiency tested filters.***
- ***Energy and cost optimized design to deliver maintenance free operations.***

CLEAN ROOM TERMINAL FILTER

- ***MS powder coated plenum***
- ***SS perforated sheet in discharge.***
- ***High efficiency tested and certified filters.***



CLEAN ROOM HVAC SYSTEM

LAMINAR AIR FLOW PLENUM

- ***SS/MS material of construction.***
- ***SS perforated sheet on air discharge.***
- ***High Efficiency Particulate Air Filter.***
- ***Sturdy design.***
- ***Modular construction.***
- ***UVGI sterilization.***

DUCT NETWORK

- ***GI/aluminum/SS sheet material of construction.***
- ***Sturdy, rustfree.***
- ***Nitrile rubber/Cross linked foam insulation.***
- ***Smallest aspect ratio.***
- ***Low noise and friction.***

HVAC CONTROL AND MONITORING SYSTEM

- ***Branded and tested switches and circuit breakers.***
- ***Temperature and RH controller***
- ***Running Hours timers.***
- ***Quality relays***
- ***Fault signal feedback.***
- ***Voltage and frequency protection***

CLEAN ROOM FURNITURE

CROSS OVER BENCH

APRON CABINET

PASS BOX

LADDER

STOOL

SS PALLETS

SOP STAND

CLEAN ROOM ACCESORIES

SHOE CLEANER

HAND DRYER

GLOVES DISPENSER

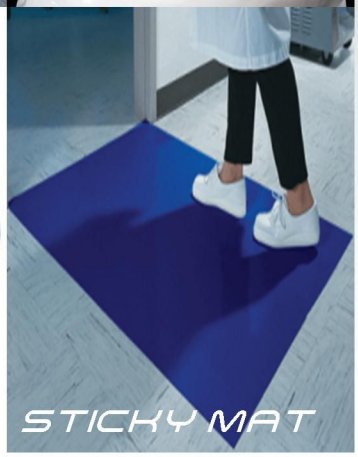
GARMENTS AND AIDE

CLEANROOM GARMEN

GLOVES

WIPER

SHOE COVER



STICKY MAT

CLEANROOM VALIDATION

Heart of cleanroom is its HVAC system installed for the cleanroom. Therefore validation of HVAC system is the basic need for validation of cleanroom.

In pharmaceutical industry requirement of HVAC system is plotted in "URS" and then same is described in "DQ" and thereafter qualification is done at installation and operation stage by recording the qualification in "IQ" & "OQ" finally the Performance Qualification analysis are done to check the installed system and observations are recorded and validated.

- **User Required Specification**
- **Generation and execution of DQ & IQ**
- **Cleanroom Validation Feasibility Studies**
- **Operational Qualification**
- **Validating Performance Qualification**
    - **Temperature recording**
    - **RH recording**
    - **ACH recording**
    - **Pressure Differential recording**
    - **Airborne Particle Count analysis**
    - **Filter Integrity test**
    - **Air Flow Visualization**

AIR BORNE PARTICULATE ANALYSIS

This test determines the quality of the client's cleanroom. We can test for the relevant sized particles in rooms of ISO Class 9 to ISO Class 4. Test reports are generated in the format of the relevant standard (EU GMP, FED 209E, ISO 14644). We use the most up-to-date particle counters on the market.

- Ensures the cleanroom is operating within design parameters and relevant standards.
- This test will document any emerging contamination trends. (Cleaning personnel can be guided to these areas)

ENVIROMENTAL TESTING

WE carry out the following environmental testing in cleanrooms:

- Noise levels
- Temperature / humidity mapping
- Luminance levels
- Air volumes / air change rates.
- Room pressure differentials
- Room recovery rates

GENERATION & EXECUTION OF IQ/OQ PROTOCOLS

we have generated and executed numerous IQ /OQ protocols for new cleanrooms. These protocols provide documented evidence that the installed cleanroom meets and operates within the design specification and regulatory standards. During execution of these protocols site SOPs, maintenance procedures and equipment manuals are also reviewed to ensure best practice is met.

- Ensures that the system has been installed in line with the design drawings.
- Ensures that the system operates in line with the design specification.
- Ensures that the cleanroom meets the relevant regulatory standards and client specifications.

HVAC SYSTEM VALIDATION

We carry out cleanroom validation on a quarterly, bi-annual or annual basis to ensure client compliance with relevant standards. Cleanroom validation gives a complete overview of how well the cleanroom is operating. We issue a comprehensive validation report following each visit which will include confirmation that all testing equipment used by us is maintained and calibrated to international standards.

- Ensures cleanroom continues to meet client design specifications and relevant standards.
- Regular validation minimizes product defects, equipment downtime and inefficiencies
- Ensures any changes can be addressed before they become a source of contamination
- This documentation will be required for cleanroom audits.

VALIDATION OF LAMINAR AIR FLOW DEVICES, MICROBIOLOGICAL SAFETY CABINETS & ISOLATORS

We carry out annual or bi-annual validation of laminar air-flow devices, microbiological safety cabinets and isolators. Tests carried out on these devices include HEPA filter integrity testing, airflow velocity and airflow visualizations. Ongoing validation of these devices is critical to protect both personnel and product.

- Ensures initial and continued equipment compliance to required standards.
- Ensures safety of personnel operating the equipment.
- Ensures the product remains uncontaminated.

ABOUT US

Filtotech Air Control System Pvt Ltd *is a multi-faceted company which initiated operations in 1997 as a manufacturer of select products for Air Pollution Control under the name & style "General Engineering Corporation". The company was shortly after its inception;* ***our*** *engineers became involved in the design of Air Handling Equipments for Pharmaceutical Industries. We began the construction of clean room products in 2002 and since then we are engaged in design and installation of Pharmaceutical & Healthcare clean rooms.*

We *have also designed and manufactured laminar flow type small movable clean rooms which are employed as local control devices for a variety of manufacturing, laboratory and technical operations & in healthcare. We maintain a staff of project managers, engineers, designers, and craftsman who are directly responsible for your engineered clean room projects and the manufacture of your clean room equipment which is built by our staff in our Kolkata, West Bengal facility*

Now, we have earned the experience of installation of Cleanroom for Injectables in addition to other solid dosage form for Pharmaceuticals. We have also installed Modular operation theaters in Healthcare through out the country.

We *are glad to add our service for Particle count, DOP/PAO test- Integrity test, Air Flow Pattern test for validation of Pharmaceutical Cleanroom.*

We *are proud of our fabrication quality of Cleanroom furniture like Crossover Bench, Apron Locker, Apron Cabinet, Pass Box etc. We have reached the required level of quality desired by Pharmaceutical Industries with the help of regular feedback from our valued customers.*

FILTOTECH AIR CONTROL SYSTEM PRIVATE LIMITED

(AN ISO 9001:2008 & CE CERTIFIED COMPANY)

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