WVU IACUC POLICY:
Non-Pharmaceutical Grade Substances Used in Animals

I. Introduction

This policy describes the expectations of the WVU Animal Care and Use Committee (IACUC) when non-pharmaceutical grade substances are administered to animals used in research, training, or teaching. The IACUC recognizes that some animal use protocols involve the administration of experimental or proprietary compounds that are not available in pharmaceutical grade. In these cases, the principal investigator (PI) is responsible for justifying their use and minimizing potential adverse effects.

According to the Guide, 8th ed (p31): “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 (USDA 1997b). 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; for example, the use of a non-pharmaceutical-grade chemical or substance may be necessary to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use.”

According to the USDA Animal Care Policy Manual, 2016 (p3.1): “Pharmaceutical-grade substances are expected to be used whenever they are available, even in acute procedures. This includes but is not limited to: compounds, medications, drugs, vehicles, and diluents. APHIS recognizes that some substances (e.g. test articles, novel compounds, and those resulting from a compounding process) are only available as a nonpharmaceutical grade product. Non-pharmaceutical-grade substances should only be used in regulated animals after specific review and approval by the IACUC. The IACUC should develop a consistent evaluation process which includes but is not limited to the scientific justification and the availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone is not sufficient justification for using a nonpharmaceutical-grade substance in regulated species, however, unavailability or shortages of pharmaceutical grade substances may lead to cost increases and the IACUC may determine that this justifies the use of the non-pharmaceutical grade substitution.”

II. Policy

- The IACUC must approve the use of non-pharmaceutical grade compounds prior to their use in live animals. With the exceptions noted below.

- Any compound administered to a live animal must be pharmaceutical grade if available.
  - One exception is non-pharmaceutical grade pentobarbital, which is currently approved for use in animals due to the limited availability and exorbitant cost of pharmaceutical grade pentobarbital.
  - Other exceptions should be considered by the IACUC on a case-by-case basis, as needed.
• If a compound is available only in non-pharmaceutical grade, the PI must provide the IACUC the following:
  - scientific justification for its use
  - any available information on grade, purity, sterility, pH, pyrogenicity, osmolality, stability of the compound
  - any available information on site and route of administration, formulation, compatibility, and pharmacokinetics of the compound
  - any available information on doses and adverse effects in experimental or other species

• The compound should be sterilized before administration to an animal, if possible. This can be accomplished by filter sterilizing and using a sterile diluent or vehicle. Method of sterilization should be described in the IACUC protocol.