THE UNIVERSITY OF TOLEDO
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

SUBJECT: Use of Non-Pharmaceutical Grade Chemicals in Research Animals

DATE: November 20, 2024

It is the general rule in the Guide for the Care and Use of Laboratory Animals (the Guide) that pharmaceutical grade compounds should be used in animal studies whenever possible. Non-pharmaceutical grade compounds may introduce unwanted experimental variables or toxic effects. Although pharmaceutical grade compounds should be used in animals whenever possible, there are circumstances when non-pharmaceutical grade compounds are acceptable. This guideline is to assure efficacy, purity, and freedom from toxic side effects in the use of non-pharmaceutical grade compounds in animals.

Definitions

Pharmaceutical grade compounds: An agent or substance listed in the FDA Green Book (approved Animal Drug Products), approved by the United States Pharmacopeia (USP), or approved by the British Pharmacopeia (BP).

Non-pharmaceutical grade compounds: An agent or substance that includes analytical grade (bulk chemicals with purity of 99.9%), technical grade (require certificate of analysis to assure they are free of toxins), reagent grade, lab grade, and food grade. New investigational drugs are generally considered non-pharmaceutical grade compounds.

Procedures

The NIH Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA) have determined that the use of non-pharmaceutical grade compounds should be based upon:

- Scientific necessity;
- Non-availability of acceptable veterinary or human pharmaceutical grade compound; and
- Specific review and approval by the IACUC

When the use of a non-pharmaceutical grade compound is proposed in an IACUC protocol it must be justified based upon these criteria.

Furthermore, selection of a non-pharmaceutical grade compound for use in IACUC protocols should consider the following:

1. Prioritization for substances is analytical grade, and then technical grade.
2. Non-pharmaceutical grade drugs should be obtained from a reliable supplier and be of substantial purity.
3. Drugs are to be dated upon receipt from a manufacturer/supplier and an expiration date established. Unless otherwise approved, this shelf life shall be two years. Compounded solutions which are prepared for injection shall be given a maximum expiration date of 30-days on the container.
4. Materials shall be properly stored to maintain their purity and activity; the requirements depending on the nature of the drug as stated in the Material Safety Data Sheet (MSDS) for the drug.
5. A description should be provided on the preparation of compounded solutions, including the use of appropriate diluents and concentrations. Prepared solutions for parenteral administration shall be passed through a sterile Millipore filter and placed into sterile multi-dose injection bottles. Sterile technique will be maintained while introducing and removing solutions from containers.

Any untoward reactions noted with the use of these prepared solutions in research animals will be reported promptly to the UToledo Attending Veterinarian, who shall document the observed reactions and provide this information to the IACUC. Reactions resulting in euthanasia or death shall be examined post-mortem.

Permission for using non-pharmaceutical grade materials for administration to animals is to be approved by the UToledo IACUC on a case-by-case basis in the animal use protocol.