The Society of Veterinary Hospital Pharmacists
Position Statement on Compounding of Drugs for Use in Animals

Purpose: The Society of Veterinary Hospital Pharmacists (SVHP) is an international professional organization of veterinary hospital pharmacists. Recognizing that compounding is essential to providing high quality pharmaceutical care for some animal patients, SVHP, in keeping with our educational mission, seeks to identify concerns and offer guidance in compounding for veterinary patients. Therefore, SVHP endorses the following position statement on compounding for animals.

SVHP POSITION STATEMENT ON COMPOUNDING OF DRUGS FOR USE IN ANIMALS

1. Prescriptions for all compounded preparations shall be initiated by a veterinarian based on an individual patient's need within the context of a valid veterinarian-client-patient relationship. Compounded medication may be dispensed to veterinarians for office use where applicable state/provincial law permits. Items compounded for office use may only be administered in the veterinarian's office and not dispensed for use outside of the veterinarian's office.
2. Compounding for veterinary patients shall comply with regulations promulgated by state/provincial boards of pharmacy, federal regulations, and legislative statutes.
3. SVHP supports food chain safety and discourages compounding for food animals. Food safety concerns preclude the use of compounded preparations unless information exists to assure avoidance of illegal residues in food. The extralabel use of specific drugs is banned in food-producing animals. Food animals are defined by "intended use" rather than species.
4. Use of a compounded preparation in animals not intended for food should be limited to:
   - Compounds for which supportive evidence for safety & efficacy in the target species exists
   - Disease conditions for which response to therapy or drug concentration can be monitored
   - Those individual patients for which no approved product or route of drug delivery satisfies the medical need of the patient
5. Use of a compounded preparation must be accompanied by counseling of the caregiver regarding administration, storage and handling, medication therapy monitoring, including potential adverse reactions, and applicable warnings regarding risk of caregiver exposure.
6. Compliance with occupational health and safety precautions is essential. This applies to practitioners, support personnel, and caregivers. Disposal of compounded preparations and associated waste should not negatively impact human or environmental health.
7. Pharmacists should professionally communicate their concern regarding a prescription for a compounded preparation to the prescriber and refuse to fill the prescription if:
   - An approved product or route of delivery satisfies the medical need of the patient
   - They believe there are contraindications to the use of the compounded preparation
8. Pharmacists providing compounded preparations for animals shall continually seek educational opportunities in veterinary pharmacotherapy and in pharmacy compounding techniques.

GUIDELINES FOR PHARMACIES ENGAGED IN COMPOUNDING FOR ANIMALS

I. Considerations prior to filling
   a. Is the pharmacist qualified to compound this preparation?
   b. Does the pharmacy have proper equipment and supplies needed?
   c. Can the drug and ingredient identity, quality, and purity be assured?
   d. Is there literature available regarding the preparation to assign an appropriate beyond –use date?
   e. What quality control measures will be used to assure that the prescription is compounded correctly?

II. The Prescription Order
   a. Elements -Consult state guidelines.
   b. Individual patient vs office use. If office use, consult state guidelines.
   c. Determine if preparation is a duplication of commercially available product
   d. Food vs Non-food vs Performance Animal
      1. Banned drugs for extralabel use and other restricted drugs in food animals (consult FDA Center for Veterinary Medicine website [www.fda.gov/cvm] for updates)
      2. Banned and restricted drugs for performance animals (Uniform Classification Guidelines for Foreign Substances)
      3. Banned drugs for non-food animals (e.g. thalidomide)
      4. Extralabel use (including compounded preparations) in food-producing animals is limited to therapeutic use.
      5. Withdrawal time for food animal use must be determined by the veterinarian

III. Formula
   a. Use a formula, preferably a USP formula, with evidence-based documentation of potency and stability.
   b. If no such formula is available USP <795> and <797> guidelines should be followed when providing a compounded preparation for an animal patient.
   c. Ensure all ingredients are non-toxic to target species, including inactive ingredients and excipients.

IV. Obtaining Ingredients
   a. Utilize an FDA approved product if available & appropriate
   b. If an FDA approved product is not available and appropriate, the Active Pharmaceutical Ingredient (API) should be of highest possible chemical grade.

Technical (commercial)	Commercial or industrial quality, generally of indeterminate quality
CP (chemically pure)	More refined than technical grade, but still of unknown quality; only partial analytical information available
USP/NF	Meets standards set by the USP/NF
FCC	Meets specifications of Food Chemical Codex
ACS reagent	High purity; meets specifications of the Reagent Chemicals Committee of the American Chemical Society
AR (analytical reagent)	Very high purity
HPLC	Very high purity; used in high pressure liquid chromatography
Spectroscopic grade	Very high purity
Primary standard	Highest purity; used in standard solutions for analytical purposes

      1. API should be obtained through FDA-registered chemical manufacturers, suppliers, & repackagers. Pharmacists and prescribers should be aware that it is often difficult or impossible to determine source of origin of API, and that the pedigree for the chemical (origin of manufacture) should be determined if possible.
      2. Certificate of Analysis and Material Safety Data Sheet (MSDS) should be obtained for each lot of API

V. Compounding Processes
   a. Observe good compounding practices:
      1. Sterile: USP <797>
      2. Non-Sterile: USP <795>

VI. Establishing Beyond-Use Date
   a. Compliance with USP Chapters (<797> and <795>)
   b. For extended beyond use date (BUD): Must have formula-specific stability data to support dating beyond USP criteria
   c. Recommend BUD should not extend the duration of therapy

VII. Completed Product
   a. Labeling in addition to state/provincial and federal requirements
      1. Client name, animal name, species
      2. Active ingredient and strength
      3. Should bear statement “For Veterinary Use Only”
      4. Compounded preparation or accompanying information should bear a statement indicating that a compounded preparation has been dispensed, for example, “This medication has been compounded specifically for this patient under the direction of your veterinarian and has not been tested by the FDA for safety and efficacy.”
      5. Appropriate withdrawal time (if applicable) as assigned by veterinarian
   b. Dispensed in an appropriate (see USP General Notices and Requirements) child-resistant container if possible

VIII. Storage and Handling
   a. Store at recommended temperature avoiding exposure to extremes
   b. Use appropriate auxiliary labeling for storage and to avoid caregiver exposure
   c. Actions to maintain product integrity such as protection from light, heat or moisture.

IX. Counseling
   a. Storage and Handling instructions for caregiver (avoiding extreme temps, etc)
   b. Administration (demonstrate appropriate techniques according to species)
   c. Instructions for monitoring therapeutic response and adverse reactions (signs of toxicity) appropriate for the species

X. Quality Assurance
   a. Refer to USP Chapters < 797>, <795>

XI. Continuing Education regarding veterinary pharmacotherapy and compounding for animal patients

SVHP ENCOURAGES:

1. The collection of clinical data for routinely compounded products, such as product successes or failures, adverse effects, and other clinically relevant issues derived from follow-up communications with the prescribing veterinarian or the client
2. Critical evaluation of the safety and efficacy of discontinued animal or human drug products, especially those drug products removed for reasons of safety or efficacy, prior to compounding a preparation containing those drug products.
3. Clinical drug studies documenting the safety and efficacy of compounded dosage forms in animal patients utilizing appropriate randomized, blinded, controlled clinical studies
4. Collaboration among pharmacy and veterinary professional organizations in establishing education and training programs for pharmacists and veterinarians in areas of compounding and dispensing for animals.
5. Assessment and revision of pharmacy school curricula to include compounding as a specialty area or an area of emphasis, and to make sure that compounding for animals is included in the syllabus.
6. Achievement of Pharmacy Compounding Accreditation Board (PCAB) accredited status by compounding pharmacies.
7. Collaboration of state Boards of Pharmacy and Veterinary Medical Boards in an effort to develop and synchronize state rules and regulations regarding use and preparation of compounded medications for animals and to achieve collaborative inspective authority.

SVHP DISCOURAGES:

1. Prescribing of compounded preparations for use in animals unless there is medical rationale for use of a compounded preparation over an approved product.
2. Compounded preparations that duplicate or nearly duplicate commercially available drug products without clinical evidence supporting the need to avoid use of the commercially available product.
3. Agreements that provide financial incentives to prescribers to refer clients for services.
4. Preparation and distribution of compounded “samples” containing active pharmaceutical ingredients.
5. Anything that contradicts the concepts of veterinarian-driven compounding, compounding only for individualized needs, and the concept of compounding when no other method or route of drug delivery is practical.
6. Claims of efficacy for compounded preparations in the absence of published safety and efficacy data in the target species.
7. Use of bovine origin products whose source of origin is outside the USA.

The SVHP recommends the following resources for pharmacists preparing compounds for animal patients:

1. The Pharmacists’ Pharmacopoeia, USP, Rockville, MD (www.usp.org/products/pharmacistspharm)
2. The United States Pharmacopeia/National Formulary, USP, Rockville, MD (www.usp.org)
3. American Society of Hospital Pharmacists. ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies. *Am J Hosp Pharm*. 1994; 51:1441–8 (www.ashp.org)
4. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) 21CFR530 (www.fda.gov/cvm/amducatoc.htm)
5. The FDA CPG 608.400 – Compounding of Drugs for Use in Animals (www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg608-400.html)
6. The National Association of Boards of Pharmacy (NABP) Good Compounding Practices Applicable to State Licensed Pharmacies (www.nabp.net)
7. The AVMA Position Statement on Compounding (November 2000) (www.avma.org/issues/drugs/compounding/position_statements.asp)