

# NXTflex-n

## *Hardware for Flexible Isolator*

PharmNXT Biotech's flexible isolator system "NXT Flex-N" is a cost-effective solution for high-quality containment and isolation of pharmaceutical applications.

These isolators save time and money by allowing you to retrofit existing processing equipment while achieving nanogram containment levels. All materials meet FDA standards, and the design accommodates cGMP as well as operator ergonomics.

These isolators typically provide operator safety up to OEL 5 for handling potent and toxic powers in modern process plants.



## **What is Containment:**

All Active Pharmaceutical Ingredients (API's) are biologically active, even at very low quantities. Therefore, it is vital not to expose operating personnel handling these compounds to levels that would result in adverse biological effects being experienced.

To facilitate this, a containment strategy needs to be employed. When dealing with API's, it involves preventing hazardous materials from escaping into the workplace and into the surrounding environment. Essentially this involves isolating the product from personnel and the environment. This in turn protects the product itself, personnel working on the process and the surrounding environment.

Here at PharmNXT Biotech, we design, manufacture, and install flexible isolators for this exact purpose. Our business is based on the well-known philosophy "contain at source" and we incorporate this into our designs. The "contain at source" philosophy is now the most favored philosophy among containment engineers and all the regulatory bodies.

## NXT Flex - N

### Introduction:

All our flexible isolators are custom designed to suit our customers' requirements. Our flexible isolators can be manufactured from one of the following anti-static materials:

- Polyurethane (PU)
- Linear Low-Density Polyethylene (LLDPE)

Many of our flexible isolators are manufactured from PU as this is the most transparent and user-friendly material. However, if the PU is not suitable for our customer, due to solvent compatibilities or other reasons, we can manufacture the flexible isolators from one of our other materials which will satisfy the customer's requirements.

We currently have custom-designed many flexible isolators for the pharmaceutical industry and these are installed on processes across India ensuring safe and contained operations.

### Applications:

"NXT Flex-N" flexible isolators can attain high levels of containment for the following applications in Pharma and BioPharma manufacturing

#### API: (Handling Cytotoxic drugs/ Oncology drugs)

- Drum Sampling
- Reactor Charging
- Filtration and Drying
- Milling and Sieving
- Micronizing
- QC, Weighing, and Dispensing

#### OSD and Formulations:

- Granulation, Blending,
- Fluid Bed Drier
- Tablet pressing, Tablet Coating,
- Encapsulation and Blister Packing
- Roller Compaction,
- QC, Pack-off, Repacking, Weighing, and Dispensing

## Advantages:

- Compact and ergonomic design according to process requirement
- FDA-compliant film material with high transparency & tensile strength
- Stainless steel support structure for instant assembly of the system
- Retrofit design for existing equipment
- Eliminates the cost of the expensive plant by reducing capital costs.
- Ability to rapidly upgrade existing equipment to handle highly potent products.
- Custom designed to suit the operator's needs.
- Improved ergonomics.
- Allow for safe, effective, and operator-friendly use.
- Reduced need for PPE.
- Lower risk of cross-contamination.
- Protecting the product from contamination.
- Protecting the operating personnel and the environment
- Reduced cleaning and cleaning validation costs.
- Fast turnaround/installation.
- Low capital and operating costs

## Technical Specifications:

- Manufacturing as per the AGS and ISO requirement
- Anti-Static and clear flexible Film
- Gas tight zippers for Airlocks
- Design to meet up to OEL 5 for potent molecules
- Dedicated AHU unit
- 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
- Safe change Push-Push filters for air exchange
- Integrated WIP system for the isolator cleaning operation
- Multichambered design option
- RTP/continuous liner/SBV/ integration as per the process requirement
- Excellent on-site service

## NXT Flex - N

### **Air Handling Unit:**

The main purpose of our Air Handling Units (AHUs) is to suck contaminated air out of a production room through the ducting provided, filter the air within the AHU and the clean filtered air then leave the AHU out of the exhaust. As the AHU is sucking the air out of the room, filters will need to be strategically placed around the room to allow sufficient amounts of clean air into the room to replace the air that is sucked away by the AHU.

The damper on the AHU can be adjusted to control the room's air changes per hour. There are also Magnahelic gauges on the AHU to show the efficiency of the filters within the unit. When the filter blocks, there is a procedure for the safe change out of the filter, using the glove bag provided with the AHU.

### **Features of Air Handling Units:**

- Portable design/ Mobile unit
- 1 Filter for Supply and 2 filters for exhaust into AHU.
- Safe change out of filters available.
- Damper provided to control air ow.
- Magnahelic Gauges for Exhaust Filter

### **Quality Assurance**

Our "NXT Flex-N" 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.



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#### **MANUFACTURING PLANT**

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