INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POLICY
Non-Pharmaceutical-Grade Substances Used in Animals

Approval Date: 4/16/2024
Next Review Date: 4/16/2027

Purpose: The use of pharmaceutical-grade compounds in laboratory animals ensures that the compounds administered meet established documentable standards of purity and composition which in turn help ensure research animal health and welfare, as well as the validity of experimental results. The use of lower grade chemicals/compounds with higher levels of impurities or poorly formulated non-commercial preparations can introduce unwanted experimental variables or even toxic effects, and so should be avoided if at all possible. Although pharmaceutical grade compounds should be used in experimental animals whenever possible, the use of non-pharmaceutical-grade compounds in experimental animals is an acceptable practice under certain circumstances. For example, in the case of new investigational compounds, they would be the only grade and formulation available.

Procedures that may cause more than momentary or slight pain or distress to animals must be relieved by sedation, analgesia, or anesthesia using veterinary or human pharmaceutical-grade substances, unless the use of a non-pharmaceutical-grade substance is scientifically necessary, appropriately justified, and approved by the IACUC.

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.

Use of non-pharmaceutical-grade substances, when pharmaceutical-grade alternatives are not available, for the following reasons:

- An equivalent veterinary or human pharmaceutical-grade compound does not exist or it is unavailable.
- The equivalent veterinary or human pharmaceutical-grade compound is not available in the appropriate formulation or concentration required.
- Although there is an equivalent veterinary or human drug available, the chemical grade is required to replicate methods from previous studies.
- The equivalent veterinary or human pharmaceutical-grade compound contains preservatives or inactive ingredients which may confound the research goals of the study.
- with pH 6-8, and purity and sterility requirements are met:
    - Onsite manipulation with standard laboratory precautions using aseptic procedures
    - Use of sterile diluents
    - Use of sterile containers if prepared/maintained for >24 hours prior to use
    - >95% purity documented from vendor

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The use of non-pharmaceutical-grade compounds must be justified and approved by the IACUC prior to their use in live animals. Non-pharmaceutical-grade compounds should be requested only for reasons of scientific necessity or lack of available veterinary or human pharmaceutical-grade products. Cost savings will not be considered adequate justification for using non-pharmaceutical grade compounds in animals.

The IACUC protocol application should include the following information for each nonpharmaceutical-grade compound:
• Scientific justification for its use.
• Any available information on grade, source, purity, sterility, pH, pyrogenicity, osmolality, stability of the compound. Other exceptions should be considered by the IACUC on a case-by-case basis, as needed.

The IACUC is responsible for evaluating the potential adverse consequences of non-pharmaceutical-grade substances when used for research. In making its evaluation, the IACUC may consider factors including, for example:
- grade,
- purity,
- sterility,
- acid-base balance,
- pyrogenicity,
- osmolality,
- stability,
- site and route of administration,
- compatibility of components,
- side effects and adverse reactions,
- storage, and
- pharmacokinetics.

References

1. OLAW FAQ: OLAW FAQ F4: Use of non-pharmaceutical grade substances in animals
2. OLAW: Use of Non-Pharmaceutical-Grade Chemicals and Other Substances in Research with Animals https://grants.nih.gov/grants/olaw/120301_NPG_slides.pdf
   A listing of pharmaceutical-grade drugs and biologics is available through the FDA database. The Orange Book is the reference for FDA-approved human drugs. The Green Book is the reference for FDA-approved veterinary drugs.

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3. James Madison University: Guidelines for the Use of Non-Pharmaceutical Grade dugs https://www.jmu.edu/researchintegrity/iacuc/guidelines/iacuc-non-pharmaceutical-grade.pdf

Non-pharmaceutical-grade substances should only be used in regulated animals after specific review and approval by the IACUC

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