



MM.29 The hospital has a system for safe preparation of non-sterile compounded preparations (extemporaneous compounds).

- MM.29.1 There is a multidisciplinary policy and procedure on non-sterile compounding of oral and topical preparations not readily available from manufacturers.
 - MM.29.2 The pharmaceutical care has proper facilities for non-sterile compounding that include clean work bench with smooth surface, stainless steel sink with water supply, and storage cabinets.
 - MM.29.3 The pharmaceutical care has essential equipment and glass wares that include sensitive balance, electric heater, mortar and pestle, beakers, flasks, and measuring cylinders.
 - MM.29.4 The pharmaceutical care has a preparation manual (formulation book) that is properly referenced.
 - MM.29.5 A log book is maintained for preparation name, strength, prepared quantity, batch number, preparation date and expiration date, prepared by and checked by.
 - MM.29.6 When non-sterile compounded preparations are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.
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Standard Intent:

Not all pharmaceuticals are readily available from the manufacturer. It is the responsibility of pharmacy to provide a safe pharmaceutical product. Pharmacists are the only health care providers formally trained in the art and science of compounding medications. Therefore, pharmacists are expected, by the medical community and the public, to possess the knowledge and skills necessary to compound extemporaneous preparations. Pharmacists have a responsibility to provide compounding services for patients with unique drug product needs (such as unusual strength or concentration for the very young, the very old, unconscious or those who can't swallow tablet or capsule). A well-equipped pharmaceutical laboratory must include necessary equipment, glass wares, chemicals, sink, work bench, etc. Formulation manual, work sheet, and log book are maintained for all compounded preparations. An internal batch number should be created and printed on the final product label.

When the hospital is outsourcing extemporaneous preparations from an outside vendor, the pharmacy team should have copy of the valid contract. In order to ensure compliance of the vendor with CBAHI quality and safety standards, contract monitoring should be conducted at least annually with corrective actions accordingly. CBAHI contract monitoring form for extemporaneous preparations must be used.