**University of Louisiana at Lafayette**

**Policy and Guidelines for the Use of Non-Pharmaceutical Grade Compounds in Laboratory Animals**

**Introduction**

Study Directors and Investigators are expected to use pharmaceutical grade compounds whenever possible. This policy is based on guidelines presented by OLAW, USDA, and AAALAC International. A pharmaceutical-grade compound is defined as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia, eg. US Pharmacopeia (USP) or equivalent (Note: Everything produced by Sigma/Aldrich is non-pharmaceutical grade). The Food and Drug Administration (FDA) maintains a database listing of FDA approved commercial formulations for both [human](http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm) and [veterinary](http://www.accessdata.fda.gov/scripts/animaldrugsatfda/) drugs. It is important to note that investigational test articles by definition are non-pharmaceutical grade compounds, as these are non-clinical materials manufactured for research purposes. Furthermore, these investigational compounds are not intended for use in humans, until human clinical trials are initiated. Investigational drugs do not have a pharmaceutical grade substitute unless it is a marketed drug used as a control.

**Study Director/Investigator Guidelines**

When compounds are used for the clinical treatment of animals or to prevent or reduce/eliminate animal pain or distress, pharmaceutical grade compounds must be used whenever possible. Although it is preferred that Pharmaceutical Grade Compounds are used in experimental investigation when available, the use of Non-Pharmaceutical Grade may be appropriate to accomplish scientific aims. When Non-Pharmaceutical Grade Compounds are required for study, the compound must be described and a scientific justification must be provided in the Animal Procedure Statement (APS) for review by the IACUC. The IACUC will use the following factors in its review:

1. Scientific justification is provided, such as:
2. A pharmaceutical grade compound is not available.
3. A pharmaceutical grade compound is not available in the appropriate concentration or formulation or the appropriate vehicle control is unavailable;
4. The non-pharmaceutical grade compound is required to generate data that are part of an ongoing study or to generate data that are comparable to previous work.
5. The chemical properties of the compound are appropriate for the study and the route of administration (e.g., the purity, grade, stability in and out of solution, solution vehicle properties, pH, osmolality, and compatibility of the solvent and other components of final preparation). In some cases the reagent-grade of the compound may be as or more pure than the pharmaceutical-grade; and
6. The method of preparation, labeling (i.e., preparation and use-by dates), administration and storage of formulations should be appropriately considered with the aim of maintaining their stability and quality (i.e., to prevent inadvertent co-administration of infectious agents or contaminants).

In all cases, principal investigators and study directors will be expected to use professional judgment to determine the appropriate test material and to ensure use of an agent with the least likelihood for causing adverse effects.

Adopted: June 19, 2014