

Policy Regarding the Use of Non-Pharmaceutical-Grade Compounds in Living Animals

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 [e.g., the U.S. Pharmacopeia (USP), British Pharmacopeia (BP), National Formulary (NF), European Pharmacopoeia (EP), Japanese Pharmacopeia (JP), etc.]. These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy.

The use of non-pharmaceutical-grade compounds often is necessary to accomplish the scientific aims of a research project. In these instances, the IACUC must consider the health and well-being of the animals while aiding the researcher in minimizing potentially confounding experimental variables and maximizing reproducibility of the research. The IACUC distinguishes between two scenarios when considering the use of non-pharmaceutical-grade compounds:

Clinical Use - compounds used for the clinical treatment of animals and to prevent or reduce/eliminate animal pain or distress. Whenever possible, pharmaceutical-grade compounds must be used for anesthesia and analgesia.

Research Use - compounds used to accomplish the scientific aims of the study. If available, and suitable, pharmaceutical-grade compounds are preferred; but when non-pharmaceutical-grade preparations are used, the IACUC and the investigator must consider such factors as purity, sterility, vehicle, stability, pH, osmolality, site and route of administration, potential for adverse effects, and storage.

The IACUC must review and approve the use of non-pharmaceutical grade compounds on a case-by-case basis. The investigator is responsible for describing the use of the compound in sufficient detail that the IACUC can evaluate the potential for pain and/or distress in the research animals on which the product is being utilized. The investigator also is responsible for reporting adverse outcomes that arise from the use of non-pharmaceutical grade products.