Piramal
Pharma Solutions

THE BENEFITS OF ISOLATOR TECHNOLOGY

INTRODUCTION

Isolator technology has become increasing more popular in the use of high-potency drug manufacture. Isolators offer many operating benefits while assuring higher product sterility and operator safety. The small environment of the isolator is easier to control then that of a whole cleanroom. A completely decontaminated environment exists inside the isolator where the drug and manufacturing materials only come in direct contact with the processing system. Unlike a cleanroom environment, this assures a higher product sterility and operator safety.

An isolator is an enclosure sealed to provide a standard of leak tightness containing within it a qualified, controlled environment at variance with the surrounding conditions. The intent is to create an airtight barrier around a piece of equipment or process which provides absolute separation between the operator and product. The specific environment inside the isolator can have humidity control and unidirectional airflow. This helps provide an aseptic process protecting the product from the operator as well as the operator from potentially potent product handling. The isolator's systems separate the external Grade D environment from the Grade A processing line, minimizes its exposure to human interaction, and offers fewer opportunities for microbial contamination during processing.

Operators perform tasks inside the isolator through glove ports. When operators have their hands inside of the isolator gloves, movements are slow and deliberate as to not disturb the air flow.

Different types of isolators are used for different purposes when manufacturing a pharmaceutical drug product. Two main types of isolators are used for aseptic processing: opened and closed. Closed isolators employ connections with auxiliary equipment for material transfer. Open isolators have openings to the surrounding environment that are carefully engineered to segregate the inner isolator environment from the surrounding room. In isolators that house filling lines, unidirectional airflow sweeps over and away from exposed sterile materials. Interface isolators are attached to exit doors of pass-through isolators, autoclaves, depyrogenation ovens, and lyophilizers to allow direct transfer of media, supplies, glassware, product, etc. into the isolator system.

Piramal pharma Solutions (PPS) will soon have the technology to complete multiple material transfers commonly made during the processing of a batch. With the installation of a new Steriline Isolator, PPS will utilize the rapid transfer ports (RTPs) as an effective transfer mechanism for aseptic transfer in and out of the isolator. To prevent the ingress of air from the surrounding room, HEPA-filtered unidirectional airflow in the area of the port is implemented. Environmental monitoring (EM)

ensures acceptable microbiological quality of air, surfaces, and gloves as well as particle levels within the isolator and is monitored regularly. The use of vaporized hydrogen peroxide (VHP) ensures a high level of surface disinfection inside of the isolator system. Individual VHP cycles are qualified using a series of biological indicators (BIs) throughout the isolator to confirm decontamination of all locations.

Isolators are cleaned to reduce any bioburden prior to VHP decontamination and to remove any product residue from secondary product contact surfaces to prevent cross-contamination between batches. This is confirmed through analytical testing. Before cleaning an isolator, all post-use environmental monitoring activities are performed. After the isolator is cleaned per intended use, a VHP cycle is initiated prior to the next batch. Isolators are also inspected regularly for damage. Isolators using a docking connection performs a VHP cycle after the connection is secure. After being successfully VHP decontaminated, the port doors of the isolators can be opened. The glove ports are then used by the operators to transfer materials, equipment, and product to the appropriate isolator. When transfer is complete, the doors are closed and the isolators are undocked.

At Piramal, we employ state-of-the-art mobile isolator technology in our manufacturing facility and will be adding the new stationary Steriline soon. Both technologies will help to provide a physical barrier that protects our staff from toxic substances and encloses your product in a Grade A environment. Similar fixed isolators are used in our development labs to mimic manufacturing operations and enable formulation and analytical development on toxic substances. Through the use of these high containment isolators, our scientists create and maintain a controlled sterile environment enabling us to process potent drug classes including cytotoxins, steroids, hormones, and acutely toxic substances..

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.

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