

**Colorado State University
Institutional Animal Care and Use Committee
(IACUC)**

Policy on the Use of Non-Pharmaceutical-Grade Substances

Background

The use of pharmaceutical-grade substances ensures that toxic or unwanted side effects are not introduced into studies conducted with animals and ensures the health and welfare of the animals.¹ Federal regulations require that investigators use pharmaceutical-grade substances in live animals being used in research and teaching activities whenever they are available, even in acute procedures. Pharmaceutical-grade substances are ones which are approved by the U.S. 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 the British Pharmacopeia (BP).²

Use of Non-Pharmaceutical Grade Substances

However, the administration of non-pharmaceutical-grade (NPG) substances (e.g. investigational compounds, veterinarian- or pharmacy-compounded drugs, or other drugs) may be necessary in order to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is not available. For instance, in studies seeking to test novel compounds, no pharmaceutical-grade compound would be available.

Requirement for IACUC Review of Non-Pharmaceutical-Grade Substance Use

If an NPG substance is used, then the highest grade available should be used. Prior to use, the following types of pharmaceuticals and reagents should be considered in the order presented:

- FDA approved veterinary or human pharmaceutical compounds
- FDA approved veterinary or human pharmaceutical compounds used to compound a needed dosage form
- USP-NF, BP, or other pharmacopeia recognized pharmaceutical-grade substance used in a needed dosage form
- Analytical grade bulk chemical used to compound a needed dosage form
- Other grades and sources of compounds

Additional considerations:

- Chemical properties of the compound should be appropriate for the study and the route of administration
- Method of preparation, labeling (preparation and use-by dates), administration and storage of formulations should be appropriately considered with the aim of maintaining their stability and quality

¹ [Guide for the Care and Use of Laboratory Animals](#)

² [OLAW FAQ F4: May investigators use non-pharmaceutical-grade substances in animals?](#)

The following are considered appropriate scientific justifications for the use of NPG substances; other justifications can be considered by the IACUC:

- Pharmaceutical-grade equivalent of the substance is not commercially available
- No equivalent veterinary or human drug is available for experimental use
- NPG substance is required to generate data that are part of an ongoing study or to generate data that are comparable to previous work
- NPG substance is not commercially available in the appropriate concentration or formulation, or the appropriate vehicle is unavailable
- Equivalent veterinary or human drug does not meet the non-toxic vehicle requirements for specified route of administration

Institutional Endorsement

The “Policy on the Use of Non-Pharmaceutical-Grade Substances” approved by the IACUC on March 25, 2021 for recommendation to the Institutional Official supports the research, teaching, and service mission of Colorado State University, and ensures that the welfare of animal subjects used therein will be protected. Therefore, as the Institutional Official, I declare the IACUC-recommended policy to be the institutional policy of the Colorado State University Animal Care and Use Program.



April 15, 2021

Institutional Official

Date