



ADMINISTRATIVE RULES OF MONTANA



24.174.841 STERILE PRODUCTS

- (1) Policies and procedures must be prepared for the compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceutical products. The policies must include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies and procedures must be current and available for inspection by a designee of the Board of Pharmacy.
- (2) An institutional pharmacy compounding sterile products must have an isolated area designed to avoid unnecessary traffic and airflow disturbances.
- (3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity, or have policies and procedures in place limiting the pharmacy's scope of sterile product preparation.
- (4) An institution preparing cytotoxic drugs must have a vertical flow Class II biological safety cabinet. Cytotoxic drugs must be prepared in a vertical flow Class II biological safety cabinet.
 - (a) Protective apparel including nonvinyl gloves, gowns, and masks must be available, and gloves must be worn at all times.
 - (b) Appropriate containment techniques must be used in addition to aseptic techniques required for sterile product preparation.
 - (c) Prepared doses of cytotoxic drugs must be clearly identified, labeled with proper precautions, and dispensed in a manner to minimize risk of cytotoxic spills.
 - (d) Disposal of cytotoxic waste must comply with all applicable local, state, and federal laws.
 - (e) Written procedures for handling cytotoxic spills must be included in the policies and procedures manual.
- (5) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.
- (6) All aseptic environmental control devices must be certified by an independent contractor for operational efficiency at least every 12 months or when relocated, according to Federal Standard 209E. Prefilters must be inspected periodically and replaced if needed.
- (7) Inspection and replacement dates must be documented and maintained for a period of at least two years.

- (8) Documented records of ongoing quality assurance programs, justification of expiration dates chosen, and employee training records and technique audits must be available for inspection by the Board of Pharmacy.
- (9) The board expects pharmacies/pharmacists engaged in compounding to have policies and procedures to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of United States Pharmacopeia (USP) Chapter 795 "Compounding Nonsterile Preparations" and USP Chapter 797 "Pharmaceutical Compounding-Sterile Preparations."
- (10) Immediate use compounds defined in ARM 24.174.301(21) are prepared in an air quality environment that does not meet International Organization of Standardization (ISO) Class 5 or better conditions. A preparer of immediate use compounds is not required to wear gloves or gown if the compounds are prepared using aseptic manipulation, only sterile ingredients, products, components, and devices, and the following conditions are met:
 - (a) no more than three sterile ingredients, products, components, and devices are used;
 - (b) only simple manipulation techniques are employed;
 - (c) the preparer completes the preparation without interruption and with no direct contact contamination;
 - (d) the administration must begin within one hour of preparation;
 - (e) if prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour "beyond use date"; and
 - (f) preparations do not involve the use of hazardous materials.
- (11) Multi-dose vial defined in ARM 24.174.301(29) may be used until the expiration date noted on the vial. The beyond use date (BUD) may be up to one month or the manufacturer's assigned BUD, whichever is shorter from the time of initial entry, in accordance with the pharmacy policies and procedures.
- (12) A same-day use product, defined in ARM 24.174.301(41), that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile ingredients, products, components, and devices, may be classified as low- or medium-risk provided that it meets all of the following conditions:
 - (a) only simple manipulation techniques employed;
 - (b) the environment meets or exceeds the following conditions:
 - (i) the mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;
 - (ii) there is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet; and
 - (iii) the buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process.
 - (c) the environment is cleaned daily;

- (d) batch preparation will not exceed eight CSPs;
 - (e) administration of the preparation must begin within 24 hours of preparation; and
 - (f) the preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown, and a mask.
- (13) The beyond use date (BUD), as defined in ARM 24.174.301(2), for a single-dose vial:
- (a) shall be no greater than one hour from the time of initial entry if accessed in an environment of less than ISO 5; or
 - (b) may be up to 24 hours from the time of initial entry if appropriately stored and accessed only in an environment equal to or better than ISO 5.
- (14) Low-risk and medium-risk level compounded sterile preparation (CSP) is determined by the potential for microbial contamination during preparation, and high-risk level CSP by the potential for not being properly sterilized before administration to patients.
- (a) Low-risk conditions:
- (i) CSPs prepared using aseptic manipulation with an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components, and devices;
 - (ii) no more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;
 - (iii) manipulations limited to:
 - (A) aseptically opening ampoules;
 - (B) penetrating sterile stoppers on vials with sterile needles and syringes; and
 - (C) transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing.
 - (iv) in the absence of sterility testing, preparations must be properly stored prior to administration as follows:
 - (A) BUD less than or equal to 48 hours at controlled room temperature;
 - (B) BUD up to 14 days under refrigeration; or
 - (C) BUD up to 45 days in solid frozen state at minus 20 degrees centigrade.
- (b) Medium-risk conditions:
- (i) CSPs compounded aseptically under low-risk conditions, but with the addition of one or more of the following conditions:
 - (A) multiple individual or small doses of sterile precuts are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;
 - (B) the compounding process includes complex aseptic manipulations other than single volume transfer; or

- (C) the compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.
- (ii) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:
 - (A) BUD less than or equal to 30 hours at controlled room temperature;
 - (B) BUD up to nine days under refrigeration; or
 - (C) BUD up to 45 days in solid frozen state at minus 20 degrees centigrade.
- (c) High-risk conditions:
 - (i) CSPs compounded from nonsterile ingredients including products manufactured for other routes of administration, or a nonsterile device is employed before terminal sterilization;
 - (ii) exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:
 - (A) sterile contents of commercially manufactured products;
 - (B) CSPs that lack effective antimicrobial preservatives; or
 - (C) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.
 - (iii) Prior to terminal sterilization:
 - (A) nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;
 - (B) compounding personnel are improperly gloved or garbed; or
 - (C) water containing preparations are stored for more than six hours.
 - (iv) in the absence of sterility testing, preparations must be properly stored prior to administration as follows:
 - (A) BUD less than or equal to 24 hours at controlled room temperature;
 - (B) BUD up to three days under refrigeration; or
 - (C) BUD up to 45 days in solid frozen state at minus 20 degrees centigrade.
 - (v) all nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water, then thoroughly drained or dried immediately before use.
 - (vi) terminal sterilization is required as follows:
 - (A) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter; or
 - (B) sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron pore filter entirely within an air quality environment better than or equal to ISO 5.

Authorizing statute(s): 37-7-201, MCA

Implementing statute(s): 37-7-201, 37-7-307, 37-7-308, MCA

History: NEW, 2002 MAR p. 3605, Eff. 12/27/02; AMD and TRANS, from ARM 24.174.1121, 2015 MAR p. 302, Eff. 3/27/15.