



University of Maryland College Park Animal Care and Use Standard

Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals

Purpose: This standard describes requirements for the use of non-pharmaceutical grade compounds in animals.

Background: Pharmaceutical Grade Compounds (PGCs) are chemicals, drugs or biologics that are approved by the FDA or for which a chemical purity standard has been established by a recognized foreign or domestic pharmacopeia. These standards help to ensure that the products are of the appropriate chemical purity and quality to ensure stability, safety and efficacy. The use of lower grade chemicals or compounds with higher levels of impurities or poorly formulated non-commercial preparations can introduce unwanted experimental variables or even toxic effects.

The Office of Laboratory Animal Welfare (OLAW) has stated that although the potential animal welfare consequences of complications are less evident in non-survival studies, the scientific issues remain the same as in survival studies and therefore apply to non-survival studies. The use of a non-PGC euthanasia agent must meet the same standards as for use in any other application.

Standards: PGCs (including human and veterinary formulations) are to be used whenever possible. This includes research activities, and when the health and well-being of an animal are at risk such as anesthesia, analgesia, euthanasia and veterinary care. This standard pertains to all components, both active and inactive, contained in the preparation to be administered. The vehicle used to facilitate administration of a compound is as important of a consideration as the active compound in the preparation. Use of non-PGCs must be clearly described and scientifically justified in the Animal Study Protocol (ASP). Cost savings alone is not an adequate justification for using non-PGCs.

Methodology: When the use of non-PGCs is necessary, the following applies:

1. The use of non-PGCs must be scientifically justified in the ASP. Scientific justification may include:
 - a PGC is not available;
 - a PGC is not available in the appropriate concentration or formulation or the appropriate vehicle control is not available; or
 - the non-PGC is required to generate data in a manner consistent with previous studies.
2. The use of non-PGCs in laboratory animals should be clearly described (including the scientific justification) in the ASP. This description, at a minimum, should include the following:
 - method of preparing and storing the drug including methods used to ensure pH, stability and sterility (e.g., buffered, stored in a cooler, stored in a dark container to prevent degradation by light, final product autoclaved or passed through a 0.22 micron filter in a biological safety cabinet, storage in sterile vials with rubber stoppers, etc.); and

- address the grade or purity being proposed (e.g., the highest grade equivalent chemical reagent will be used; a non-toxic vehicle appropriate for the route of administration will be used).