



Institutional Animal Care & Use Committee

Use of Non Pharmaceutical Grade Compounds

I. Purpose

The purpose of this IACUC policy is: To communicate the IACUC's expectations regarding the use of materials in or on animals. To provide guidance to end-users to enable them to be compliant with these expectations. To prevent or minimize potential toxic or unwanted side effects associated with the administration of non-pharmaceutical grade materials to laboratory animals.

II. Scope

Investigators are expected to use pharmaceutical-grade compounds whenever they are available^{4, 5,6,7,8}, to avoid toxicity or side effects that may threaten the health and welfare of the animals and/or interfere with the interpretation of research results. Non-pharmaceutical grade compounds should only be used after specific review and approval by the IACUC of the written justification for use in an animal protocol.

III. Definitions

- A. Pharmaceutical grade compound - an active or inactive drug, biologic or reagent for which a chemical purity standard has been established by any recognized pharmacopeia, such as the: US Pharmacopeia (USP)/National Formulary (NF), British Pharmacopeia (BP), or Pharmacopoeia of the Council of Europe (EP). These include, but are not limited to, pharmaceutical compounds approved for human or veterinary use approved by the U.S. Food and Drug Administration (FDA).
- B. Chemical Purity Grades – the majority of chemicals are manufactured to comply with the International Organization for Standardization (ISO) regulation ISO 9001:2008, and laboratory chemicals manufactured to standards set by the American Chemical Society (ACS).
- C. Biologics – biological molecules, obtained either by collection or extraction and purification from living systems, or by production in recombinant expression systems, or by de novo chemical synthesis. In terms of FDA licensed products, examples include antitoxins, antivenins, blood, blood derivatives, immune serums, immunologic diagnostic aids, toxoids, vaccines, and related articles.
- D. 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 is considered a non-pharmaceutical grade compound.

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IV. Process

The appropriate chemical properties of a non-pharmaceutical grade compound should be considered by the Investigator for the proposed study and route of administration. The grade/purity, 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, are among the properties and practices that impact quality of the compound for achieving the scientific aims of the study.

Scientific justification for the use of non-pharmaceutical compounds may include the following reasons⁹:

- A. Non-availability of an equivalent veterinary or human drug
- B. Specific exception to an available veterinary or human drug, for example:
 - 1. Insufficient strength of the active compound in an available formulation
 - 2. Presence of an excipient or preservative is unacceptable for proposed studies (e.g. toxic via planned administration route, nature of excipient would affect experimental model or compromise data collection)
 - 3. Use of an available formulation requires further change (e.g. dilution or other addition) and offers no advantage over formulation from a high-quality reagent
- C. Scientific necessity for comparability to previous research or to replicate specific experimental model

4 9 CFR Chapter1, Subpart A, sections 1, 2, and 3

5 US Department of Agriculture /Animal and Plant Health Inspection Service - Animal Care Policy #3 Veterinary Care, March 25, 2011.

6 PHS Policy on Humane Care and Use of Laboratory Animals, Guide for the Care and Use of Laboratory Animals, 8th edit. 2011.

7 Office of Laboratory Animal Welfare: LAW Position Statement: Non-Pharmaceutical Grade Substances:

http://grants.nih.gov/grants/olaw/positionstatement_guide.htm#nonpharma

8 Association for Assessment and Accreditation of Laboratory Animal Care International, FAQ http://www.aaalac.org/accreditation/faq_landing.cfm#B9

9 Cost savings is not included as an appropriate justification for use.