Hazardous Pharmacy Compounding Isolator: Top Questions Before You Buy the Isoclean® Healthcare Platform Isolator (HPI-G3)

A decision guide for hospital pharmacy directors, compounding managers, and procurement teams, moving beyond brochure specifications into the engineering, compliance, and operational realities of the Isoclean® Healthcare Platform Isolator (HPI-G3).

Introduction

When hospitals and compounding pharmacies evaluate an isolator for hazardous drug preparation, the conversation often starts with specifications such as airflow, filtration, pressure, and footprint. But the real decision rarely hinges on a single feature. It's about fit: fit with your facility, your workflow, your compliance obligations, and your long-term strategy.

This guide addresses the most common (and most important) questions buyers ask, moving beyond surface-level answers into the engineering logic, operational trade-offs, and regulatory context behind each one.

Should the Isolator Be Total Exhaust or Recirculating, and Does It Need to Be Ducted?

One of the earliest and most consequential design decisions is how the isolator manages the air it processes. Two strategies exist, and each carries distinct implications for safety, facility infrastructure, and operating cost.

Total Exhaust / Single Pass	Recirculating
• 100% of supply air is drawn fresh from the environment • 100% of exhaust air is expelled outside (none is recirculated) • Required when drugs may volatilize at compounding temperature • Higher HVAC demand and energy consumption • Requires robust building exhaust infrastructure	• Approximately 70% of air is filtered and returned to the work zone • Approximately 30% of air is exhausted externally • More energy-efficient; lower HVAC demand • Requires less building exhaust requirement, suitable for facilities which ducted is mandated with limited exhaust infrastructure.

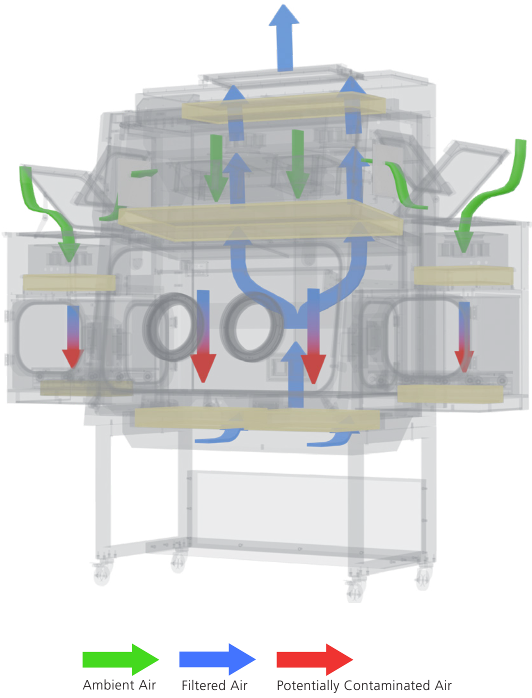

Figure 1. the Isoclean® Healthcare Platform Isolator (HPI-G3) with Filter Below Work Zone with Total Exhaust/Single Pass Airflow Regime

Regulatory Landscape: Not One Size Fits All

Regulatory expectations for hazardous drug compounding isolators vary significantly across regions, and understanding these differences is essential when defining the appropriate exhaust strategy. In the United States, USP <800> mandates that all containment primary engineering controls (C-PECs) used for sterile hazardous drug compounding be externally vented, ensuring that contaminated air is discharged outside the building to minimize personnel exposure and environmental contamination [1].

In contrast, Singapore adopts a more flexible, risk-based approach. The Ministry of Health's *Guidance on Pharmacy Compounding (2016)* recommends that primary engineering controls and the background environment for hazardous compounded sterile preparations be externally vented wherever possible; however, when this is not feasible, alternative safeguards may be implemented. These include the use of closed system transfer devices (CSTDs), increasing room air changes per hour (ACPH), and conducting half-yearly HEPA filter integrity testing [2]. Meanwhile, in Australia, regulatory expectations take a more prescriptive stance on filtration, requiring the use of an activated carbon filter downstream of the HEPA exhaust filter on the cytotoxic drug safety cabinet exhaust system to address potential vapor-phase contaminants [3].

Given these regional differences, there is no single "universal" requirement for exhaust configuration. It is therefore critical to evaluate local regulations, facility constraints, and risk management strategies together before finalizing the isolator design.

Why Drug Volatility Is Critical Variable

CLINICAL EXAMPLE

Drugs such as certain antineoplastic agents like Carmustine and Mustargen can generate vapor even at 23°C [4]. Any isolator used for their compounding must be configured as single pass (total exhaust) with ducted connection to the building exhaust system. **It's not a choice; it is mandatory for safety.**

HEPA and ULPA filters are mechanical particle filters, they capture particulate matter with extraordinary efficiency (>99.995% at 0.1–0.3 microns for the H14 filters used in HPI-G3. However, they do not capture vapor or gases. Certain hazardous drugs become volatile at or near room temperature or during the thermal changes of the compounding process. If the isolator's exhaust contains vapor from such drugs, a recirculating unit will return that vapor to the work zone, and some fraction will escape into the room, representing an unacceptable exposure risk to personnel

Understanding Building Exhaust Requirement: CMH and Static Pressure

When a ducted isolator is selected, the facility's HVAC system must be capable of handling the isolator's exhaust demand. Two numbers define this requirement:

Parameter	Characteristics	Preferred Environment
CMH (m^3/hour)	Cubic meters of air per hour that the building exhaust system must remove from the isolator	Determines whether the HVAC fan capacity is adequate. Under sizing leads to insufficient airflow through the isolator, compromising containment.
Static Pressure (Pa)	The resistance (measured in Pascals) that the building exhaust duct system presents against the isolator's exhaust fan	Every meter of ductwork, every bend, and every fitting add resistance. If cumulative static pressure exceeds the isolator fan's capability, airflow drops below design specification.

As a reference point, the HPI-G3 series with filter below the work zone requires the following building exhaust capacity with 30% tolerance:

Building Exhaust Requirement		HPI-2G	HPI-3G	HPI-4G
Recirculating	1 pass chamber	531 cmh @ 200 Pa	647 cmh @ 250 Pa	765 cmh @ 300 Pa
	2 pass chamber	595 cmh @ 250 Pa	711 cmh @ 300 Pa	828 cmh @ 350 Pa
Total Exhaust (Single Pass)	1 pass chamber	1062 cmh @ 400 Pa	1295 cmh @ 500 Pa	1530 cmh @ 600 Pa
	2 pass chamber	1189 cmh @ 500 Pa	1422 cmh @600 Pa	1657 cmh @ 700 Pa

KEY TAKEAWAY

The choice between total exhaust and recirculating is a facility-level decision with consequences for safety, regulatory compliance, and operating cost. It must be made before equipment is specified, not after it arrives. Early engagement with your facility engineering team is essential, not optional.

To assess whether your existing building exhaust system can accommodate a new isolator installation, a mechanical engineer should calculate the total static pressure of the proposed ductwork run, accounting for the straight-run duct length, number and type of bends, any restrictions, and vertical rise. This calculation, compared to the isolator's published building exhaust requirement and the available HVAC capacity, determines whether the existing infrastructure is adequate or whether upgrades are necessary.

Do I Need an External Exhaust Blower?

For any ducted HPI-G3 installation, the answer is yes. The isolator's internal fans are designed to manage airflow within the cabinet; they are not intended to overcome significant external ductwork resistance. An external exhaust blower, installed in the ductwork typically near the point where the duct exits the building or connects to the central exhaust system, provides the additional draw required to maintain design-specified airflow through the isolator under real-world conditions.

Selecting the correct external blower requires careful calculation of:

1. Required Airflow Volume

The blower must be rated to move at least the isolator's specified building exhaust volume (CMH) under the calculated static pressure of your specific duct installation. Confirm the figure from the building exhaust requirement table for your chosen HPI-G3 model and configuration and add a margin for duct resistance.

2. Total System Static Pressure

Sum the static pressure losses for every element of the duct run: straight lengths (approximately 1–3 Pa per meter depending on duct diameter and velocity), elbows and bends, dampers, and any exhaust termination fittings. The blower's rated pressure must exceed this total at the required flow rate.

3. Redundancy Planning

For pharmacies operating continuous compounding workflows, maintaining uninterrupted containment is critical. A single-blower failure can not only halt operations but, if not immediately detected, may also compromise containment and increase the risk of exposure. To mitigate this, it is important to assess whether your operational risk profile justifies additional safeguards, such as a standby blower with automatic switchover. At a minimum, facilities should implement a rapid-response maintenance protocol and ensure that alarms are fully integrated with the building management system (BMS) for real-time monitoring and response. Supporting this, the Esco HPI-G3 with filter below the work zone is equipped with a standard zero-volt dry contact, enabling seamless communication with both external blowers and the BMS to facilitate prompt alarm signaling and system coordination.

4. Anti-Blowback Protection

In installations where the duct run is shared, or where air pressure at the external termination could create positive pressure events, an anti-blowback valve (available as an accessory for HPI-G3 models) should be installed. This prevents any reversal of airflow into the isolator chamber during momentary pressure fluctuations.

ESCO SUPPORT

Esco can assist in specifying a compatible external exhaust blower to match your HPI-G3 configuration and site-specific ductwork parameters. Contact your regional Esco representative with your duct layout drawings and the isolator model under consideration.

How Large Will the Isolator Actually Be, Once Fully Configured?

The dimensions published in a product brochure describe the base unit alone. In most real-world installations, the fully configured system with the accessories required for your workflow and compliance obligations will occupy considerably more space than those figures suggest. Planning space based on brochure dimensions is one of the most common and costly mistakes in isolator procurement.

The following components and options add to the installed footprint and height of the HPI-G3 with Filter Below Workzone:

Addition	Dimension Impact	Notes
Pass-through chamber(s)	Increases total unit width by ~325 mm per chamber	Up to two pass chambers can be configured (left, right, or both). Essential for maintaining sterility during material transfer in negative pressure environments.
Top exhaust collar (with ducting)	+260 mm additional height	Required for ducted configurations. The HPI-G3 smart fit design means no additional height is added when specifying the carbon filter option with top exhaust collar. In the case of limited building height, a customized side exhaust collar can be provided.
Anti-blowback valve	Approximately +420 mm additional height from the exhaust collar	Fitted in-line at the exhaust collar outlet. Prevents pressure reversal events from propagating into the chamber.
Fixed-height stand (713 mm)	Adds 713 mm to base unit height	Available with levelling feet or casters.
Fixed-height stand (864 mm)	Adds 864 mm to base unit height	Available with levelling feet or casters.

Addition	Dimension Impact	Notes
Telescoping stand (660–885 mm)	Adds 660–885 mm; adjustable in 25.4 mm increments	Not recommended for hard-ducted units (where a sealed, qualified connection is required). Suitable with flexible ducting.
Hydraulic height-adjustable stand	Adds approximately 685–935 mm height range	Enables seated and standing work positions. Note: hard-ducted configurations are not recommended with a height-adjustable stand unless a flexible duct section is included.
Customized PLC/ HMI with automated pressure hold test	Variable — consult Esco	Customized configurations may differ from standard footprint drawings. Always request updated drawings from the manufacturer when specifying custom options.

PLANNING GUIDANCE

Before finalizing room layout, confirm the total installed height of the isolator, including the stand and all top-mounted accessories against your room's clear ceiling height. Allow clearance above the unit for filter change access and any overhead ductwork connections. Think in terms of workflow, not just equipment dimensions: operator movement, transfer paths, and emergency egress must all be factored into the space plan.

How Do We Transport the Isolator Inside the Building?

An isolator that cannot navigate the path from loading dock to compounding room is not a viable isolator, regardless of its technical merits. This is a logistics consideration that must be addressed during the planning phase, not on delivery day.

The HPI-G3 arrives as unassembled unit. Key minimum clearance dimensions to verify against your building's corridors, doorways, and lifts are:

845 mm

Minimum door width for **HPI-G3 with filter** below work zone

825 mm

Minimum door width for **HPI-G3 without filter** below work zone

If access through a specific doorway or lift is restricted, the HPI-G3 can be delivered in chamber-dismantled state: the process chamber and pass chamber(s) can be separated, transported through restricted openings, and re-assembled on-site by qualified Esco service personnel. This requires prior arrangement and will affect the installation timeline, hence plan accordingly.

For multi-store facilities, verify lift car dimensions (width, depth, and weight capacity) against the shipping weights of the selected configuration. The HPI-2G, for example, has an estimated shipping weight of approximately 835 kg, well within a standard goods lift capacity, but always worth confirming.

What Determines the Total Cost of an Isolator?

Isolator pricing is not a fixed catalogue figure; it is the output of a project scope. Two buyers specifying apparently identical isolators can arrive at meaningfully different total costs depending on their configuration choices, site conditions, and procurement requirements.

The principal cost drivers are:

1. Base Configuration and Customization

Standard HPI-G3 units are priced according to chamber width, pressure configuration (positive/negative), airflow regime (recirculating/single-pass), and pass chamber quantity. Custom configurations: such as integrated PLC/HMI with automated pressure hold testing, non-standard glove port sizing, or modified external chamber height, and additional features require engineering review and carry additional cost.

2. Accessories and Add-Ons

Options such as hydraulic height-adjustable stands, carbon filters, IV bars with hooks, UV lamps, glove leak testers, sharps disposal systems, electrical outlets, CCTV-brackets, and anti-blowback valves each add to the base price. Specify only what your workflow genuinely requires.

3. Automation and Monitoring Features

Integration with Building Management Systems (BMS) via dry contact / relay outputs are standard on the HPI-G3. More advanced automation such as automated pressure hold testing with PLC control represents a significant but often justifiable additional investment for high-volume or high-risk compounding environments.

4. Installation and Commissioning

Site preparation, ductwork installation, electrical connection, and on-site commissioning by qualified personnel are costs that are sometimes overlooked in initial budget exercises. These can represent 15–25% of the equipment cost depending on site complexity.

5. Qualification (IQ/OQ)

For pharmacy applications, a formal qualification is typically required. The scope and therefore cost of qualification depends on the regulatory framework applicable to the facility and the risk classification of the drugs being compounded.

INSIGHTS

The question is not simply *"What does the isolator cost?"* but *"What is the total investment required to have a compliant, qualified, operational compounding capability?"* These figures (equipment, accessories, installation, commissioning, and qualification) are the number that belongs in the capital budget.

Is the Isolator Compliant with USP <800>?

The HPI-G3, configured with negative pressure and ducted airflow system, is designed to meet the engineering control requirements specified in USP <800> for hazardous drug compounding. It complies with the referenced testing standards including CETA CAG-001-2005, CETA CAG-002-2006, and ISO 10648-2 (Class 2 containment enclosure).

However, a critically important qualification applies: an isolator alone does not produce USP <800> compliance. USP <800> is a comprehensive standard governing the entire hazardous drug management system within a facility. The isolator is one component within that system.

Compliance also depends on:

- Negative pressure containment maintained in both the isolator and the compounding room
- Validated airflow design and HEPA filtration (H14 minimum)
- Formal written SOPs for all drug handling procedures
- Personnel training and competency assessment
- Facility layout meeting buffer room and ante-room pressure differential requirements
- Environmental monitoring program
- Ongoing qualification and periodic re-testing

REGULATORY NOTE

USP <800> also specifies that the compounding room the space in which the isolator is located) for sterile hazardous drug must itself be maintained at negative pressure relative to adjacent areas. Specifying a compliant isolator within a non-compliant room does not satisfy the standard's requirements. Facility design and isolator procurement must be addressed as a unified project.

What Pressure Strategy Should Be Used?

Pressure control is one of the most fundamental design parameters in isolator specification. The HPI-G3 is factory-configured for either positive or negative pressure as the two strategies serve different primary purposes.

Hazardous Sterile Drug Compounding **Negative Pressure**	Non-hazardous Sterile Drug Compounding **Positive Pressure**
The work zone and pass chamber are maintained at a pressure below that of the surrounding room (~ min. -25 Pa in the process chamber and min. -37 Pa in pass chamber). In the event of a breach or leak, air flows inward (from the room into the isolator) rather than outward. This prevents hazardous drug particulate and vapor from escaping into the environment and reaching the operator. Required by USP <800> for hazardous drug compounding. The HPI-G3's breach containment system ensures that in the event of a glove failure, the unit generates inward airflow of ≥ 0.4 m/s (≥ 0.51 m/s for models with filter below), actively protecting the operator.	The work zone is maintained at a pressure above that of the room. Any breach causes air to flow outward, protecting the product inside from environmental contamination. This configuration is appropriate for non-hazardous sterile preparations where product sterility is the primary concern and there is no operator exposure risk.

IMPORTANT ⚠

For hazardous drug compounding, negative pressure is the required configuration, this is not a matter of preference but of regulatory compliance and personnel safety. Additional considerations include the toxicity classification of the drugs being prepared, any sterility requirements that may apply concurrently, and the risk of cross-contamination between products. Where both hazardous and non-hazardous preparations are compounded within a single pharmacy, separate isolators configured for the appropriate pressure regime should be considered.

How Can Ergonomics Be Optimized?

Pharmacists and pharmacy technicians who prepare chemotherapy and other hazardous drug preparations may spend several hours per shift working at an isolator. Poor ergonomic design is not merely a comfort issue, it directly affects accuracy, fatigue, and ultimately the safety of the compounded preparation and the operator.

The HPI-G3 incorporates a number of design features that directly address the ergonomic demands of sustained compounding work:

Feature	Ergonomic Benefit
Ergonomically sloped frameless front visor with rounded edges	Reduces glare from overhead lighting, improves reach angle into the work zone, and eliminates crevices that would otherwise accumulate contamination and complicate cleaning.
200 mm circular glove ports (oval 200×300 mm upgrade available)	Minimizes shoulder and wrist strain by positioning the operator's hands at a natural working angle. No exposed bolts or nuts that could snag gloves or collect contamination.
Horizontal sliding tray between pass chamber and process chamber	Eliminates the need to reach through the pass chamber opening to retrieve materials, significantly reducing shoulder fatigue and the risk of glove contact with potentially contaminated surfaces.
Foot switch for inner pass chamber door	Allows hands-free opening of the electromagnetic interlock between the pass chamber and process chamber. The operator can initiate a material transfer without interrupting ongoing work or compromising glove integrity.

Feature	Ergonomic Benefit
Optional hydraulic height-adjustable stand	Accommodates both sitting and standing work postures and adjusts to individual operator height. Critical for multi-operator pharmacies where the same isolator is used by personnel of different statures across different shifts.
Optional IV bar with hooks	Provides dedicated hanging points for infusion bags, TPN containers, and other items that would otherwise occupy valuable work surface area. Particularly beneficial for high-throughput chemotherapy and TPN compounding workflows.
LED lighting (>650 Lux at work surface)	Consistent, shadow-free illumination throughout the work zone reduces eye strain and supports accurate label verification and preparation checks.
Sound level ≤ 67 dBA	Below the threshold at which sustained noise exposure causes fatigue or impairs concentration during complex compounding procedures.

KEY TAKEAWAY

An isolator used daily, sometimes for consecutive hours, must support human performance, not merely contain it. When evaluating isolators, observe an experienced operator working in the unit under realistic conditions. Fatigue, awkward postures, and repeated reaching are risks that do not appear in specification tables but manifest clearly in practice.

Can Third-Party Equipment Be Integrated Inside the Isolator?

It is frequently necessary to place ancillary equipment such as: balances, peristaltic pumps, label printers, or monitoring devices within the isolator's work zone. This is entirely achievable with the HPI-G3, but integration requires deliberate engineering rather than simply placing equipment inside and closing the gloves. The challenges of in-isolator integration fall into four categories:

Heat Generation

- Equipment with motors, heating elements, or continuous power draw generates heat inside a sealed chamber
- Elevated temperatures affect drug stability, accelerate degradation, and can cause airflow anomalies
- Heat load must be estimated and factored into the isolator's thermal management design

Cable Routing

- Power and data cables must pass through the isolator wall without compromising chamber integrity
- HPI-G3 supports customized cable penetrations, gasketed, sealed, and compatible with pressure hold testing
- Electrical outlets inside the chamber are available as a standard option

Cleaning Compatibility

- Equipment placed inside the isolator will be subject to the same cleaning and decontamination agents used on the work surface
- Confirm material compatibility between your cleaning and decontamination agents and any equipment housing, keypads, or displays
- Equipment with complex geometries or open ventilation slots complicates surface decontamination

Space and Airflow

- Equipment placed in the work zone displaces available workspace and can disrupt the unidirectional laminar airflow designed to maintain ISO Class 3 conditions
- Large or tall items should be positioned to minimize airflow shadowing behind them
- Take into account free space for inner door opening space
- Total equipment volume within the chamber should be reviewed as part of the airflow qualification

DESIGN RECOMMENDATION

Specify all intended in-chamber equipment to Esco at the time of order. Cable penetration requirements, electrical outlet positions, and any heat load considerations can then be engineered into the unit at the factory, minimizing post-installation modifications that may require re-qualification of the chamber.

How is Cleaning and Decontamination Performed?

Cleaning and decontamination of a hazardous drug compounding isolator is not simply a housekeeping function; it is a critical safety procedure governed by USP <800> and subject to formal SOP requirements. The sequence and method matter as much as the frequency. USP <800> specifies a four-stage surface treatment sequence for hazardous drug compounding environments, DDCD:

1. Deactivation

Application of an agent specifically selected for its ability to inactivate or chemically neutralize hazardous drug residues. The agent selected must be validated for efficacy against the specific drugs compounded. Contact time and coverage are critical; surfaces must remain wet for the specified contact period.

2. Decontamination

Removes residue from surface using cleaner agents (e.g: germicidal detergents)

3. Cleaning (Residue Removal)

Physical removal of drug residue and gross contamination from all surfaces within the work zone, pass chamber, and any in-chamber equipment. Detergent-based cleaning agents are typically used. This stage removes the material that would otherwise protect drug residue from subsequent decontamination agents.

4. Disinfection

Application of a sporicidal or broad-spectrum antimicrobial agent to reduce microbial bioburden to acceptable levels. For sterile compounding applications, this stage is required in addition to decontamination and must be validated as part of the facility's environmental monitoring program.

The HPI-G3's interior construction directly supports effective cleaning: the 316L stainless steel work surface and interior panels have a 4B finish with large-radius internal corners that eliminate the ledges and right-angle joints where drug residue accumulates. Removable trays allow access to the chamber floor and provide flat surfaces that can be removed for thorough.

Optional Surface Decontamination Enhancements

SOP REQUIREMENT

Cleaning, decontamination, and disinfection procedures must be clearly defined and documented in validated SOPs before the compounding program goes live. In addition, the isolator's material compatibility with the selected chemical agents should be carefully verified to prevent damage and ensure long-term performance. For example, chlorine-based solutions should not be used on stainless steel surfaces. Instead, suitable cleaning agents for stainless steel include alcohol-based solutions, mild detergents, and low-concentration bleaches.

Likewise, polycarbonate components require special attention, high concentrations of caustic soda (e.g., 20% solution at 25 °C or higher) should be avoided.

UV lamp option: The HPI-G3 is available with an optional integrated UV lamp for supplementary surface disinfection. UV irradiation efficacy is highly dependent on achieving the minimum required irradiance (microwatts per cm^2) across all surfaces within the chamber, surfaces shielded from direct UV exposure will not be treated. *UV lamps should be considered a supplementary measure, not a replacement for chemical decontamination protocols*

What Happens During Failures or Breach Scenarios?

The performance of an isolator during abnormal conditions is at least as important as its routine performance. Failure scenarios glove puncture, power interruption, pressure loss, and blower failure represent the moments when the containment system's design quality is truly tested. Specifying an isolator without understanding its failure behavior is an incomplete evaluation.

The HPI-G3 incorporates the following protective mechanisms for failure scenarios:

Failure Scenario	HPI-G3 Response
Glove breach / puncture	The isolator's built-in containment breach system responds by increasing inward airflow at the breach point. In negative pressure configuration, the unit generates inward airflow velocity of ≥ 0.4 m/s (for units without filter below) or ≥ 0.51 m/s (for units with filter below the work zone), actively directing airflow away from the operator and toward the chamber interior. This performance is verified at factory and confirmed annually during qualification via the Containment Breach Test protocol.
Loss of pressure / airflow	The Sentinel™ Gold control system continuously monitors work zone and pass chamber pressure differentials and downflow airflow velocity. Deviations beyond set thresholds trigger the alarm package (audio-visual alert), providing immediate notification to the operator and via dry contact relay output to the Building Management System.
Power failure	In the event of a complete power loss, the unit fans stop. The chamber's negative pressure is no longer actively maintained. Operators should have a defined procedure for securing work in progress and ensuring no material egress. An optional additional mechanical latch is available to prevent pass chamber doors from inadvertently opening during a power outage.

Each HPI-G3 unit is individually factory-tested before shipment. Site testing, including the breach test and the appropriate performance qualification tests should be repeated at installation and annually thereafter as part of the ongoing qualification program.

How Is Isolator Performance Verified?

Performance verification for a pharmacy isolator is not a single test; it is a structured series of tests that together confirm the unit is functioning as designed and that the compounding environment meets the required standards. The HPI-G3 supports the following verification protocols, both at factory and on-site during qualification:

1. Chamber Pressure Testing (Static and Dynamic)

Verifies that the isolator maintains its design pressure differentials both at rest (no compounding activity) and during normal operation, in accordance with CETA CAG-002-2006. Static pressure confirms the integrity of the sealed chamber; dynamic pressure confirms stability under realistic working conditions.

2. Smoke Pattern Test

Visualizes the direction and character of airflow within the work zone using smoke or tracer particles. Confirms that the downflow is laminar (unidirectional) and that there are no recirculation zones that could allow contamination to accumulate or escape.

3. Filter Leak Test (HEPA Integrity)

Verifies the integrity of each HEPA/ULPA filter as installed, confirming that there are no leaks around the filter frame or through the filter media. Performed in accordance with IEST-RP-CC034.1.04

4. Downflow Velocity Test

Measures air velocity at multiple points across the work surface to confirm that the unidirectional downflow meets the specified velocity (0.4 m/s ±20%) uniformly across the work zone.

5. Breach Test

Simulates a glove failure and measures the inward airflow velocity generated at the breach point. For a compliant result, the HPI-G3 must demonstrate ≥ 0.4 m/s (units without filter below) or ≥ 0.51 m/s (units with filter below). This test directly demonstrates the unit's ability to protect the operator in the event of glove failure.

6. ISO 10648-2 Pressure Hold Test

The HPI-G3 is a Class 2 Containment Enclosure, factory-tested in accordance with ISO 10648-2. The test requires compressed air to be injected to 280–290 Pa; the countdown begins when pressure drops to 250 Pa. Measurements are taken every five minutes over 30 minutes and computed to confirm a leak rate of less than 0.25% per hour. This test may also be performed on-site during periodic qualification using the optional automated pressure hold test system.

7. Operator Comfort Tests

Measurement of noise level (≤67 dBA), illumination (>650 Lux), and vibration at the work surface, confirming that the operating environment meets standards that support sustained accurate work.

How About Chamber and Glove Integrity Testing?

Periodic verification of chamber integrity between formal qualification cycles is an important operational safeguard, particularly for high-throughput or high-risk compounding environments.

Chamber Integrity

The standard HPI-G3 supports manual ISO 10648-2 Class 2 pressure hold testing, which requires external compressed air supply (either facility-provided or via an optional mobile compressor). For environments where daily or more frequent chamber integrity checks are operationally justified, the HPI-G3 can be factory-customized with an integrated PLC/HMI system that automates the pressure hold test with auto-closing valves, streamlining the process and eliminating operator variability.

Glove Integrity

Glove integrity testing should be performed routinely, ideally at the start of each compounding session and whenever a glove is suspected to have been compromised. The HPI-G3 is compatible with a manual glove leak tester available as an optional accessory, which features a built-in digital pressure differential gauge for real-time quantitative measurement, quick-connect fitting, and a straightforward single-glove test procedure. The glove leak tester must be selected to match the isolator's glove port diameter, the standard HPI-G3 is equipped with 200 mm circular glove ports.

SAFE-CHANGE GLOVE REPLACEMENT

The HPI-G3 incorporates a safe-change cuff ring system that allows gloves to be replaced mid-process without interrupting operations and without exposing the operator or the environment to the chamber atmosphere. This is a critical safety feature for high-volume cytotoxic compounding, where glove replacement may be required multiple times per shift.

The procedure is documented and should be included in personnel training program.

Scan the QR code to watch and learn more about the **Glove & Sleeve Replacement Procedure**

How Complex Is Installation and Validation?

Implementing a pharmaceutical isolator involves considerably more than receiving and plugging in a piece of equipment. The process from delivery to fully validated compounding capability typically involves five distinct phases, each requiring coordination between the pharmacy, facilities management, and specialist validation personnel.

1. Site Preparation

Before the isolator arrives, the compounding room must be ready: electrical supply installed to specification, HVAC system balanced and operating, ductwork complete and connected to the external exhaust system, and sufficient clear space to maneuver and position the unit. Site readiness is consistently cited as the primary cause of installation delays.

2. Installation and Commissioning

Physical installation of the isolator, connection to utilities (electrical, compressed air if applicable, exhaust ductwork), and initial commissioning, confirming that the unit powers up, achieves design pressure differentials, and that all alarms, controls, and BMS interfaces operate as specified.

3. Installation Qualification (IQ)

Documented verification that the isolator has been installed correctly, that the installation conforms to the manufacturer's specifications and the user requirement specification, and that all utilities, accessories, and connected systems are as intended.

4. Operational Qualification (OQ)

Documented evidence that the installed isolator operates within its defined operational parameters, including all performance tests. The OQ establishes the baseline performance data against which future periodic qualifications will be compared.

The timeline from delivery to fully qualified operation varies with site complexity. More complex projects, multi-unit installations, significant facility modifications, or facilities new to formal pharma compounding practice, may require considerably longer.

Conclusion: Think System, Not Just Equipment

Selecting a hazardous drug compounding isolator should never be approached as a simple equipment purchase. It is, in reality, the foundation of a complete containment strategy that must seamlessly integrate with your facility design, operational workflow, and regulatory framework. The most successful implementations come from asking the right questions early in the process, well before procurement, so that critical factors such as airflow design, pressure strategy, exhaust requirements, and space planning are properly aligned. Equally important is understanding that every decision involves trade-offs, whether between ducted and recirculating configurations, flexibility and cost, or containment performance and energy efficiency.

By taking a holistic, system-level view, organizations can ensure that the isolator not only meets current compliance expectations but also supports safe, efficient, and sustainable operations over time. Ultimately, a well-planned isolator system does more than contain hazards, it enhances operator confidence, maintains product integrity, and provides long-term value as regulatory standards and operational demands continue to evolve.

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Disclaimer

This white paper is intended for informational purposes only and provides a general overview of key considerations when selecting isolators for hazardous drug compounding applications. Regulatory requirements, operational risks, and facility conditions may vary by region and application; therefore, users should consult qualified engineering, regulatory, and quality professionals when developing or implementing containment strategies.

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