

Compounding Reference Chart – Physical Requirements

GLOSSARY OF ACRONYMS

ABHR – Alcohol Based Hand Rub

ACPH – Air Changes Per Hour

BSC – Biological Safety Cabinet

C-PEC – Containment Primary Engineering Control

CACI – Compounding Aseptic Containment Isolator

PEC – Primary Engineering Control

CAI – Compounding Aseptic Isolator

CAI – Compounding Aseptic Isolator

CVE – Containment Ventilated Enclosure

ISO Class – International Organization for Standardization Classes of air cleanliness for airborne particulates in clean rooms and clean areas

LAFW – Laminar Airflow Workbench

PPE – Personal Protective Equipment

*Refer to Non-Hazardous Sterile Preparations document; Table 1, section 5.3.1, page 16 for particle allowances per ISO Class

	Rooms Needed	Room Requirements	Garb Required	Necessary Equipment
<p><u>LEVEL A</u> <u>Non-Sterile</u></p> <p>Simple and moderate compounds based on risk assessment of drugs being used</p>	Separate Area	<ul style="list-style-type: none"> - designed and arranged to prevent cross contamination - away from high traffic areas in the pharmacy - large enough to work comfortably and to store equipment - sink with hot and cold running water and sewage disposal to complete proper hand hygiene - work surfaces and furniture constructed of smooth, impermeable, non-porous materials that are resistant to damage from cleaning and disinfecting products (i.e. stainless steel) 	<ul style="list-style-type: none"> - disposable gown - gloves - surgical mask - hair net - short nails (no nail polish or artificial nails) - no jewelry on hands and wrists 	
<p><u>LEVEL B</u> <u>Non-Sterile</u></p> <p>Allergenic products or products that could have unintended effects (i.e. hormones)</p>	Dedicated non-sterile, non-hazardous compounding room	<ul style="list-style-type: none"> - separate from the rest of the pharmacy - provides a larger workspace to store all materials and equipment - sink with hot and cold running water and sewage disposal to complete proper hand hygiene - uninterrupted workflow and greater protection from cross contamination - entirely closed off (doors and windows well sealed) - either ventilated appropriately or have a ventilated containment device 	<ul style="list-style-type: none"> - disposable gown - gloves - surgical mask - hair net - short nails (no nail polish or artificial nails) - no jewelry on hands and wrists 	ventilated containment device if compounding room is not adequately ventilated (i.e. an HVAC system installed within the room)

Non-Hazardous Sterile	Rooms Needed	Room Requirements	Garb Required	Necessary Equipment
<p>(Level A & B Sterile)</p> <p>All sterile compounds not involving antineoplastic drugs</p>	<p>Anteroom and Clean Room</p>	<p>Both:</p> <ul style="list-style-type: none"> - ALL surfaces, fixtures and furniture must be constructed of smooth, impermeable, non-porous materials that are resistant to damage from cleaning and disinfecting products (i.e. stainless steel) - for low and medium risk compounding (sec 5.3.2.5 – Non-Hazardous Sterile Preparations) no wall separation is needed, but there must be displacement air flow with a velocity of 40 feet / minute from clean-area to ante-area <p>Anteroom:</p> <ul style="list-style-type: none"> - ISO Class 8 air quality must be maintained, unless it is a shared non-hazardous and hazardous drug anteroom, in which case ISO Class 7 must be maintained - separated into “dirty” area and “clean” area by a visible demarcation line - must have at least 20 ACPH - kept under positive pressure relative to non-controlled area (pharmacy) adjacent to anteroom - storage space for PPE - hands-free sink with hot and cold running water and sewage disposal (large enough to wash hands and fore-arms without touching sides) - soap dispenser - nail picks - ABHR - hand drying system - mirror to verify garbing - clock - waste container - eyewash station - pass-through for transferring products into clean room and/or cart reserved for use in “clean” area <p>Clean Room:</p> <ul style="list-style-type: none"> - PEC is installed in the clean room - kept under positive pressure relative to anteroom - ISO Class 7 air quality must be maintained - at least 30 ACPH or more 	<ul style="list-style-type: none"> - disposable gown that has long sleeves, closed front, fitted cuffs - sterile gloves - surgical mask - hair net - beard cover - shoe covers -short nails (no nail polish or artificial nails) -jewelry removed from fingers, wrists, forearms, face, tongue, ears and neck 	<p>PEC installed in clean room is either:</p> <ul style="list-style-type: none"> - LAFW - CAI

LEVEL C	Rooms Needed	Room Requirements	PPE Required	Necessary Equipment
<p>Non-Sterile</p> <p>Compounds involving antineoplastic drugs</p>	<p>Room dedicated to hazardous drug/material compounding</p> <p style="text-align: center;">OR</p> <p>Separate room (non-hazardous compounding room) with assurances that it is meticulously cleaned so there is no risk of cross contamination with hazardous materials before compounding other preparations</p>	<ul style="list-style-type: none"> - be under negative pressure - physically separate from other preparation rooms (if not having a shared hazardous and non-hazardous non-sterile compounding room) - have an appropriate air exchange of at least 12 ACPH - be externally vented through HEPA filtration - have a C-PEC - sink with hot and cold running water to complete proper hand hygiene as well as an eye wash station (water sources and drains must be at least 1 meter away from C-PEC) <p>*If sharing a compounding room with non-hazardous non-sterile compounding Level C requirements must be in place for the shared room</p>	<ul style="list-style-type: none"> - disposable gown that has long sleeves, closed front, fitted cuffs, resists permeability by hazardous products - double glove (chemo gloves) - mask (surgical masks do not provide respiratory protection. N95 or N100 will protect against airborne particles) - hair net - shoe covers - goggles and face shield, or a full-face respirator - short nails (no nail polish or artificial nails) - no jewelry on hands and wrist 	<p>C-PEC installed</p> <ul style="list-style-type: none"> - Either a Class I BSC or a CVE - A Class II BSC or CACI may be used <p>- For occasional non-sterile hazardous compounding, a C-PEC used for sterile hazardous compounding can be used but MUST be decontaminated, disinfected and cleaned before and after the non-sterile hazardous preparation</p>

LEVEL C	Rooms Needed	Room Requirements	PPE Required	Necessary Equipment
<p><u>Sterile</u></p> <p>Compounds involving antineoplastic drugs</p>	<p>Anteroom and Clean Room</p> <ul style="list-style-type: none"> - designated for hazardous compounding only <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> - if space limitations, an anteroom may be shared for hazardous and non-hazardous compounding 	<p>Both:</p> <ul style="list-style-type: none"> - maintain ISO Class 7 air quality - air into rooms must go through HEPA filtration - must have at least 30 ACPH - one or more observation windows installed for visual verification steps in compounding - ALL surfaces, fixtures and furniture must be constructed of smooth, impermeable, non-porous materials that are resistant to damage from cleaning and disinfecting products (i.e. stainless steel) <p>Anteroom:</p> <p>*If Anteroom is shared between hazardous and non-hazardous sterile compounding Level C requirements must be in place for the shared room*</p> <ul style="list-style-type: none"> - positive air pressure relative to main pharmacy area - separated into “dirty” area and “clean” area by a visible demarcation line - storage space for PPE - hands-free sink (large enough to wash hands and fore-arms without touching sides) - soap dispenser - nail picks - ABHR - hand drying system - mirror or other means to verify garbing - clock - cytotoxic waste container - eyewash station - pass-through for transferring products into clean room and/or cart reserved for use in “clean” area <p>Cleanroom:</p> <ul style="list-style-type: none"> - C-PEC is installed in the clean room - negative air pressure relative to anteroom - return air must be externally vented - return air exhausts at bottom of walls, forcing particles to flow downward - large enough to facilitate compounding, allow for proper cleaning and disinfecting and proper workflow 	<ul style="list-style-type: none"> - non-shedding scrubs - disposable gown that has long sleeves, closed front, fitted cuffs, resists permeability by hazardous products - double glove (chemo gloves) - mask (surgical masks do not provide respiratory protection. N95 or N100 will protect against airborne particles) - hair net - shoe covers - goggles and face shield, or a full-face respirator - beard cover - short nails (no nail polish or artificial nails) - jewelry removed from fingers, wrists, forearms, face, tongue, ears and neck 	<p>C-PEC installed in clean room:</p> <ul style="list-style-type: none"> - Must be externally ventilated - Comply with ISO Class 5 - Either Class II or III BSC or CACI

Hazardous drugs require a specified storage room that:

- All air is exhausted outside
- Negative air pressure relative to adjacent rooms
- At least 12 ACPH (air changes per hour)
- Proper signage (“Hazardous Products Present”)
- Shelves with lips to prevent products from falling and breaking

Hazardous sterile preparations requiring refrigeration can be stored in a fridge kept in the hazardous clean room for this purpose only.

Level A and B Risk Assessment:

Factors to consider:

- Concentration of ingredients in product
- Physical characteristics of ingredients (liquid VS solid VS powders, water soluble VS lipid soluble)
- Quality of ingredients being handled
- Frequency of making the compound
- Exposure to compounding personnel
- Risk of microbial contamination
- Availability of appropriate facilities and equipment
- NIOSH/WHMIS classification of product
 - NIOSH List of Hazardous Drugs - <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>
 - WHMIS - <http://whmis.org/>

Most simple or moderate non-sterile compounds can be made following Level A requirements. It would be possible to prepare a non-sterile simple preparation, which contains a drug categorized by NIOSH as hazardous (i.e. Clonazepam, Carbamazepine) and follow Level A if the hazardous drug is in a small quantity and has the physical characteristics conducive to minimizing contamination of the immediate area and risk to the compounding personnel.