NXTrigid-n

Negative Pressure Isolator

NXT *Rigid-N* systems are designed to meet the challenges and market requirements for low OEL containment systems in the Pharmaceutical, Biotechnology, and formulation industries. The concept of isolator technology, which is well-known in the pharmaceutical industry, protects the process from the operator and or the operator. Although the development and improvement of the isolator technology are continuous, it should be noted that the most significant changes have been in the form of its increased acceptance, backed by guidelines and standards produced by regulatory bodies.

PharmNXT Biotech's Negative Pressure Rigid Wall Isolators system "NXT *Rigid-N*" is a high-quality containment isolator system, specially designed for creating controlled negative pressure inside the isolator. It also can effectively control & monitor operating parameters and safeguard the operator & the surroundings from the highly potent products.

PharmNXT Biotech can successfully design and manufacture the Rigid Isolator for any pharmaceutical process required for R&D and the production scale containment.

NXT Rigid - N

Applications:

"NXT *Rigid-N*" Rigid wall isolators provided very high levels of containment and are used for the following applications in Pharma and BioPharma manufacturing.

API: (Handling Cytotoxicdrugs/ Oncology drugs/Peptides)

- Reactor Charging
- Filtration
- Drying
- Milling
- Sieving
- Micronizing
- Weighing and Dispensing
- Packing and repacking
- R&D testing

OSD and Formulations:

- Granulation
- Blending,
- Drying (Fluid Bed Drier)
- Tablet pressing,
- Tablet Coating,
- Encapsulation and Blister Packing
- QC, (Pack-off)
- Weighing and Dispensing

Advantages:

- Closed loop control system with differential negative pressure
- Ergo trail and cGMP design with rugged 316L Stainless Steel
- PLC/HMI integration for controlled environment
- Oxygen monitoring/nitrogen inertization
- Custom-built design: suitable for site requirement
- Controlled environment: Temperature, Humidity, Oxygen, Nitrogen
- Safe change Push-Push filters for air exchange
- Integrated WIP/CIP system for the isolator cleaning operation
- Excellent on-site service

Technical Specifications for negative pressure Rigid Isolator:

- Manufacturing as per the AGS and ISO requirement
- Multi-chamber design
- Controlled Negative Pressure differential pressure environment to achieve contentment up to OEL 5
- Safety Interlocks and breach alarms for the safety of the operator
- RTP/continuous liner/SBV/Passbox integration as per the process requirement
- Auto leak test option available

PharmNXT Biotech Support: Design to delivery

Design:

We generate conceptual design based on process requirements, Final product specifications, User requirement specifications, and standards operating procedure

Mock-Up (Ergo modeling):

We can arrange a full-scale mock-up at the factory which reflects the process parameters and any ancillary equipment or device to be integrated along with the isolator

Customer review and comments take into consideration respective changes and modifications

Manufacturing:

A dedicated state-of-the-art facility to manufacture the isolator with high-quality stainless-steel alloy. Committed and highly experienced team of skilled professionals to ensure the quality build manufacturing of insulator systems.

Factory Acceptance Test:

Dedicated facility to conduct FAT of equipment. Once the isolator system is fully built and internally tested with design parameters, a Factory acceptance test is to be performed by witnessing customers including a variety of tests and standard operating procedures to meet the process parameters.

FAT included all test parameters as specified by ISO 10644 and ISO 10648-2 for a controlled environment

Testing and Validation:

- **HEPA Filter Integrity:** Filter Leak Tests verify the integrity of the Supply and exhaust Push-Push HEPA filters.
- **Velocity and ACPH:** Downflow Velocity Tests verify adequate airflow velocities and recommended ACPH of isolator
- **Pressure Leak Test:** Isolator leak tested as Class 2 Containment Enclosure for process and pass chambers by ISO 10648-2
- **Particle Count Test:** Particle count (Air Cleanliness Tests) verify air cleanliness by ISO 14644-1.
- **Recovery Time Test:** It determines the amount of time required for the isolator main chamber to recover to its original state condition in the event of a contamination event.
- **Breach Test:** The breach test verifies user protection in case of a glove failure. The unit will become negative pressure with an inward velocity of 0.7 m/s.
- **Differential Pressure Test:** It verifies that the isolator is running smoothly with given parameters of differential pressure.

Quality Control:

Our "NXT *Rigid-N*" isolator systems are designed, developed, and manufactured by ISO 9001 certified quality management system. They undergo extensive testing before shipping. We make sure our products are manufactured according to cGMP and are suitable for the cleanroom process.

Support

PharmNXT Biotech supports users from the design to the execution phase of a new production facility and existing production facility with the most comprehensive support program, that ensures the successful design, implementation, and validation of the manufacturing facility. PharmNXT Biotech offers end-to-end solutions for Pharmaceutical, Biopharmaceutical, and Vaccine manufacturing.

PharmNXT
Make In India For The World

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