HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Infection Prevention and Control Department		
Document:	Multidisciplinary Policy and Procedure (MPP)		
Title:	IPC Guidelines for Pharmacy Department		
Applies To:	All MCH Department		
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1. PURPOSE:

1.1 To provide clear guidelines for pharmaceutical staff on the correct procedures for preparation, storage and monitoring of sterile products kept in the pharmacy and to prevent the contamination of sterile products prepared within and outside the pharmacy.

2. DEFINITONS:

2.1 The Pharmacy Department is an important area for infection control because its' products are potentially dispensed to all patients. Contamination of medications or other pharmaceuticals whether caused by faulty manufacturing, handling, or storage can have disastrous effects. Therefore, strict adherence to proper infection control procedures by Pharmacy personnel is essential to the prevention of healthcare-associated infections

2.2 A compound sterile preparation (CSP) is a sterile drug that was prepared by compounding or underwent other handling or manipulation prior to administration.

2.3 Compounding is the process of combining drug ingredients to prepare medications that are not commercially available or to alter commercially available medications to meet specific patient needs such as dye-free or liquid formulations

3. POLICY:

3.1 Pharmacist and pharmacy technicians are the professionals responsible for the preparation and storage of compound sterile and non-sterile products. Failure to follow sterile compounding standards and proper aseptic technique could lead to intrinsic and extrinsic contamination, which may result in microbial colonization or infection in the patient.

3.3 Compound sterile preparation (CSP) room/ area is cleaned and disinfected with an approved detergent/disinfectant and by assigned well trained housekeeper in cleaning/disinfection method.

3.4 Pharmacy is responsible for preparing & storing most sterile medications. Understanding the risks inherent in sterile compounding and incorporating established standards are essential for patient safety.

3.5 Compound sterile preparation (CSP) is restricted to competent pharmaceutical HCW except during emergency situations, it could be covered with HCW familiar with aseptic techniques and proper use of appropriate PPE.

3.6 Hand hygiene, use a sterile device (e.g., a needle) each time a vial is accessed and avoid touch contamination of sterile supplies, Disinfect the rubber stoppers of containers and the diaphragms of vials with 70% alcohol wipe prior to use. etc

3.7 Patient morbidity and mortality can result from contaminated pharmaceutical items. Sterile pharmaceutical products can become contaminated via two general methods:

3.7.1 Intrinsic contamination: occurs during the manufacturing process.
Extrinsic contamination: occurs subsequent to manufacturing (during the Admixture process or while the infuscate is used.

4. PROCEDURE:

4.1 Methods for Preventing Contamination of Compounded Sterile Preparations

4.1.1 Aseptic technique during CSPs. Practice aseptic technique to prevent contamination of pharmaceuticals which are associated with epidemics. Remove any hand / wrist jewelry and perform hand scrubbing before each procedure.

4.1.1.1 Scrub nails, hands, and forearms with antimicrobial soap before handling sterile products.

4.1.1.2 Wear a gown closed at the collar with knit cuffs, a facemask, shoe covers, hair covers, and a cover for facial hair upon entering the preparation area.

4.1.1.3 Wear sterile gloves before preparing intravenous (IV) admixtures.

4.1.1.4 Gloves should be removed when exiting the preparation area.

4.1.1.5 Gloved personnel should not touch any surface outside of the hood.

4.1.1.6 Disinfect the rubber stoppers of containers and the diaphragms of vials with 70% alcohol wipe prior to use.

4.1.1.7 Use a sterile device (e.g., a needle) each time a vial is accessed and avoid touch contamination of sterile supplies.

4.1.1.8 Develop protocols to validate the aseptic technique for each person preparing sterile products and repeated at periodic intervals.

4.1.1.9 Do not eat, drink or smoke in the preparation area.

4.1.2 Use of SDVs and MDVs

4.1.2.1 Manufacturers' expiration dates apply to stability and sterility of unopened vials.

4.1.2.2 Dedicate all single-dose and single-use injectable medications and solutions for use on a single patient and entered one time.

4.1.2.3 Use SDVs whenever possible for compounding of parenteral preparations.

4.1.2.4 The use of Pharmacy Bulk Packages (PBPs) which are vials containing many single doses are intended for use in an ISO 5 environment for IV additive services. They are not intended for direct patient use or for use outside of the appropriate aseptic environment (i.e., IV hood).

4.1.2.5 Discard after 6 hours SDVs or PBPs (containers of many injectable single-doses) used in ISO class 5 air cleanliness conditions, unless otherwise specified by the manufacturer.

4.1.2.6 Dedicate the use of MDVs to a single patient whenever possible. If MDVs must be used for more than one patient, they should be kept or accessed in the immediate patient treatment area (e.g., patient rooms, operating rooms)

4.1.2.7 Document the date, time and initial in all MDVs once opened or reconstituted.

4.1.2.8 Refrigerate any opened MDVs as recommended by the manufacturer.

4.1.2.9 Clean the rubber diaphragm of the MDVs with 70% isopropyl alcohol before inserting a device into the vial.

4.1.2.10 Access the MDVs with a sterile device each time.

4.1.2.11 Avoid touch contamination of the MDVs.

4.1.2.12 Discard MDV when empty, when suspected or visible contamination occurs, or when the manufacturer's expiration date (listed on the vial, e.g., 28 days) is reached.

4.1.2.13 Follow manufacturer's expiration date for MDVs without preservatives listed on the vial (e.g., 24 hours at room temperature or 72 hours in the refrigerator from first vial entry).

4.1.3 Engineering Controls CSP: It is recommended that in preparing compound sterile procedures use a primary engineering control device (e.g., laminar air flow hood (LAFH) or biological safety cabinet (BSC) capable of maintaining International Organization for Standardization (ISO) class 5.

4.1.3.1 **Laminar air flow hood (LAFH) or biological safety cabinet (BSC):**

4.1.3.1.1 Operate the LAFH continuously. Before processing sterile products, the hood should be running for a period of time long enough to purge room air from the work area (at least 30 minutes or as per the manufacturer's recommendations).

4.1.3.1.2 Do not disrupt the air flow between the HEPA filter and any sterile objects to avoid contamination.

4.1.3.1.3 Complete all work at least 6 inches from the edge in the interior of the LAFH.

4.1.3.1.4 Disinfect the work surfaces and all accessible interior surfaces of the hood with a hospital-approved disinfectant before beginning work.

4.1.3.1.5 Clean the exterior surfaces of the hood daily with a hospital-approved disinfectant.

4.1.3.1.6 Inspect the containers of the ingredients used to prepare the sterile product for defects, product integrity, and the expiration date.

4.1.3.1.7 Do not use defective or expired products.

4.1.3.1.8 Defective products should be reported to the Ministry of Health using the Drug Quality Report.

4.1.3.1.9 Disinfect the entire surface of all ampoules, vials and containers with 70% isopropyl alcohol before entry into the LAFH, and allow them to air dry.

4.1.3.1.10 Handle all ampoules, vials, needles and syringes in such a way as to maintain asepsis and avoid unnecessary turbulence within the LAFH.

4.1.3.1.11 Ensure certification of the LAFH annually, or more frequently as needed, and maintain certification records.

4.1.3.2 **Cleaning & disinfection of LAFH**

4.1.3.2.1 Disinfect the work surfaces and all accessible interior surfaces of the hood with a hospital approved disinfectant before beginning work.

4.1.3.2.2 Clean the exterior surfaces of the hood daily with a hospital-approved disinfectant.

4.1.3.2.3 Inspect the containers of the ingredients used to prepare the sterile product for defects, product integrity, and the expiration date.

4.1.3.2.4 Do not use defective or expired products.

4.1.3.2.5 Disinfect the entire surface of all ampoules, vials and containers with 70% isopropyl alcohol before entry into the LAFH, and allow them to air dry.

4.1.3.2..6 Handle all ampoules, vials, needles and syringes in such a way as to maintain asepsis and avoid unnecessary turbulence within the LAFH.

4.1.3.3 **Maintenance of LAFH:-** Ensure certification of the LAFH annually, or more frequently as needed, and maintain certification records.

4.1.3.4 **Sterile Product Preparation Area**

4.1.3.4.1 Separate the functional areas from other areas.

4.1.3.4.2 Should have a controlled airflow under positive pressure that should not be disrupted by air ducts, vents or excess traffic that could produce air currents, introducing contaminants.

4.1.3.4.3 Should be free of particle-shedding materials such as cardboard boxes or powdered gloves. Such materials should not be stored in any area surrounding the hood.

4.1.3.4.4 Should not have carpets, drapes or other particulate-shedding materials in the preparation area.

4.1.3.4.5 Should have minimal personnel traffic confined to those persons directly engaged in IV admixture procedures or their supervision. etc.

4.1.3.5 **Authorized Personnel for CSPs:**Pharmacist and pharmacy technicians are the professionals responsible for the preparation and storage of compound sterile and non-sterile products. - Failure to follow sterile compounding standards and proper aseptic technique could lead to intrinsic and extrinsic contamination.

4.1.3.6 **Quality Control Monitoring**:

4.1.3.6.1 Use single-dose vials whenever possible for admixing parenteral preparations.

4.1.3.6.2 Monitor the temperature of refrigerators used in pharmacy to store medications

continuously and set alarms to indicate excessively high or low temperatures.

4.1.3.6.3 Examine the final sterile product for any leaks, cracks, turbidity or particulate matter.

4.1.3.6.4 Label all mixed parenteral fluids appropriately

4.1.4 Compound sterile preparation (CSP) room/area is a functionally separate facility which is under positive pressure.

4.1.4.1 The location of compound sterile preparation (CSP) room/area if physically separated from other areas of pharmacy.

4.1.4.2 Availability of pressure gauge / fixed monitor for continuous monitoring of positive pressure differentials.

4.1.5 The doors of the compound sterile preparation (CSP) room/area are equipped with an auto-closure mechanism.

4.1.5.1 The doors of the compound sterile preparation (CSP) room are equipped with an auto-closure mechanism.

4.1.5.2 Self-closing doors / doors with auto closure mechanism will ensure pressure control inside the CSP room.

4.1.6 Mixing IV medications is performed in the laminar airflow hood or safety cabinet, with air supplied through High-Efficiency Particulate Air (HEPA) filter.

4.1.6.1 Laminar air flow hood or safety cabinet is designed to generate laminar air flow and supplied air is through HEPA Filter installed in the opening channel of hood / biosafety cabinet.

4.1.6.2 Document stating last time when HEPA Filter was being changed. (PPM for the safety cabinet/hood, quality monitoring, and checking of safety cabinet/hood)

4.1.6.3 Laminar Flow Cabinets create particle-free working environments by projecting air through a filtration system and exhausting it across a work surface in a laminar or uni-directional air stream. They provide an excellent clean air environment

4.1.6.4 Laminar airflow is defined as air moving at the same speed and in the same direction, with no or minimal cross-over of air streams (or "lamina").

4.1.7 Compound sterile preparation (CSP) room/area is cleaned and disinfected with an approved detergent/disinfectant and by assigned well trained housekeeper in cleaning/disinfection methods.

4.1.7.1 Cleaning and disinfection schedule of the compound sterile preparation (CSP) room/area and MSDS of disinfectants used in CSP. Authorized and trained housekeeping must be dedicated for housekeeping surfaces ONLY i.e. floors, walls, ceilings, hand washing sinks, emptying trash receptacles etc

4.1.7.2 The process of cleaning and disinfection is being carried out inside the CSP room (Technique i.e. from inside to outside, from top to down etc.)

4.1.7.3 If the floor and other areas are kept clean and tidy. (Randomly wipe any surface to confirm.)

4.1.7.4 Place where cleaning equipment and detergent / disinfectants are being kept

4.1.7.5 Working surface (under the laminar air flow hood) is regularly disinfected by an approved disinfectant using non-lining wipes. A lint free cloth is a special type of cleaning cloth that does not give up any fluff / fibers when used and less likely to generate electrostatic charges.

4.1.7.6 Disinfection process to be documented in daily log sheets after each work process / work shift on LAFH in order to promote accountability and evidence

4.1.8 Maintenance records for hoods and safety cabinets are available.

4.1.8.1 Quality control records & Periodic Preventive Maintenance (PPM) records of hoods and safety cabinets

4.1.8.2 All maintenance records must be kept in the CSP, documentation only with the maintenance department isn't enough.

4.1.9 All supplies and containers used in CSPs preparations are sterile.

4.1.9.1 Availability of all required supplies and containers in the CSP.

Example of sterile supply: Sterile gloves , gowns, syringes, single use containers like ampules, single dose vials, IV bags, irrigation bottles etc. and multidose vials MDVs

4.1.9.1.1 Ensure sterility of containers

* Pharmaceutical container is a device in which drug is enclosed & is in direct contact with drug e.g., single dose containers, multidose containers. light resistant containers, aerosol containers etc. * Ensuring sterility of all supplies during compounding is of utmost important in order to avoid contamination & subsequent infection risk to patients.

4.1.10 Storage: The Pharmacy is responsible for the appropriate storage of pharmaceuticals throughout the institution. The following applies to parenteral admixtures:

4.1.10.1 Store parenteral admixtures according to the manufacturer's recommendations.

4.1.10.1 Remove expired medication from patient care areas, and ensure its proper disposal.

4.1.10.2 Store admixed parenteral solutions in the refrigerator for up to 1 week, provided that refrigeration begins immediately after preparation and is continuous. The stability of admixed ingredients may dictate a shorter or longer refrigeration period.

4.1.10.3 Check the temperature of refrigerator used to store pharmaceuticals daily (twice, if used to store vaccines). The temperature recorded electronically or on a log that is dated and signed by the person performing the temperature check.

4.1.10.4 Maintain room temperature between 20 to 25ºC.

4.1.10.5 Strictly follow manufacturer's recommendation for storage and handling of medications.

4.1.11 Pharmacy Responsibilities Involving Antimicrobial Control. Concerns about antimicrobial resistance causing increased morbidity, mortality and healthcare costs have led to recommendations for controlling antimicrobial use.

4.1.11.1 Establish a system to control and monitor antimicrobial usage.

4.1.11.2 Participate in the development of programs for formulary and antimicrobial control

4.1.11.3 Collaborate with physicians regarding patient-specific recommendations for optimal antimicrobial use.

4.1.12 Preparation of Compounded Sterile Preparations in Patient Care Areas Outside the Pharmacy

4.1.12.1 Preparing IV medication outside the Pharmacy do not typically use a primary engineering control device (e.g., laminar airflow workbench), thus individuals mixing CSPs must be trained and must follow the following recommendations:

4.1.12.1.1 Follow aseptic technique when preparing CSPs.

4.1.12.1.2 Use immediately any CSPs prepared outside an ISO 5 device.

4.1.12.1.3 Follow the same recommendation mentioned above regarding the use of SDVs and MDVs and for storing medications.

4.1.12.1.4 Administration of IV medications:

4.1.12.1.4.1 Disinfect the IV access port prior to administration of the medication or solution.

4.1.12.1.4.2 Administer medication according to the six rights of medication administration (i.e., name of medication, route, time, patient, dosage, and documentation).

4.1.12.1.4.3 Do not administer any medication prepared by another practitioner.

4.1.12.1.5 Follow safety precautions when handling sharp items:

4.1.12.1.5.1 Dispose needles/sharps at the point of use in a leak-proof, puncture-resistant sharp container with the biohazard label.

4.1.12.1.5.2 Do not recap needles.

4.1.12.1.5.3 Replace sharp container when ¾ full.

4.2 Compounded Sterile Preparations (CSPs) Area in Pharmacy Layout:

4.2.1 IV preparation area:

4.2.1.1 If IV solutions are prepared in the pharmacy, a sterile work area with a laminar-flow workstation designed for product protection shall be provided.

4.2.1.1 The laminar-flow workstation shall include a non-hydroscopic filter rated at 99.97 per cent (HEPA).

4.2.1.2 The laminar-flow workstation shall have a visible pressure gauge for the detection of filter leaks or defects

4.2.1.3 A hand washing station should be provided.

4.2.2 Hazardous drug preparation IV preparation room:

4.2.2.1 A separate room shall be provided for the preparation of hazardous drug IV admixtures under a Class II (Type A1, B1, or B2) or Class III biological safety cabinet (BSC).

4.2.3 Ante-area:

4.2.3.1 Where personnel hand hygiene and garbing procedures, staging of components, order entry, CSPs labelling, and other high-particulate-generating activities are performed.

4.2.3.2 A hand washing station should be provided.

4.2.3 Buffer Area or Clean Room:

4.2.3.1 Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

4.2.3.2 Ante-area and buffer areas may be separated by a line of demarcation or by a physical barrier like a wall, door, and pass-through

4.2.3.3 Buffer area must have at least 30 air changes per hour (ACPH), or as little as 15 ACHP if a laminar air-flow workbench provides as much as 15 ACHP.

4.2.3.4 HEPA-filtered air must be introduced at the ceiling and air return vents should be mounted low on the walls.

4.2.3.5 Class II (Type A1, B1, or B2) or Class III biological safety cabinet (BSC) should be provided.

4.2.3.6 A temperature of 20 degrees Celsius or cooler should be maintained by the heating, ventilation, and air conditioning system (HVAC).

4.2.3.7 Surfaces of ceilings, walls, floors, fixtures, counters, and cabinets in the buffer area must be smooth, impervious, free from cracks and crevices, non-shedding, and resistant to damage by disinfectants.

4.3 Commonly prepared sterile products are susceptible to microbial contamination. – Specific organism has the ability to proliferate in different fluids:

4.3.1 Klebsiella, Serratia, and Enterobacter species can multiply in 5% dextrose.

* Candida albinos can grow slowly whereas Staphylococcus, Proteus, Escherichia coli, and Pseudomonas aeruginosa die slowly in dextrose

* Pseudomonas aeruginosa Acinetobacter, and Serratia will grow in distilled water

* Pseudomonas aeruginosa, Enterobacter, and Serratia can grow in lactated Ringer's solutions.

Microbial growth, with the exception of Candida species, is possible in 0.9% sodium chloride.

4.4 Risk Assessment of General Categories of CSPs Microbial Contamination:

4.4.1 Immediate Use: CSPs prepared outside of an ISO 5 device, which are intended for immediate use.

4.4.2 Low-Risk Level With 12-Hour Beyond-Use Dating (BUD): CSPs prepared in ISO class 5 air cleanliness conditions in an unclassified segregated compounding area with ambient air.

4.4.3 Low-Risk Level: CSPs prepared in ISO class 5 air cleanliness conditions located within ISO class 7 or 8 buffer areas. The compounding procedure involves simple aseptic manipulations using no more than three commercially available ingredients and not more than two entries into any one final container.

4.4.4 Medium Risk Level: CSPs prepared under batch conditions (multiple individual doses) or CSPs for individual patients using more complex aseptic manipulations (e.g., parenteral nutrition solution

and patient-controlled analgesia) prepared in ISO class 5 air cleanliness conditions in an ISO class 7 or 8 area

4.4.5 High-Risk Level: CSPs prepared from nonsterile ingredients or nonsterile devices or prepared in air quality less than ISO class 5 air cleanliness.

4.5 All healthcare personnel assigned in the CSP area should be proficient in the following core competencies:

4.5.1 Personal Hygiene .Before entering a designated compounding area, compounding personnel should:

4.5.1.1 Remove personal outer garments (e.g., coats, jackets, scarves, headscarves, sweaters).

4.5.1.2 Remove all cosmetics because they shed particles.

4.5.1.3 Remove all hand, wrist, and other exposed jewelry (e.g., rings, watches, bracelets)

4.5.1.4 Keep nails clean and neatly trimmed (remove nail polish, and artificial nails).

4.5.1.5 Ensure coverage of head hair and facial hear such as beard.

4.5.1.6 PPE for the cleanroom should be donned and removed in a prescribed manner.

4.5.1.7 PPE should be changed each time by the CSP personnel' when they are leaving the CSP area.

4.5.2 Hand Hygiene & Attire: Proper preparation for sterile, nonhazardous drug compounding must include effective hand hygiene. Wearing attire occurs in the ante area and should be sequenced as follows (from "dirtiest to "cleanest").

4.5.2.1 Don shoe covers, hair and beard covers, and a mask.

4.5.2.2 Perform hand hygiene.

4.5.2.3 Don gown, fastened securely at the neck and wrists.

4.5.2.4 Sanitize hands using an ABHR and allow hands to dry.

4.5.2.5 Don sterile powder-free gloves.

4.5.2.6 Gloves must be inspected by personnel on a routine basis during the compounding process to check for tears or holes.

4.5.3 Waste Disposal: All waste products should be collected in suitable plastic bags and removed on a daily basis at the end of the working session.

4.5.4 Spills Management: All spills and breakages should be cleaned up immediately by healthcare personnel trained in the appropriate management measures and based on the approved health care facility policy and procedure.

4.5.6 Packaging and Labeling: Packaging must be appropriate to preserve both sterility and stability until the BUD.

4.5.7 Temperature & Humidity Monitoring: The facilities should maintain room temperature 20 °C or cooler & from 30-60 humidity level to ensure the effective compounding measures.

4.5.8 Cleaning and Disinfection: Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 N/A

5.2 **Materials and Equipment**

5.2.1 N/A

6. RESPONSIBILITIES:

6.1 It is the responsibility of Pharmacy Department to follow this policy.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 General Directorate of Infection Prevention and Control in Healthcare Facilities (GDIPC). Infection Control Requirements in Design, Construction and Renovation in Healthcare Facilities 1443 – 2021 V.1
8.2 Healthcare Associated Infections (HAIs) Second Edition. MOH Surveillance Manual. Last updated: November 2023
8.3 The GCC Infection Prevention and Control Manual .3rd Edition. 2018
8.4 General Directorate of Infection Prevention and Control in Healthcare Facilities (GDIPC). Infection Prevention and Control Guideline in the Compound Sterile Preparations (CSPs).2023-1445. V.1

9. APPROVALS:

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