

medication without knowing and documenting drug allergy in the patient drug profile. The pharmacy is authorized to stop dispensing any medication the patient is allergic to until clarification is made with the prescriber. A qualified and licensed pharmacist reviews each prescription or order new to the patient for appropriateness except in emergency situations. This occurs prior to dispensing by a pharmacist or a technician. When questions arise, the individual who prescribed or ordered the medication is contacted for verification. Any changes in medication order shall be documented in patient's medical record. To prevent dispensing errors, dispensed medicine must be double checked by another pharmacist before leaving the pharmacy. As authorized by the pharmacy and therapeutics committee, the pharmacist is allowed to dispense generic substitution without consulting the prescriber unless the prescriber specifies "dispense as written".

MM.26 The hospital has a system for safe preparation of sterile compounded preparations.

- MM.26.1 The hospital has a manual for proper aseptic technique and intravenous admixture (e.g., the guidelines of the Saudi Food and Drug Authority, the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).
- MM.26.2 Sterile compounded preparations are performed by the pharmaceutical care except during emergency or urgency situations in which a delay could harm the patient or when product stability is short.
- MM.26.3 Sterile compounded preparations are performed in the clean room by pharmaceutical care staff, qualified in intravenous admixture and aseptic technique.
- MM.26.4 The hospital provides and documents training and competency assessment of non-pharmaceutical care staff involved in compounding sterile preparations outside the pharmaceutical care department during emergency or urgency situations.
- MM.26.5 There is full compliance with aseptic technique in all medication preparation areas all over the hospital.
- MM.26.6 Visual inspection is performed for all compounded sterile products by a trained individual for particulate, discoloration, or evidence of loss of integrity.
- MM.26.7 The pharmaceutical care has a clean room that is a functionally separate facility to maintain product sterility.
- MM.26.8 The design of the clean room is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).
- MM.26.9 The pharmaceutical care uses ISO Class 5 laminar airflow hood for preparing sterile injectable preparations and all other sterile preparations.



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- MM.26.10 The laminar airflow hood is tested at least every six months and in accordance with the manufacturer's requirements, the Saudi Food and Drug Authority guidelines and the professional organizations' standards (e.g., American Society of Health-System Pharmacists, United States Pharmacopoeia USP).
- MM.26.11 The hospital implements the written and approved guidelines on intravenous drug stability and compatibility.
- MM.26.12 Any sterile preparation compounded outside the clean room (e.g., in the patient care area during emergency or urgency situation) is done in an appropriate environment (location, space, cleanliness, traffic, etc.) to prevent contamination.
- MM.26.13 The pharmaceutical care regularly (at least once a month) inspects all areas where sterile preparations are compounded outside the pharmaceutical care clean room.
- MM.26.14 The pharmaceutical care monitors the performance and qualifications of non-pharmacists permitted to prepare sterile compounded medications outside the pharmaceutical care department.
- MM.26.15 There are written guidelines for safe recycling of returned (un-used) sterile preparations.
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Standard Intent:

Parenteral medications account for >40% of all medications administered in institutional practice. The intravenous route is the most dangerous route of administration since all natural barriers are bypassed when the drug is given directly into the vein, so the administration of a contaminated solution can have very serious consequences. Contamination occurs when proper control over manipulation is not maintained. Contaminations may be introduced from the environment, equipment, supplies, and personnel, it is essential to control all these different sources at the time aseptic technique is carried out. Giving a patient a contaminated product can cause serious adverse effects including death.

The compounding of medications is a fundamental part of pharmacy practice. Qualified pharmacists and pharmacy technicians are responsible for compounding and dispensing sterile preparations of correct ingredient identity, purity, strength, stability and compatibility, and sterility and for dispensing them in appropriate containers that are labeled accurately and appropriately for the end user. The safety of intravenous admixture product depends on the skills of the operator, compliance with aseptic techniques, and IV room cleanliness. The pharmacy should have updated and reliable information resources for drug stability and compatibilities and establish guidelines for recycling of returned (un-used) sterile drugs.