ADA Forsyth®

Animal Program Policy

Title:	**Use of Non-pharmaceutical Grade Compounds**
Date Created:	02/06/2012
Date Reviewed:	09/30/2026

The IACUC, reflecting the regulations and guidance put-forth by the Animal Welfare Act, Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Guide for the Care and Use of Laboratory Animals, mandates all compounds injected into animals must be of pharmaceutical-grade, including solvents and vehicles. In addition to being pharmaceutical grade, all materials for injection must be sterile. These considerations are to avoid toxic or unwanted side effects in animal experiments.

A *pharmaceutical grade compound* is a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary (USP-NF), or British Pharmacopeia (BP

Non-pharmaceutical-grade medications can only be used in research/teaching activities utilizing animals after review and approval by the IACUC. This policy applies to all species. The following circumstances must be met for an exemption to the policy to be considered by the IACUC:

1. An acceptable veterinary or human pharmaceutical-grade product is not available, or is available but not suitable. .
2. The use of non-pharmaceutical-grade compounds is scientifically justified.
3. Additional aspects of the compound to be used are described as listed below.

Protocol requirements for approval of use of non-pharmaceutical grade compounds

- Use of non-pharmaceutical grade compounds, especially if one is available, must be justified.
- When the use of non-pharmaceutical grade compounds is proposed, additional aspects of the material to be used must be addressed in the protocol including:
    - purity – highest purity available should be used
    - formulation – are there any components in the material in addition to the active ingredient?
    - pH
    - pyrogenicity/endotoxin level
    - osmolality – solutions should be similar to normal saline in osmolality
    - stability – how will the material be stored, and will it degrade over time leading to lower purity?
    - pharmacokinetics, if applicable
- Vehicle(s) used should be pharmaceutical grade or the use of non-pharmaceutical grade vehicle justified. Sterility of injectable material must be ensured, preferably by filtration through a 0.2 micron filter.

References:

- Public Health Service Policy on Humane Care and Use of Laboratory Animals, FAQ F.4

- *Guide for the Care and Use of Laboratory Animals: Eighth Edition*, National Academy Press, 2010 (pg.31) http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf