

<b>Institutional Animal Care and Use Committee</b>		<b>UNTHSC</b>
<b>Title:</b> Use of Non-pharmaceutical Grade Compounds in Animals		
<b>Document #:</b> 011	<b>Version #:</b> 03	
<b>Approved by IACUC Date:</b> February 25, 2020		

**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.

According to the *Guide for the Care and Use of Laboratory Animals, 8<sup>th</sup> Edition*, “The use of pharmaceutical-grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures. The use of non-pharmaceutical-grade chemicals or substances should be described and justified in the animal use protocol and be approved by the IACUC“(Pg. 31).

**B. RESPONSIBILITIES**

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.

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 are expected to be used whenever they are available, even in acute procedures.
- b. Medications and anesthetics/analgesics/euthanasia agents must be pharmaceutical grade.
- c. All injected compounds and diluents must be sterile when used for survival animal procedures.
- d. Diluents do not need to be pharmaceutical grade but must be sterile.
- e. Experimental compounds do not need to be pharmaceutical grade when used in research paradigms as opposed to being used as therapeutic agents.
- f. 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.
- g. Exceptions to these guidelines must be justified and submitted to the IACUC for review and may be granted for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product.

- h. **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.
  - v. Issues related to quality assurance such as proper preparation, storage, and shelf life have been addressed.
- i. Note: 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.

**D. REFERENCES:**

- a. The Guide for the Care and Use of Laboratory Animals (2011), National Academies Press, Washington, D.C.
- b. Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.
- c. NIH Office of Laboratory Animal Welfare: <http://grants.nih.gov/grants/olaw/fags.htm#f4>