



Animal Experimentation Ethics Committee Policy: Use of Non-Pharmaceutical Grade Compounds

Objective	To communicate AEEC's expectations regarding the use of non-pharmaceutical grade compounds on animals
Approved	7 May 2024
Version	1

Scope

Investigators are expected to use pharmaceutical-grade compounds whenever they are available to reduce pain, treat the disease that may threaten the health and welfare of the animals and/or interfere with the interpretation of research results. Non-pharmaceutical grade compounds may only be used with justification for the research studies of the project after review and approval by the AEEC.

Definitions

Pharmaceutical Grade Compound - A compound, such as a drug, biologic chemicals, or reagent, for which a chemical purity standard has been established by a recognized pharmacopeia. This includes, but is not limited to, the US Pharmacopeia (USP)/National Formulary (NF), British Pharmacopeia (BP), or Pharmacopoeia of the Council of Europe (EP). The category encompasses pharmaceutical compounds approved for human or veterinary use by the U.S. Food and Drug Administration (FDA).

Non-Pharmaceutical Grade Compound - A compound supplied by its manufacturer solely for experimental testing. As such, it does not have established chemical purity standards. This category includes but not limited to, novel compounds, nanoparticles, biofilms, herbal extracts prepared by the research group.

Principles

Pharmaceutical Grade Compounds must be used, when available, for all animal-related procedures.

When using a non-pharmaceutical grade compound, the chemical properties should be considered by the Principal Investigator for the proposed study and route of administration. The grade/purity, side effect, toxicity, solubility, taste, light sensitivity, potency, concentration, pH, osmolality, stability, formulation (buffer or solvent), and potential contaminants (e.g., chemical, biological, and microbial, including pyrogenic substances), as well as handling and storage procedures, may impact quality of the compound for achieving the scientific aims of the study, and animal welfare.

Scientific justification for the use of non-pharmaceutical compounds may include the following reasons:

- Non-availability of an equivalent veterinary or human drug.
- The available human or veterinary drug is not concentrated enough to meet experimental requirements or the correct formulation for the route of administration.
- The available human or veterinary drug contains preservatives or inactive ingredients which confound the research goals of the study.
- Scientific necessity for comparability to previous research or to replicate specific experimental model.

Financial concerns or cost savings is not an adequate justification for using non-pharmaceutical-grade compounds in animals.

For all species, any non-pharmaceutical chemical agents administered parenterally (by injection) must be sterilized and maintained in a sterile container. All containers must be legibly labelled to provide the mixing and expiration dates and the name and concentration of the primary compound.

PI should provide the details of the non-pharmaceutical compound, including source, formulation and vehicle for compound, preparation of compound, storage conditions and shelf-life (if applicable) in their AEEC application.

References

National Research Council, (2011). Guide for the care and use of Laboratory Animals. 8th ed. Washington, DC: The National Academies Press, p.31.

National Institutes of Health (NIH), 2023. Guidelines for the Use of Non Pharmaceutical Grade Compounds in Laboratory Animals. Available at:
https://oacu.oir.nih.gov/system/files/media/file/2023-05/b14_pharmaceutical_compounds.pdf
(Accessed: 20 February 2024).