



Albert Einstein College of Medicine

Use of Non-Pharmaceutical Grade Compounds in Animal Research Policy

I. Purpose

Pharmaceutical grade compounds must be used in all situations where the health and well-being of the animal are at risk (anesthesia, analgesia, emergency drugs, euthanasia) and for routine veterinary care (non-research). Details of this policy, as well as limited exceptions, follow.

II. Scope

This policy applies to all research experiments and programs at Einstein.

III. Policy

A. Use of Non-Pharmaceutical Grade Compounds

Under certain circumstances, the use of non-pharmaceutical grade chemical compounds in experimental animals may be a necessary and acceptable component of biomedical research. Non-pharmaceutical grade chemical compounds may be used for scientific investigation provided that a scientific justification is provided. Acceptable reasons for use of non-pharmaceutical or chemical grade agents may be:

- Scientific necessity
- Non-availability of an acceptable veterinary or human pharmaceutical-grade product.

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

OLAW has also stated that while the possible implications of the use of non-pharmaceutical grade compounds in non-survival studies appears less evident, the scientific issues remain the same and professional judgment, as outlined, must be used.

NOTE: Cost savings alone is not an adequate justification for using non-pharmaceutical-grade compounds.

The NIH recommends that the following order of choice should be applied:

- FDA approved veterinary or human pharmaceutical compounds;
- FDA approved veterinary or human pharmaceutical compounds used to compound a needed dosage form;
- USP/NF or BP pharmaceutical grade compound used in a needed dosage form;
- Analytical grade bulk chemical used to compound a needed dosage form (requires justification in animal use protocol);
- Other grades and sources of compounds (requires justification in animal use protocol).

B. Requirements

The compounds administered should 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 whenever a higher grade is available.

In the case of new investigational compounds, they are the only grade and formulation available and are therefore acceptable for use in animals (provided their use is described in an approved animal protocol).

C. Issues to be Addressed in Animal Use Protocols

If the use of specific non-pharmaceutical grade drugs is required, their use in laboratory animals should be clearly delineated and justified in the Animal Use Protocol and/or covered by an IACUC policy developed for their use. The following must be addressed in the animal use protocol:

- The PI should address animal welfare and scientific issues related to the use of the compounds, including potential for contamination, safety, efficacy, and the inadvertent introduction of confounding research variables.
- The method of preparation of the drug and the storage conditions must be described. In particular, a detailed description of the methods used to ensure sterility of the drug must be included (e.g., 0.22-micron filter, storage in sterile vials with rubber septum to maintain sterility).
- The PI should address the grade/purity being proposed, the formulation of the final product, and issues such as sterility, pyrogenicity, stability, pH, and osmolality, site/route of administration, pharmacokinetics, physiological compatibility, and quality control.

IV. Definitions

Medical materials: Items used clinically or for research purposes that may have an expiration date assigned by the vendor for the purpose of guaranteeing sterility.

Pharmaceutical grade compound: Drug, biologic, reagent, etc. which is approved by the FDA or for which a chemical purity standard has been written/established by USP/NF, BP

Analytical grade bulk chemical: ~99% purity; Certificate of Analysis is usually available

New investigational compound: Supplied by its manufacturer for testing in an experimental setting only and for this reason would not have chemical purity standards established; by default, it is considered a non-pharmaceutical grade compound.

Chemical Grade: Compounds or agents which may be chemically identical to their pharmaceutical grade counterparts, but do not conform to recognized standards for purity and bioavailability.

V. Effective Date

Effective as of: 21 February 2018.

VI. Policy Management and Responsibilities

Einstein's Institutional Animal Care and Use Committee (IACUC) is the Responsible Office under this Policy. The Institutional Official for the IACUC is the Responsible Executive for this policy. The IACUC Chairperson is the Responsible Officer for the management of this policy.

VII. Approved (or Revised)

	
_____ Institutional Official	_____ Date

Revision dates: 6/20/2012, 5/19/2015, 2/21/2018