

Institutional Animal Care and Use Committee		UNT Health
Title: Use of Non-pharmaceutical Grade Compounds in Animals		
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A. BACKGROUND INFORMATION

It is important to use pharmaceutical grade substances, when available, to avoid toxicity or side effects that may affect the health and well-being of the animal, and in turn could interfere with research findings. Therefore, the use of non-pharmaceutical-grade chemicals or substances should be described, justified, and approved in the animal care and use protocol. (The Guide, Pg. 31)

Pharmaceutical grade indicates compliance with US Pharmacopeia (USP) standards of strength, quality and purity and requires the use of official USP reference standards (for production). Production standards for each drug are listed in monographs in the USP-NF (national formulary). Chemical grade substances often contain inorganic and organic impurities, and/or water and are not produced according to USP-NF standards and are considered appropriated for laboratory (in vitro) use only.

A non-pharmaceutical grade compound is a chemical not formulated or manufactured for use in human or veterinary medicine. Chemicals, compounds, substances, solutions or reagents obtained from a chemical supply company and prepared in a research laboratory are considered non-pharmaceutical grade.

B. RESPONSIBILITIES

- a. OLAW and USDA understand the need to use non-pharmaceutical-grade substances in order to meet scientific and research goals; however, the IACUC is responsible for evaluating the potential adverse consequences of non-pharmaceutical-grade substances.
- b. It is the responsibility of the Principal Investigator (PI) to follow the procedures outlined below regarding non-pharmaceutical substances.

C. PROCEDURES

- a. Pharmaceutical-grade medications, anesthetics, analgesics, and euthanasia agents are expected to be used whenever they are available, even in acute procedures.
- b. While experimental compounds do not need to be pharmaceutical grade when used in research paradigms as opposed to being used as therapeutic agents, all relevant animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction and new variables when using non-pharmaceutical grade compounds should be considered.
- c. **Non-pharmaceutical grade** substances may be acceptable when:
 - i. There is scientific necessity.
 - ii. There are no equivalent pharmaceutical grade compounds available.

- iii. Approved by the IACUC
- iv. There is a schedule of monitoring that allows the detection of adverse events related to the use of non-pharmaceutical grade compounds. Any adverse events should be reported to DLAM and IACUC in a timely manner.
- v. Issues related to quality assurance such as proper preparation, storage, and shelf life have been addressed.

D. REFERENCES:

- a. [Institute of Laboratory Animal Resources \(2011\). Guide for the Care and Use of Laboratory Animals. National Academies Press, Washington, D.C.](#)
- b. [PHS Policy on Humane Care and Use of Laboratory Animals, NIH, Office of the Director, Revised 2015.](#)
- c. [Office of Laboratory Animal Welfare, National Institutes of Health. Frequently Asked Questions, PHS Policy on Humane Care and Use of Laboratory Animals, Section F, Question 4](#)