PACUC Policy

USE OF NON-PHARMACEUTICAL GRADE COMPOUNDS

It is the policy of PACUC that whenever compounds are administered to animals and whenever pharmaceutical grade compounds are available, they must not be substituted with non-pharmaceutical grade compounds. A pharmaceutical grade compound is a drug, biologic, reagent, etc. which is approved by the FDA or for which a chemical purity standard has been written/established by a recognized pharmacopeia (e.g., USP, NF or BP). Issues such as sterility, pyrogenicity, stability, pharmacokinetics and quality control have usually been addressed during the course of pharmaceutical grade compound production – the same may not be true for substances formulated in your laboratory.

Compounds used for the clinical treatment of animals or used to reduce / eliminate pain or distress must be pharmaceutical grade and used within expiration date unless justified and approved by PACUC.

The above requirements also apply to acute/terminal procedures.

For compounds used to accomplish the scientific aims of a study, if available, pharmaceutical grade compounds are preferred.

For reference please see:
PHS Office of Laboratory Animal Welfare (OLAW) - May investigators use non-pharmaceutical-grade compounds in animals http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4
and
Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) - Non-Pharmaceutical-Grade Compounds http://www.aaalac.org/accreditation/faq_landing.cfm#B9
and
USDA Policy#3 Veterinary Care, Pharmaceutical-Grade Compounds in Research http://www.aphis.usda.gov/animal_welfare/policy.php?policy=3
and