

Institutional Animal Care & Use Program - UTEP	
Title: Use of Non-Pharmaceutical Grade Compounds	
Policy#: 015	Date in Effect: 21 November 2014
Version #: A	Rev Date:
In Effect <input checked="" type="checkbox"/> Rescinded <input type="checkbox"/>	Date Rescinded:

A) RESPONSIBILITIES

It is the responsibility of all personnel using animals at UTEP to abide by this policy. Exceptions to this policy must be approved by the IACUC when good justification is provided to deviate from this policy.

B) APPLICATION

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

C) REFERENCES

- 1) USDA Animal Care Policies, Policy #3, Veterinary Care:
http://www.aphis.usda.gov/animal_welfare/downloads/policy/Policy%203%20Final.pdf.
- 2) Frequently Asked Questions About the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*:
http://grants2.nih.gov/grants/olaw/faqs.htm#useandmgmt_4.
- 3) Food and Drug Administration (FDA) Database:
<http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
- 4) [FDA-approved Human Drugs \(Orange Book\)](#):
http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=orange%20book&utm_content=1.
- 5) [FDA-Approved Veterinary Drugs \(Green Book\)](#):
<http://www.fda.gov/animalveterinary/products/approvedanimaldrugproducts/default.htm>.

D) DEFINITIONS

- 1) Pharmaceutical Grade Compound: A drug, biologic or reagent that has attained FDA approval, OR is listed in the USP-NF (United States Pharmacopeia-National Formulary) or the BP (British Pharmacopeia).
- 2) Compounded Drug: An FDA-approved drug that has undergone customized manipulation by a veterinarian or pharmacist to meet the needs of a research study; such compounded drugs must be prescribed by a licensed veterinarian.

E) BACKGROUND

- 1) For animal research and teaching, investigators are expected to use pharmaceutical-grade compounds whenever these are available, even in acute procedures. Issues such as sterility, pyrogenicity, stability, pharmacokinetics, and quality control have usually been addressed during the course of producing pharmaceutical-grade compounds, but one cannot say the same for substances formulated in the research laboratory. Non-pharmaceutical grade substances may include (but are not limited to) experimental or novel compounds, medications, drugs, and substances such as vehicles or diluents.

F) PROCEDURES

- 1) *The use of non-pharmaceutical-grade chemical compounds in experimental animals can be, however, a necessary and acceptable component of biomedical research, providing it meets the below criteria in order to secure IACUC approval:*
 - a) Non-pharmaceutical-grade chemical compounds may be used in research/teaching utilizing animals if their use is reviewed and approved by the IACUC before they are used. The following areas must be addressed in the justification submitted to the IACUC for their consideration of an exception to this policy:
 - (1) Scientific necessity must be documented;
 - (2) An acceptable veterinary or human pharmaceutical-grade compound is not available; and,
 - (3) Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals.

- (a) The IACUC may research and approve the use of some non-pharmaceutical grade substances in special cases and when a suitable alternative substance cannot be procured.
- b) In preparing proposals to use non-pharmaceutical-grade chemical compounds, investigators should address the quality of the preparations they propose to use, *i.e.*, issues of **purity, stability, sterility, pH, pyrogenicity, osmolality, site and route of administration, compatibility of components, side effects and adverse reactions, storage and pharmacokinetics**. Investigators should explain if, how, and to what extent, purity and sterility will be maintained in the preparation and administration of a compound, in particular when it is administered parenterally. Information about stability and pharmacokinetics should be given when available.