



OFFICE OF RESEARCH

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Institutional Animal Care and Use Committee

Non-Pharmaceutical Grade Components

IACUC Policy #1

The use of non-pharmaceutical grade compounds may introduce toxic or unwanted side effects that could negatively impact the health and well-being of experimental animals. For this reason, both AAALAC International and The Guide recommend that all substances administered to animals be pharmaceutical grade. The AWC may approve the use of non-pharmaceutical grade compounds due to availability or scientific necessity if the use is appropriately described and justified in the animal protocol.

Definitions:

Pharmaceutical Grade Compound: any active or inactive drug, biologic, or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia [e.g. the U.S. Pharmacopeia (USP), British Pharmacopeia (BP), National Formulary (NF), etc.]

Regulations:

Guide for the Care and Use of Laboratory Animals, ILAR, NAS, 2011, pg 31: Pharmaceutical grade compounds 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 care and use protocol and be approved by the IACUC.

Policy:

Substances that are administered to animals should be USP grade. The use of a non-pharmaceutical grade compound must be described and justified in an approved IACUC protocol before use in experimental animals. Investigators must ensure that laboratory preparations of non-pharmaceutical grade substances are prepared in a manner that reduces the potential for contaminants and toxicity. Investigators are also responsible for selecting a concentration that ensures that the desired dosage is administered in the approved volume.

Appropriate justifications may include:

- The substance is not available in a pharmaceutical grade formulation
- Pharmaceutical grade alternatives cannot be used for scientific/procedural reasons (i.e. interference from nose cones, adverse interactions with parameters being studied)
- The USP grade compound is not available in the appropriate concentration or the appropriate vehicle control is not available

- Use of a non-pharmaceutical grade substance is required to ensure continuity/comparison to previous work/data
- The chemical properties (purity, stability, pH, solvent, etc.) are more appropriate for the study or route of admission
- Cost savings is not an appropriate justification

Laboratory prepared formulations:

- Must be appropriately labeled (Contents, concentration, expiration/preparation date)
- Should be sterile (autoclave or microfiltration, as appropriate)
- Should be compatible with the site and route of administration (purity, pH, solubility, osmolality, stability)
- Should address any additional applicable properties (pyrogenicity, pharmacokinetics)

The methods used to prepare laboratory formulations and address the items listed above must be included in the animal protocol and approved by the IACUC.

Investigators are responsible for determining the expiration date of laboratory formulations. If this information is not available, the committee recommends that solutions be prepared fresh each day that they are used.

References:

- *8th Edition, NRC Guide for the Care and Use of Laboratory Animals (2011)*
- *USDA Animal Welfare Act Regulations 9 CFR Part 3, Chapter1 3.81d*