

IACUC Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals at UWM

Last Reviewed: 4/2022

Revision History:

- A **pharmaceutical grade compound** is any active or inactive drug, biologic, reagent, etc. which is approved by the FDA or for which a chemical purity standard has been written/established by any recognized pharmacopeia (book/compendia) such as: US Pharmacopeia (USP), National Formulary, British Pharmacopeia.
 1. For all species, pharmaceutical grade compounds should be used whenever they are available.
 2. For all species, permission must be obtained from the IACUC to administer any non-pharmaceutical chemical compounds. Cost in itself is not considered an adequate reason to employ non-pharmaceutical chemical compounds.
 3. For all species, any non-pharmaceutical substances may be acceptable when:
 - There are no equivalent pharmaceutical grade compounds available
 - Approved by the IACUC
 - Scientifically necessary
 - There is a schedule of monitoring that allows the detection of adverse events related to the use of non-pharmaceutical grade compounds
 - Issues related to quality assurance such as proper preparation, storage and shelf life have been addressed in the IACUC protocol form
 - These factors would include:
 - Appropriate drug reconstitution, preparation and/or compounding
 - Drug purity, sterility, pH, osmolality, concentration, et cetera
 - Drug safety, efficacy, and shelf-life
 - Site and route of administration
 - Training, experience, and performance of personnel involved in usage
 - Personnel Responsible for monitoring preparation and use
 - Side effects and adverse reactions

*Not all factors may be applicable.

*If the “shelf life” is not obtainable, it is recommended that the drug solution be re-prepared each day it is used.

Regulations: USDA Policy 3 states the following regarding use of non-pharmaceutical grade compounds in animal experimentation:

Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-Pharmaceutical-grade chemical compounds should only be used in regulated animals 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 alone are not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals.

OLAW: May investigators use non-pharmaceutical-grade compounds in animals?

OLAW agrees with the USDA that pharmaceutical-grade¹ chemicals and other substances, 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. However, it is frequently necessary to use investigational compounds, veterinarian or pharmacy-compounded² drugs, and / or Schedule I³ controlled substances to meet scientific and research goals.

Guide for the Care and Use of Laboratory Animals; Eighth edition:

“The use of pharmaceutical-grade chemicals and other substances ensures that toxic and unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures. The use of non-pharmaceutical –grade chemicals or substances should be described and justified in the animal use protocol and be approved by the IACUC; for example, the use of non –pharmaceutical-grade chemicals of substance may be necessary to meet the scientific goals of a project when a veterinary or human pharmaceutical-grade product is unavailable.” pp. 31

¹ 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 \(BP\)](#).

² Veterinary compounding is the customized manipulation of an approved drug by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a research study. ³ United States Department of Justice Drug Enforcement Agency controlled substances Schedule I and II-IV drugs may be used in biomedical research according to the standards of the [Code of Federal Regulations 1301.13](#).
