

University of Kansas-Lawrence
Institutional Animal Care and Use Committee

Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Research Animals

Purpose: In accordance with the *Guide for the Care and Use of Laboratory Animals (Guide)*, USDA Animal Care Resource Guide Policies, and OLAW guidance, pharmaceutical-grade chemicals and other 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. These guidelines describe IACUC expectations regarding the use of non-pharmaceutical grade compounds in research animals at the University of Kansas.

Applicability: These guidelines apply to all chemical agents and compounds, including analgesic, anesthetics, investigational drugs, and fluids administered to research animals for research, teaching, or testing purposes.

Guidelines:

- A. Investigators are expected to use pharmaceutical-grade compounds whenever they are available, even in non-survival procedures.
- B. When selecting compounds the following order of choice should be applied:
 - a. FDA approved veterinary or human pharmaceutical compounds in the approved dosage form and used without modification;
 - b. FDA approved veterinary or human pharmaceutical compounds used to compound a needed dosage form;
 - c. USP/NF, BP, or other pharmacopeia recognized pharmaceutical grade compounds used in a needed dosage form;
 - d. Compounds shown to be equivalent to pharmaceutical grade through appropriate testing used in the needed dosage form (requires justification);
 - e. Analytical grade bulk chemical used to compound a needed dosage form (requires justification);
 - f. Other grades and sources of compounds (requires justification).
- C. The use of non-pharmaceutical-grade compounds in experimental animals may be acceptable under certain circumstances, based on:
 - a. Scientific necessity;
 - b. Non-availability of an acceptable veterinary or human pharmaceutical-grade compound;
 - c. Non-availability of an acceptable alternative pharmaceutical-grade compound;
 - d. Specific review and approval by the IACUC.
- D. Cost savings alone is not justification for use of non-pharmaceutical grade compounds in research animals.
- E. The use of investigational compounds to meet research goals is permissible with IACUC approval
- F. When developing and reviewing an Animal Use Statement proposing use of non-pharmaceutical grade compounds, the investigator and IACUC should consider grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the compound to be administered, as well as animal welfare and scientific issues related to use.
- G. The IACUC may approve use of non-pharmaceutical-grade compounds in the following situations:

- a. If no equivalent veterinary or human drug is available for experimental use, then the highest grade equivalent chemical reagent should be used and formulated aseptically and with a non-toxic vehicle as appropriate for the route of administration.
- b. Although an equivalent veterinary or human drug is available for experimental use, the chemical-grade reagent is required to replicate methods from previous studies because results are directly compared to those of replicated studies.
- c. Although an equivalent veterinary or human drug is available, dilution or change in formulation is required.
- d. The available human or veterinary drug is not concentrated enough to meet experimental needs.
- e. The available human or veterinary drug does not meet the non-toxic vehicle requirements for the specified route of administration.
- f. The pharmaceutical grade drug is effectively unavailable.

References

- Institute for Laboratory Animal Research. 2011. Guide for the care and use of laboratory animals, 8th ed. Washington (DC): National Academies Press.
- United States Department of Agriculture. 2011. Animal care resource guide policies, policy #3 veterinary care.
- Office of Laboratory Animal Welfare. 2014. Frequently asked questions PHS policy on humane care and use of laboratory animals. Accessed at http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4
- Office of Animal Care and Use, National Institutes of Health. 2016. Guidelines for the use of non-pharmaceutical grade compounds in laboratory animals. Accessed at https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/pharmaceutical_compounds.pdf

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