Institutional Animal Care & Use Program - UTEP	
Title: Use of Non-Pharmaceutical Grade Compounds	
Policy#: 015	**Date in Effect**: 21 November 2014
Version #: C	**Rev Date**: 27 April 2020 27 January 2025
In Effect ☒ **Rescinded**	**Date Rescinded**:

A) RESPONSIBILITIES

It is the responsibility of all personnel using laboratory animals at The University of Texas at El Paso (UTEP) to abide by this policy. Exceptions to this policy must be approved by the Institutional Animal Care and Use Committee (IACUC).

B) APPLICATION

This policy applies to all animal use in research and teaching at UTEP.

C) DEFINITIONS

1) Pharmaceutical Grade Compound: A drug, biologic or reagent that is approved by the FDA, OR is listed in the USP-NF (United States Pharmacopeia-National Formulary) or the BP (British Pharmacopeia).
2) Non-Pharmaceutical Grade Compound: A compound that is analytical grade, bulk chemical, chemical grade, or reagent grade, including investigational compounds. These are typically purchased from chemical companies (e.g., Sigma®).

D) BACKGROUND

The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture (USDA) consider that the use of any non-pharmaceutical grade compound should be based on scientific necessity or the lack of availability of an acceptable veterinary or human pharmaceutical-grade compound and either considerations must be reviewed and approved by the IACUC. Cost saving is not considered an adequate justification for the use of non-pharmaceutical-grade

compounds in laboratory animals. The use of pharmaceutical-grade compounds in laboratory animals ensures that the compounds administered meet established documentable standards of purity and composition, which in turn help ensure research animal health and welfare, as well as the validity of experimental results. The use of lower grade chemicals/compounds with higher levels of impurities, or poorly formulated non-commercial preparations can introduce unwanted experimental variables or even toxic effects and so should be avoided if possible.

E) PROCEDURES

1) For animal research and teaching, investigators are expected to use pharmaceutical-grade compounds whenever these are available, even in acute procedures.
2) The use of non-pharmaceutical-grade chemical compounds in experimental animals can be, however, a necessary and acceptable component of research, providing it meets one of the criteria below in order to secure IACUC approval:
    a) The research activity requires the use of non-pharmaceutical-grade compounds for reasons of scientific necessity. For non-pharmaceutical anesthesia or euthanasia use in mice and rats, a scientific justification and a description of why pharmaceutical grade alternatives (*e.g.,* ketamine-xylazine, isoflurane, etc.) cannot be used in a given animal model is required by the IACUC.
    b) Acceptable veterinary or human pharmaceutical-grade products are not available (most novel compounds are in this category).
    c) An equivalent veterinary or human drug is available for experimental use; however, the chemical-grade reagent is required to replicate methods from previous studies because results are directly compared to those of replicated studies.
    d) The available human or veterinary drug is not concentrated enough to meet experimental requirements or the correct formulation for the route of administration.
    e) The available human or veterinary drug contains preservatives or inactive ingredients which confound the research goals of the study.

3) For all species, any non-pharmaceutical chemical agents administered parenterally (by injection) must be sterile and maintained in a sterile container. All containers must be legibly labeled to provide the mixing and expiration dates and the name and concentration of the primary compound. This includes both the primary containers (*e.g.*, vial, bottle) and secondary containers (*e.g.*, syringes, fluid bags).
4) For all compound use, the IACUC should consider the grade/purity being proposed, the formulation of the final product, and issues such as sterility, pyrogenicity, stability, pH, osmolality, site/route of administration, pharmacokinetics, physiological compatibility, and quality control.

F) REFERENCES

1) PHS Policy on Humane Care and Use of Laboratory Animals, Frequently Asked Questions: May investigators use non-pharmaceutical grade substances in animals?
2) Use of Non-Pharmaceutical Grade Chemicals and Other Substances in Research with Animals. Transcript from Office of Laboratory Animal Welfare Online Seminar.

Review History	
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A	21 November 2014
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