

Clemson University
Institutional Animal Care and Use Committee (IACUC)

Policy Number: 3.4

Policy Title: The Use of Non-pharmaceutical Grade Compounds

Section 1: Purpose

The following policy is intended to provide information to Principal Investigators regarding the use of non-pharmaceutical grade compounds in research, teaching, testing, or demonstration activities involving vertebrate animals.

Section 2: Scope

This policy applies to all vertebrate animals used for research, teaching, testing, or demonstration within or associated with the University.

Section 3: Policy

Pharmaceutical Grade Substances Defined

A pharmaceutical-grade substance is any active or inactive drug, biologic, reagent, etc., manufactured under Good Manufacturing Practices (GMP) and approved, conditionally approved, or indexed by the Food and Drug Administration (FDA) or for which a chemical purity standard has been written or established by a recognized compendia (e.g., United States Pharmacopeia-National Formulary (USP-NF) or British Pharmacopeia (BP)).

A listing of pharmaceutical-grade drugs and biologics is available through the FDA database (<https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases>). The Orange Book (<https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>) is the reference for FDA-approved human drugs. The Green Book (<https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>) is the reference for FDA-approved veterinary drugs.

Non-Pharmaceutical Grade Substances Defined

Non-pharmaceutical grade substances are those that are not manufactured according to quality standards and quality/purity cannot be guaranteed.

Non-Pharmaceutical Grade Substance Use

The use of pharmaceutical-grade substances ensures that variables related to purity or quality are not introduced into studies conducted with experimental animals. Therefore, pharmaceutical grade substance use is the standard, when available, for all animal-related procedures.

In the event a non-pharmaceutical grade substance must be used, its use should be described and scientifically justified in the animal use protocol. Cost savings alone is not an adequate

justification for the use of non-pharmaceutical grade compounds. When planning the use of non-pharmaceutical substances, consideration should be given to:

- substance characteristics such as grade, purity, sterility, pH, pyrogenicity, osmolality, and stability
- administration characteristics such as the site, route, formulation, compatibility, and pharmacokinetics
- animal welfare and scientific issues relating to its use.

Non-Pharmaceutical Grade Compound use in Food Animals

The use of a non-pharmaceutical grade substances in an animal intended for human consumption is prohibited unless approved by the Attending Veterinarian (AV) or the IACUC. If the use of these substances is necessary, the ability of the animal to return to a production herd/flock is determined by the AV and the IACUC. If animals are returned to production, special, permanent identification may be required to easily recognize these individuals and prevent their entry into the food chain.