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Ministry of Health

الإدارة العامة لمكافحة عدوى المنشآت الصحية

General Directorate of Infection Prevention
and Control in Healthcare Facilities

(GDIPC)

Infection Prevention & Control Guideline in the Compounded Sterile Preparations (CSPs)

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In the name of ALLAH, Most Gracious, Most Merciful

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Purpose of the Guideline

Compounding is the process of combining drug ingredients to prepare medications that are not commercially available (i.e., neonate, pediatric, and geriatric dosage forms or ongoing manufacturer-related drug shortages) or to alter commercially available medications to meet specific patient needs, such as dye-free or liquid formulations. Failure to follow sterile compounding standards and proper aseptic technique has led to intrinsic (i.e., contamination during the manufacturing process) or extrinsic (i.e., contamination during preparation, storage, or administration within the healthcare facility) contamination, which could result in microbial infection in the patient.

Consequently, infection prevention & control (IPC) guideline in compounded sterile preparations has been constructed to ensure that sterile preparations meet the clinical needs of patients, satisfying quality, safety, and environmental control requirements in all phases of preparation, storage, transportation, and administration in compliance with established standards, regulations, and professional best practices.

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Definitions

Compounded Sterile Preparations (CSPs):

A sterile preparation is prepared by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substances that will be administered as injections, infusions, or applications to the eye whether to multiple patients or to one patient on multiple occasions.

Hazardous Drug Intravenous (IV) Preparation Room:

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.

Aseptic Technique (Regarding medication preparation):

A mode of handling, preparing, and storing medications and injection equipment/ supplies (e.g., syringes, needles, and Intravenous tubing) to prevent microbial contamination.

Beyond-Use Dates (BUDs):

Beyond-use dates (BUDs) are the date or time after which a compounded sterile preparation (CSP) must be begin following mixing of the CSP.

Buffer Area or "Cleanroom":

Is an area where a primary engineering control (PEC) is located and where activities such as preparation, compounding, and staging of CSPs occur.

ISO 5 Hood:

ISO 5 hood is a properly certified laminar air flow workbench, biosafety cabinet (BSC), compounding aseptic isolator, or compounding aseptic containment isolator.

Biological Safety Cabinet (BSC):

A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with in- ward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA- filtered exhausted air for environmental protection.

Introduction

The compounding of medications is a fundamental part of pharmacy practices. All compounding personnel, mainly pharmacists and pharmacy technicians, are responsible for compounding and dispensing sterile products and preparations of correct ingredient identity, purity, strength, and sterility and for dispensing them in appropriate containers that are labelled accurately and appropriately for the end-user.

Significant patient morbidity and mortality have resulted from both intrinsically and extrinsically contaminated compounded sterile preparations. Pharmacies play a crucial role in preventing those risks throughout all processes including compounding, repackaging, and labelling sterile medications, such as injectable products.

Compounding personnel should be ensured that sterile preparations meet the infection prevention & control (IPC) practices, clinical needs of patients, satisfying quality, safety, and environmental control requirements in all phases of preparation, storage, transportation, and administration in compliance with established standards, regulations, and professional best practices. Accordingly, standards and guidelines should be developed to ensure that sterile preparations be compounded in an area separate from other pharmacy activities and based on scientific best IPC measures.

There is an important parallel and intersection between pharmacy and infection prevention and control department. Accordingly, this guideline is intended to facilitate compounding personnel to prepare CSPs of high quality and to reduce the potential harm to patients. The recommendations in the current guideline are based on current scientific information and best sterile compounding practices.

Applicability

Infection preventionist, healthcare administrators, compounding personnel, pharmacists, pharmacy technicians, and other healthcare professionals who are responsible for the preparation, selection, and use of CSPs.

Risk Assessment of General Categories of CSPs Microbial Contamination:

Failure to achieve and/or maintain sterility of compounded sterile preparations (CSPs) can lead to serious harm, including death. It is therefore important to evaluate the risks associated with the sterility of the CSPs before starting the activity.

- The risk categories are assigned according to the corresponding probability of contaminating a CSP with microbial contamination (microbial organisms, spores, endotoxins) and chemical and physical contamination (foreign chemicals, physical matter).
- According to The United States Pharmacopeia (USP) <797>, CSPs are classified into five general categories based on the risk of microbial contamination to all compounded sterile preparations. They are:

Immediate Use:

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

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.

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.

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

High-Risk Level:

CSPs prepared from nonsterile ingredients or nonsterile devices or prepared in air quality less than ISO class 5 air cleanliness.

Unless CSPs are prepared under the Immediate-Use exclusions detailed in USP Chapter <797>, all CSPs must be (at the minimum) prepared in an ISO class 5 environment, which can be achieved by the use of a primary engineering control (e.g., laminar airflow workbench [LAFW], biological safety cabinets (BSC), or isolators designed for pharmacy compounding).

Compounded Sterile Preparation Risk Levels

Category of CSP	Device Used	Surrounding Room	Limitation	BUD
Immediate Use	None	Ambient room	Simple mixing of no more than three sterile nonhazardous components	1 hour
Low Risk 12 Hours	ISO 5 hood	Ambient room	Simple mixing of no more than three sterile components	12 hours
Low Risk	ISO 5 hood	ISO 7 clean room	Simple mixing of no more than three sterile components	48 hours at room temperature, 14 days under refrigeration, 45 days frozen
Medium Risk	ISO 5 hood	ISO 7 clean room	Mixing of all sterile components	30 hours at room temperature, 9 days under refrigeration, 45 days frozen
High Risk	ISO 5 Hood	ISO 7 clean room	Includes any non-sterile component or exceeds the BUDs of other categories	24 hours at room temperature, 3 days under refrigeration, 45 days frozen

NB: Some isolators may be certified for use outside a clean room but must meet requirements detailed in USP <797>.

Infection Prevention & Control Requirements Regarding the Design and Finishing of CSPs area:

Infection prevention & control requirements are intended to establish a safe environment for CSPs area. Specific criteria in the same area design, related to structure and finishing are significant in implementing the effective and appropriate aspects of infection control practices in the CSPs area.

Location:

- The CSPs area should be a functionally separate area inside the pharmacy unit.

Layout:

- The pharmacy shall be laid out to preclude unrelated traffic through the intravenous (IV) and hazardous drug IV preparation room

Finishing:

- Wall, floor, and ceiling surfaces should be easily cleanable and highly durable to withstand frequent cleaning and disinfection with an approved disinfectant.

Engineering Control Requirements:

Ante-area:

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

Buffer Area or Clean Area:

- Where the primary engineering control (PEC) is physically located.
- The CSP area should be under positive pressure.
- Maintenance records for hoods and safety cabinets are available.
- 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.
- High-efficiency particle air (HEPA) filtered air must be introduced at the ceiling and air return vents should be mounted low on the walls.
- A temperature of 20 degrees Celsius or cooler should be maintained by the heating, ventilation, and air conditioning (HVAC) system .

Note: A buffer area differs from an ordinary ventilated room by having the following:

a) Increased air supply.

b) HEPA filtration (the filtered air should be introduced at the ceiling, with returns mounted low on the walls; ceiling-mounted returns should not be used) including a terminal air filter (a filter at the end of the heating, ventilation, and air conditioning [HVAC] ducting).

c) Room pressurization .

- 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.
- Walls and ceilings must be made of either hard plastic or epoxy-painted gypsum board. If ceiling tiles are used, they must be coated with a hard polymer and caulked both around the perimeter and around each tile.
- Ceiling lights must be smooth, mounted flush, and sealed.
- Floors should be made of wide, heavy-duty sheet vinyl, rubber, or epoxy that is coved around the corners and rolled up onto the walls. Paint must be epoxy, acrylic, or another non-porous sealant type.

Primary Engineering Controls (PECs):

- A PEC is a device or room that provides an approved safe environment for compounding sterile preparations.
- PECs all rely on a special type of high-efficiency particle air (HEPA) filter that is >%99.99 efficient in removing particles as small as 0.3 microns in size (the most penetrating particle size [MPPS], which refers to the largest-sized particle that may escape the filter, although particles of all sizes may be captured).
- The unidirectional (horizontal or vertical) HEPA-filtered air must provide sufficient velocity to sweep particles away from the direct compounding area and maintain unidirectional flow during the preparation of CSPs.
- PEC devices include laminar airflow workbenches (LAFWs), and biological safety cabinets (BSCs).

Architecture:

- The sterile compounding area includes a well-lit buffer area, ante area, and an area for storage of sterile products and supplies.
- There shall be some demarcation designation that separates the ante-area from the buffer area.
- The doors of the compound sterile preparation (CSP) room/area are equipped with an auto-closure mechanism.
- A buffer area (or “cleanroom”) is an area where a PEC is located and where activities such as preparation, compounding, and staging of CSPs occur.
- This area should provide adequate space for the PEC and may include a limited amount of shelving and/or carts for the staging of compounding (not for storing stock).
- An ante area provides space for hand washing, garbing, and product decontamination; it also serves as a way to further segregate the buffer area from other, less-clean areas of the facility.
- Water sources, such as sinks or floor drains, are not permitted in the buffer area.
- A storage area outside the buffer and ante areas should provide adequate space for the placement of sterile products and supplies.

Compounded Sterile Preparation Personnel:

Compounding personnel are responsible for ensuring that CSPs' effective processes, practices, components, and skills are developed and maintained. These performance responsibilities include maintaining appropriate cleanliness and disinfection conditions following required infection control standards and implementing the strict aseptic technique measures.

Personnel who prepare CSPs should be trained conscientiously and skillfully in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining environmental conditions before they begin to prepare CSPs.

Training Requirements:

- Sufficient and competent personnel to carry out all aseptic activities must be maintained.
- Personnel should be aware of their responsibilities and protocols that are put in place by their healthcare facility, and they should receive adequate orientation and training when they assigned to the sterile compounding area.
- Regular continuing education and audits on skills should be made available to ensure that all staff skills are competent and current.

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

a) Hand hygiene techniques.
b) Personal protective equipment (PPEs) donning and doffing procedures.
c) Cleaning and disinfection of surfaces.
d) Aseptic manipulation.
e) Management of needle/sharps stick injuries.
f) Measuring and mixing.
g) Proper use of compounding devices.
h) Documentation of the compounding process.
i) Packaging and labelling of sterile preparations.
j) Proper cleanroom practices e.g. moving materials in and out.
k) Cleaning and maintenance of devices and equipment.
l) Handling of hazardous substances
m) Spill management and post-exposure management.
n) Safe disposal of hazardous wastes.

Personal Hygiene

Before entering a designated compounding area, compounding personnel should:

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

b) Remove all cosmetics because they shed particles.

c) Remove all hand, wrist, and other exposed jewellery (e.g., rings, watches, bracelets) as these can harbour microorganisms or interfere with hand washing or the proper fitting of PPE.

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

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

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

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

Hand Hygiene & Attire:

- Proper preparation for sterile, nonhazardous drug compounding must include effective hand hygiene.
- To minimize the number of particles introduced into the sterile compounding area and to minimize the risk of bacteria, all outer jackets and sweaters, visible jewellery, and cosmetics must be removed prior to initiating the handwashing processes.
- Personal electronic devices (e.g., cell phones, MP3 players) and any associated attachments must be removed prior to hand hygiene and garbing and should not be used within the sterile compounding area.

Hand hygiene must be performed prior to and after gowning and includes:

a) Washing hands, under the fingernails, wrists, and up to the elbow for 40-60 seconds with MOH approved antimicrobial soap.

b) Drying hands and arms with non-shedding disposable towels.

c) Sanitizing hands with an application of a waterless, alcohol-based hand rub (ABHR) with added component to achieve persistent activity prior to donning sterile gloves.

- **Wearing attire occurs in the ante area and should be sequenced as follows (from "dirtiest" to "cleanest") :**

a) Don shoe covers, hair and beard covers, and a mask.
b) Perform hand hygiene.
c) Don gown, fastened securely at the neck and wrists.
d) Sanitize hands using an ABHR and allow hands to dry.
e) Don sterile powder-free gloves.
f) Gloves must be inspected by personnel on a routine basis during the compounding process to check for tears or holes.

- When exiting the compounding area during a work shift, gowns and gloves should be removed, and proper hand hygiene and PPE must be completed before re-entering the compounding area.

General Aseptic Practices:

Practice aseptic techniques to prevent contamination of pharmaceuticals that are associated with epidemics. The following measures must be followed all the time:

- Remove any hand/wrist jewellery and perform hand scrubbing before each procedure.
- Scrub nails, hands, and forearms with antimicrobial soap before handling sterile products.
- Wear a gown closed at the collar with knit cuffs, a facemask, shoe covers, hair covers, and a cover for facial hair, when applicable, upon entering the preparation area.
- Wear sterile gloves before preparing intravenous (IV) admixtures.
- Gloved personnel should not touch any surface outside of the hood.
- Disinfect the rubber stoppers of containers and the diaphragms of vials with 70 % alcohol wipe prior to use.
- All supplies and containers used in CSPs preparations are sterile.
- Use a sterile device (e.g., a needle) each time a vial is accessed.
- Develop protocols to validate the aseptic technique for each person preparing sterile products and repeated at periodic intervals.

- Do not eat, drink, or smoke in the preparation area.
- Access to the CSP area or in the anteroom should be restricted to qualified personnel with specific responsibilities or assigned tasks.
- All supplies to be brought into the cleanroom should be wiped and surface disinfected with %70 sterile isopropyl alcohol or with approved antiseptic wipes.
- Objects that shed particles should not be brought into the cleanroom, e.g. pencils, cardboard cartons, or cotton items.
- There should be proper disinfection of work surfaces with 70 % sterile isopropyl alcohol or with approved antiseptic wipes before and after work.
- Regular disinfection of work surface during preparation should also be done.
- Personnel should avoid touching critical surfaces e.g. rubber closures of containers, syringes or needle tips that come in contact with the CSP and should be maintained sterile.
- Upon turning on the PEC, it should be left running for a minimum of 15 minutes and disinfected before use.
- The air supply in the PEC should be turned on at all times during preparation.
- An unobstructed airflow should be maintained between the cabinet HEPA filter and the area where aseptic manipulations are performed.

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.
- Disposal of waste products should be in accordance with the national healthcare facility protocols and regulations.
- All sharps and needles should be disposed of in a puncture and tamper resistant container.

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.

Packaging and Labeling

- Packaging and subsequent labelling are critical to patient safety. Packaging must be appropriate to preserve both sterility and stability until the BUD.
- Proper labelling requires an understanding of compounding risk levels and how to determine BUDs based on both stability and sterility.
- Labels for single compounded preparations must, at a minimum, include the following:
  - **a)** Names of active ingredients.
  - **b)** Amounts or concentrations of active ingredients.
  - **c)** BUD and time.
  - **d)** Storage requirements.

Quality Control Monitoring

Achieving and maintaining sterility and overall freedom from contamination of a CSP is dependent on the quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed .

- Use single-dose vials whenever possible for admixing parenteral preparations.
- Monitor the temperature of refrigerators used in pharmacy to store medications continuously and set alarms to indicate excessively high or low temperatures.

- Examine the final sterile product for any leaks, cracks, turbidity, or particulate matter.
- Label all mixed parental fluids with the following information:
  a. Patient name (for patient-specific products).
  b. Medical record number, patient location.
  c. Solution and ingredient names and concentrations.
  d. The administration regimen names and concentrations.
  e. The expiration date and time.
  f. Storage requirements.
  g. Identification of the responsible pharmacist by badge number.
  h. Appropriate additional labelling, such as any precautionary measures that need to be taken.
  i. Device-specific instructions.
  j. Any additional information in accordance with national regulations or requirements .

Pressure Differential or Air Displacement:

- Since positive-pressure rooms are required for sterile compounding, the appropriate differential pressure should be maintained.
- A pressure gauge or velocity meter shall be installed and monitored to assess the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area.
- The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.
- A pressure gauge or velocity meter must be in place to monitor airflow between relevant areas.
- Pressure in positive-pressure areas should be at least 5 Pa by using continuous pressure monitoring with an audio-visual alarming system in case of any failure.

Temperature & Humidity Monitoring:

- Any controlled temperature area used for compounding sterile preparations or for storage of sterile products or CSPs must be monitored at least once daily, and results documented in a log.
- The facilities should maintain room temperature 20 °C or cooler & from 30-60 % humidity level to ensure the effective compounding measures.
- If facilities use continuous temperature & humidity recording devices, they must be monitored and documented once daily to ensure that they are functioning properly.
- Correction actions should be performed if the monitored values not within the approved expected measures.

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.

Note

For comprehensive information about the cleaning and disinfection of the CSP area, the Best Practices of Environmental Health for Prevention & Control of Infections in Healthcare Facilities Guidelines, Version 1.1.2022 can be followed.

- Cleaning with a germicidal detergent and water will remove visible solids or soiling before disinfecting.
- Disinfection removes microbial contamination.
- Compound sterile preparation (CSP) room/area is cleaned and disinfected with an approved detergent/disinfectant and the assigned healthcare worker (HCW) should be well trained on the cleaning/disinfection process.

- Policies and procedures should be developed to ensure consistent practices, including dilution of cleaning products, method of cleaning, responsible HCW, and frequency of cleaning available and followed.
- Working surfaces (under the laminar airflow hood) is regularly disinfected with an approved disinfectant using non-lining wipes.
- It is critical that an appropriate MOH approved disinfectant should be used to clean and disinfect all surfaces of the buffer and ante areas in addition to all the PECs.
- Significant care must be exercised to avoid getting the HEPA filters wet during cleaning.
- Cleaning with a germicidal detergent will leave a residue that needs to be removed from work surfaces (e.g., counter and PEC surfaces). This residue is best removed by using 70 % isopropyl alcohol (IPA).
- The minimum frequency for cleaning surfaces used to compounded sterile preparations area:
    a. PEC should be cleaned at beginning of each shift, before each batch, every 30 minutes when compounding, after spills and when surface contamination is known or suspected.
    b. Counters and easily cleanable work surfaces and floors should be cleaned daily at least.
    c. Walls, ceilings, and storage shelving should be cleaned on a scheduled basis (e.g; weekly or monthly basis).

Note

All previous frequencies for cleaning surfaces used to compounded sterile preparations area are the minimum and should be further in case of emergency accidental contamination of any surfaces or when required.

Environmental Sampling and Testing

- Environmental monitoring is approached differently by the CDC, FDA, and USP.
- Routine environmental microbiological cultures (for air, water, or environmental surfaces) are not recommended routinely. However, and based on the CDC and FDA position, the current USP Chapter <797> on pharmaceutical compounding, environmental sampling is recommended as part of a comprehensive quality management program and required under any of the following conditions:

- When microbial growth is detected, appropriate action must be taken.
- As part of the commissioning and certification of new facilities and equipment.
- Any servicing of facilities and equipment.
- As part of the semiannual recertification of facilities and equipment.
- In response to identified problems with end products or HCW technique.
- In response to issues with CSPs, observed compounding personnel work practices, or patient-related infections where the CSP is being considered as a potential source of the infection.

Pharmacist Participation in Infection Prevention and Control Committee

Pharmacy services should be active participants in the organization's infection prevention and control committee. The committee should review the quality plan elements of pharmacy service's sterile compounding activities, including personnel training and competence, facility issues, and environmental monitoring.

Infection Preventionist Partnership with the Pharmacy

The infection prevention & control department can provide subject matter expertise to the pharmacy staff when it comes to appropriate cleaning and disinfection practices, hand hygiene, adult education on aseptic technique and other infection control-related topics, proper donning, and removal of personal protective equipment, and should implement regularly scheduled rounds.

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