Use of Non-Pharmaceutical Grade Drugs and Preparation and Storage of Compounds for Parenteral Administration

Policy No.
IACUC- 016

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9/9/2019
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1. Reference:

National Research Council. 2011. *Guide for the Care and Use of Laboratory Animals*: Eighth Edition. Washington, DC: The National Academies Press.

American Society of Health-System Pharmacists. *Handbook on Injectable Drugs*. Current Edition.

2. Background:

According to the Federal Office for Laboratory Animal Welfare (OLAW), a pharmaceutical-grade substance is any active or inactive drug, biologic, reagent, etc., manufactured under Good Manufacturing Practices (GMP) which is approved, conditionally approved, or indexed by the Food and Drug Administration (FDA) or for which a chemical purity standard has been written or established by a recognized compendia (e.g., United States Pharmacopeia-National Formulary). OLAW and the United States Department of Agriculture (USDA) agree that pharmaceutical-grade substances, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and/or interfere with the interpretation of research results. However, it is frequently necessary to use non-pharmaceutical-grade substances such to meet scientific and research goals.

3. Policy:

The use of non-pharmaceutical-grade chemicals or substances must be described and justified in the animal care and use protocol (ACUP) and be approved by the IACUC. The most common justification is lack of availability of a pharmaceutical grade compound. It is generally unacceptable to use a chemical grade compound in place of a pharmaceutical-grade compound as a cost saving measure.

When non-pharmaceutical-grade compounds are prepared for parenteral administration (e.g., injection), several characteristics of the compound become critical to the animals' health and welfare. These include the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, etc. For the IACUC to evaluate whether the compound's characteristics are appropriate for parenteral administration, the method of preparing the formulation must be included in the ACUP. Investigators needing assistance with formulations may contact Animal Resources faculty for advice.

When compounds must be diluted, mixed, or otherwise prepared for parenteral administration because commercially available products are not available in the needed concentrations, pharmaceutical grade products should be used to formulate the mixture whenever possible.

If batches of compound are mixed and stored for future parenteral use as opposed to immediately injecting after mixing (e.g. anesthetic cocktails), they must be prepared and stored in sterile injection vials

as opposed to screw top tubes or Eppendorf vials.

All stocks must be labeled with the chemical name(s), concentration(s), and an expiration or "use by" date. Expiration dates should be set so as to ensure stability of the mixture as drugs often lose stability when mixed with diluents or other chemicals. Analgesic or antibiotics may have new expiration directions based on the manufacturer printed on the label or paper insert and those label or insert directives need to be adhered. Mixture expiration dates must be no longer than the soonest of the expiration dates of the parent compounds used in to make the mixture. The *Handbook on Injectable Drugs* prepared by the American Society of Health-System Pharmacists is a useful reference on compounded formulation stability. If any signs of chemical reactions or breakdown of the compounds in a mixture are seen such as a color change or formation of a precipitate, the mixture must be discarded.