This is an amendment to 16.19.36 NMAC, Section 10 and 16 effective 11/18/2025

16.19.36.10 EQUIPMENT: Each facility compounding sterile preparations shall have sufficient equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparation of compounded sterile preparations drugs and parenteral preparations appropriate to the scope of pharmaceutical services provided and as specified in USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*.

A. All equipment shall be cleaned, maintained, monitored, calibrated, tested, and certified as appropriate to ensure proper function and operation with documentation retained for three years.

B. Primary and secondary engineering controls used to provide an aseptic environment shall be tested in the course of normal operation by an independent qualified contractor and certified as meeting the requirements presented in USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* at least every six months and when relocated, certification records will be maintained for three years. Routine viable surface sample testing of classified areas as required by USP/NF <797> (USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations) may be performed onsite by appropriately trained personnel.

C. A library of current references (hard copy or electronic) shall be available including:

(1) All *USP/NF* chapters applicable to the facility's sterile compounding practice;

(2) New Mexico pharmacy laws, rules and regulations;

(3) specialty references (stability and incompatibility references, sterilization and preservation references, pediatric dosing, and drug monograph references) as appropriate for the scope of services provided.

D. Automated compounding devices shall:

(1) have accuracy verified on a routine basis at least every 30 days per manufacturer's specifications;

(2) be observed every 30 days by the operator during the mixing process to ensure the device is working properly;

(3) have data entry verified by a pharmacist prior to compounding or have accurate final documentation of compounded preparations to allow for verification of ingredients by a pharmacist prior to dispensing; and

(4) have accuracy of delivery of the end product verified according to written policies and procedures.

[16.19.36.10 NMAC - N, 06-28-14; A, 8/13/2024; A, 11/18/2025]

16.19.36.16 COMPOUNDING VETERINARY PREPARATIONS:

A. Preparations for animals may be compounded based on an order or prescription from a duly authorized veterinarian.

B. These preparations are to be handled and filled the same as the human prescriptions.

C. Compounding of drugs for animals must be in accordance with the Animal Medicinal Drug Use Clarification Act of 1994 or successor Act.

D. A licensed pharmacy may compound veterinary drug preparations in reasonable quantities to be used by veterinarians in their office for administration to patients ("office use preparations") under the following conditions:

(1) the preparation is necessary for the treatment of an emergency condition;

(2) the preparation is not readily available from an outsourcing facility;

(3) ordering and distribution occur in compliance with applicable state and federal law;

(4) if the medication is a controlled substance, the pharmacy shall be registered with the DEA as a manufacturer; and

(5) in addition to other required labeling, such preparations shall bear a statement "For administration only. Not for dispensing or resale."

E. Prohibition on wholesaling:

(1) Office use preparations will not be distributed by a person other than the pharmacy that compounded such veterinary drug preparations.

(2) This does not prohibit administration pursuant to a prescription drug order executed in accordance with federal and state law; and the conditions of this Subsection.

F. Providing samples of compounded veterinary preparations is prohibited.

[16.19.36.16 NMAC - N, 11/18/2025]