# Policy on Use of Non-Pharmaceutical Grade Compounds

This document establishes the policy of the IACUC regarding the use of non-pharmaceutical grade compounds in vertebrate animals used in at the University of Kentucky.

## Compound Grade

Pharmaceutical grade compounds, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and / or interfere with the interpretation of research results. Extra-label use of drugs (or the use of compounded drugs) in food producing animals requires a prescription written by the licensed veterinarian.

Non-pharmaceutical grade chemical compounds should only be used after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical grade product. Cost savings is not a justification for using non-pharmaceutical grade compounds.

## Definitions

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.

Non-availability: Not commercially available from an active US vendor; includes formulations supplied as tablet, capsule, injectable, etc.

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.

USP/NF: United States Pharmacopeia/National Formulary

BP: British Pharmacopeia

FDA: Food and Drug Administration; FDA approved compounds are manufactured using USP/NF compounds.

**Responsibilities**

Investigator: Investigators are responsible for ensuring pharmaceutical grade compounds are used whenever they are available or must provide specific details regarding the non-pharmaceutical compound use being proposed and scientific justification for such use. The investigator must provide sufficient information to ensure safety and efficacy (e. g. toxicity, preparation, sterility, chemical grade, drug contaminants, pH, osmolality, stability, storage etc.) to the IACUC to permit the IACUC to assess the potential of the non-pharmaceutical grade drug to harm animal health or well-being. Typically, this would include methods to prepare and store dilutions to be administered to animals.

IACUC: The IACUC is responsible for evaluating the potential adverse consequences of such agents when used for research, teaching, and testing. The IACUC should consider available information (grade/purity, formulation, sterility, pyrogenicity, stability, pH, osmolality, site/route of administration, pharmacokinetics, physiological compatibility, storage, and quality control, etc.) as applicable and relevant to the specific circumstance.

When selecting compounds, the following order of choice should be applied:

1. FDA approved veterinary or human pharmaceutical compounds;

2. A drug preparation prepared by a licensed and accredited (Pharmacy Compounding Accreditation Board - PCAB) compounding pharmacy using FDA approved veterinary or human pharmaceutical compounds and/or USP/NF or BP pharmaceutical grade compounds to prepare a final product in a needed dosage form. In these cases, the licensed and accredited compounding pharmacy will ensure that the drug meets the appropriate criteria for its intended route of administration;

3. A final compound prepared in a non-PCAB accredited compounding pharmacy or in the laboratory using FDA approved veterinary or human pharmaceutical compounds and/or USP/NF or BP pharmaceutical grade compounds to prepare a needed dosage form. Specific details as to method of preparation, sterility, pH, osmolality, specific quality control procedures, stability, storage conditions, and expiration date must be detailed to allow IACUC review and evaluation of potential adverse effects;

4. A final compound prepared in the laboratory using any analytical grade bulk chemicals to prepare a needed dosage form. Specific details as to purity of the bulk chemical, method of preparation, sterility, pH, osmolality, specific quality control procedures, stability, storage conditions, and expiration date must be detailed to allow IACUC review and evaluation of potential adverse effects;

5. A final compound prepared in the laboratory using any other grades and sources of compounds to prepare a needed dosage form. Specific details as to purity of the bulk chemical (if known), potential contaminants (if known), method of preparation, sterility, pH, osmolality, specific quality control procedures, stability, storage conditions, and expiration date must be detailed to allow IACUC review and evaluation of potential adverse effects.

**References**

1. **Division of Compliance Policy (HFC-230 FaDA**. Guidance for FDA Staff and Industry, Compliance Policy Guides Manual Sec. 608.400 Compounding of Drugs for Use in Animals. Division of Compliance Policy (HFC-230, Food and Drug Administration).
2. **Institute of Laboratory Animal Resources (U.S.)**. 2011. *Guide for the Care and Use of Laboratory Animals*. Washington, D.C.: National Academy Press.
3. **United States., United States. Animal and Plant Health Inspection Service.** 2017. *Animal Welfare Act and animal welfare regulations*. Washington, D.C.: U.S. Dept. of Agriculture, Animal and Plant Health Inspection Service.

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