Policy on Pharmaceutical Grade Compounds in Research Animals

Revised November 15, 2005

This policy has been developed to assure that appropriately manufactured and handled compounds are used in research animals at the University of Maryland School of Medicine. In addition to ensuring compliance with Federal Regulations regarding the care and use of laboratory animals, this policy will minimize the risks of inaccurate drug concentration, bacterial growth or endotoxin contamination that can occur when pharmaceuticals are compounded from reagent-grade chemicals. The policy is as follows:

1. No reagent-grade chemicals may be used in research animals at the University of Maryland School of Medicine if a pharmaceutical-grade compound is available through human or veterinary suppliers. Examples of available pharmaceutical-grade compounds frequently used in research animals include (but are not limited to): ketamine, xylazine, diazepam, buprenorphine, cefazolin, halothane, isoflurane and (sometimes) pentobarbital.
2. If a pharmaceutical-grade compound is not available through human or veterinary suppliers, the Principal Investigator or their staff may compound the drug in their laboratory. Examples of compounds not always available through suppliers include (but are not limited to): chloral hydrate and (sometimes) pentobarbital. If the drug is to be compounded the following procedures must be followed to insure sterility of the final product:
    a. All manipulations must occur in sterile vessels using sterile instruments (spatulas, syringes/needles, dosing vials, etc…). Work should be carried out in a biosafety cabinet or chemical fume hood to reduce contamination of the area.
    b. The drug must be reconstituted with either **Sterile Water for Injection** or sterile **PBS (phosphate buffered saline)** according to the instructions provided by the manufacturer of the reagent-grade chemical.
    c. After thorough mixing, the solution must be filtered through a 0.2 micron filter (or smaller) to ensure removal of bacteria and other contaminants.
    d. After filtering, the solution must be placed in a sterile vial. The vial must be labeled with the drug name, concentration of the solution, the date of compounding and the expiration date (*six months from the date of compounding*).
    e. The solution must be handled in a manner to ensure continued sterility of the contents.
    f. The expiration date of the compounded solution is **six months from the date of compounding**. Any solution remaining after six months must be discarded and not used in laboratory animals.

If you require assistance determining if a compound is readily available or for instruction on how to contact a supplier of pharmaceutical grade chemicals, please contact a Veterinary Resources Veterinarian at 6-3540.

References:

Policy #3: Veterinary Care. Animal Care Resource Guide. USDA, APHIS, Animal Care. Issue Date: January 14, 2000
Animal Welfare Act Section 13
9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40
9 CFR, Part 3, Section 3.110