

GAP IDENTIFICATION TOOL

Adapted from NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations

2017

**GAP Identification Tool Instructions**

Please refer to and read the Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations prior to completing this gap identification tool. The questions asked within the document are based on “shall or must” statements in the Model Standards.

This gap tool is designed to give you an understanding of how compliant your sterile compounding practices are and doesn’t include all the of musts or shalls that are in NAPRA but includes many of the elements and will aid you in setting up a plan to become compliant.

Model Standards can be found at [www.NAPRA.ca](http://www.NAPRA.ca)

Each question has a drop-down list; you must choose one of the available selections.

Please answer all questions in the identification tool.

Note: You may need to consult with your engineering and maintenance department to be able to answer some of the questions related to air changes per hour.

| **ID** | **Gap Identification Question(s)** | **Choose One Response that Accurately Represents Your Facility** |
| --- | --- | --- |
| 1 | Do **all** compounding personnel pass an initial gloved finger-tip sample before working in the compounding area? |  |
| 2 | Do **all** compounding personnel pass a initial media fill test before working in the compounding area for non-hazardous sterile products? |  |
| 3 | Compounding personnel who fail the written or practical assessment **immediately stop** sterile compounding activities and redo training? |  |
| 4 | **All personnel** (pharmacists, pharmacy technicians and pharmacy assistants) assigned to the compounding of sterile preparations are assessed at least once a year for low or medium risk level; and at least twice a year for high risk level preparations? |  |
| 5 | A competency assessment program for cleaning and disinfecting personnel **is implemented** in the workplace? (see appendix 3 for a list of elements) |  |
| 6 | The air supplied to areas used for compounding non-hazardous sterile preparations pass-through a terminally fitted **high-efficiency particulate air (HEPA) filter** to ensure a very high level of cleanliness? |  |
| 7 | Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program **for facilities**? (see Appendices 5 and 6) |  |
| 8 | Particle counts are performed by trained, qualified personnel at least **every 6 months** as part of an internal quality control program for the **primary engineering control (PEC)**? (see Appendices 5 and 6 in NAPRA) |  |
| 9 | Water sources, sinks and drains are **not** located in the clean room? |  |
| 10 | Work surfaces and furniture used in the anteroom and cleanroom **ARE** constructed of smooth, impervious, non-friable and non-porous materials? |  |
| 11 | If a pass-through is not equipped with an interlocking system that prevents both doors from being open at the same time, a procedure has been implemented whereby only one door is open at a time? |  |
| 12 | Compounding personnel and anyone else who accesses controlled areas wear appropriate protective clothing, as exactly described in **Table 5 (page 33) of the NAPRA Model Standards**? |  |
| 13 | **PPE is worn** for the compounding of sterile preparations includes the following: Shoe covers, hair cover, beard cover (if applicable), surgical mask, sterile non-powdered gloves, non-shedding gown (enclosed at neck and sleeves that fit snuggly at the wrist)? |  |
| 14 | The pharmacy has procedures in place to prevent personnel with rashes, sunburn, open sores, conjunctivitis and other infections from preparing sterile compounds? |  |
| 15 | Cleaning and disinfecting personnel (housekeeping staff) **fully comply** with hand hygiene and garbing procedures before entering sterile compounding areas and performing housekeeping duties? |  |
| 16 | **Daily cleaning and disinfecting** occurs for the following surfaces and areas and there is documented proof? (e.g. Counters, Carts, Floors) |  |
| 17 | **Monthly cleaning and disinfecting** occurs for the following surfaces and areas and there is documented proof? (Walls, Ceilings, Shelves) |  |
| 18 | **Beyond-use dates** are assigned to final preparations according to stability and the risk level associated with microbial contamination? (Low, Medium and High risk level BUDS) |  |
| 19 | The BUD assigned to the preparations **DOES NOT** **EXCEED** the limits outlined in NAPRA without performing sterility testing that is in accordance to USP 71? |  |
| 20 | Single dose vials that have been punctured in the PEC **ARE** discarded after 6 hours? (This includes pharmacy bulk vials that do not contain preservative) |  |
| 21 | **Before entering** the anteroom, personnel always remove personal outer garments (e.g., coat, hat, jacket scarf, sweater, vest, boots and outdoor shoes)? |  |
| 22 | **Before entering** the anteroom, personnel always remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)? |  |
| 23 | **Before entering** the anteroom, personnel always remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos? |  |
| 24 | **Before entering** the anteroom, personnel always remove nail polish and other nail applications? |  |
| 25 | Where packaging allows, compounding equipment and products are **disinfected with sterile 70% isopropyl alcohol** just before being introduced into the clean room? |  |
| 26 | A biomedical refrigerator or freezer **is used for storing products, ingredients and final compounded sterile preparations** that need to be refrigerated or frozen (see section 5.3.3.2). |  |
| 27 | The pharmacy **has implemented** an environmental sampling plan that measures viable air and surface particles and has a documented plan of where sampling occurs including frequency? |  |
| 28 | For **each** employee, a gloved fingertip sample after the media fill test is completed annually for low- and medium-risk sterile compounding and every 6 months for high-risk sterile compounding and documented proof? |  |
| 29 | The cleanroom **meets** ISO 14644-1 for cleanroom particulate airborne cleanliness at the ISO 7 level and there is documentation to support this? |  |
| 30 | Sterile Isopropyl Alcohol is used to clean the primary engineering control (PEC)? |  |
| 31 | The anteroom has a **line of demarcation** clearly separating the clean and dirty side? |  |
| 32 | Does your pharmacy prepare **high-risk** compounds? |  |
| 33 | If your pharmacy prepares **high-risk** compounds, is the method of sterilization **validated and documented** prior to the release of the product? (example: Filter integrity test) |  |
| 34 | Cardboard **does not** enter the anteroom or cleanroom? |  |
| 35 | Alcohol based hand rub (AHBR) **with persistent activity** is used to perform hand antisepsis? |  |
| 36 | Bins used to introduce supplies or products into the cleanroom are **always** disinfected prior to use? |  |
| 37 | The cleanroom is verified to have a **minimum of 30 air changes per hour** (ACPH)? |  |
| 38 | The anteroom is verified to have a **minimum of 20 air changes per hour** (ACPH)? |  |
| 39 | The PEC is cleaned and disinfected with clean wipes and germicidal disinfectant detergent, followed by sterile 70% isopropyl alcohol, at the **start and end of the day or shift (minimum twice per day)?** |  |
| 40 | Finished compounded sterile preparations are inspected for container closure integrity? (leakage etc.) |  |
| 41 | Transportation of sterile preparations to the patient location prevents damage and maintains appropriate temperatures during transit? |  |
| 42 | A policy is established for the labelling of compounded sterile preparations according to provincial /federal legislation? |  |
| 43 | The pharmacy has policies and procedures for the compounding of non-hazardous sterile preparations?  (list of suggested P&Ps can be found in Appendix 1 of the NAPRA Model Standards for Non-Hazardous Sterile Preparations). |  |