

Use of Non-Pharmaceutical Grade Drugs

Summary/Purpose: To provide guidance in regard to the use of non-pharmaceutical grade drugs in the care and use of Laboratory Animals at the University of Mississippi.

Description:

The following addresses the guidance provided in the APHIS Animal Care Resource Guide, Issue Date March 25, 2011 – Policy # 3 regarding non-pharmaceutical grade compounds in research (http://www.aphis.usda.gov/animal_welfare/policy.php?policy=3).

The Animal Welfare Act (AWA), Public Health Service Policy on Humane Care and Use of laboratory Animals and the Guide for the Care and Use of Laboratory Animals, require that all animals used in research be provided adequate Veterinary Care. The United States Department of Agriculture in their Animal Care policies published in March of 2011 states: “Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures.” To assure that animals used in research and teaching at the University of Mississippi (Oxford Campus) receive adequate Veterinary Care, the Institutional Animal Care and Use Committee has developed the following Policy.

Definition:

Pharmaceutical Grade – meets pharmaceutical standards. There are several criteria by which pharmaceutical grade drugs are judged. Lists of chemical compounds available in pharmaceutical grade can be found in either the human or veterinary PDR.

Non-pharmaceutical-grade compounds can be used only in research/testing activities utilizing animals if reviewed and approved by the IACUC.

The following circumstances must be met for consideration by the IACUC:

1. The research activity requires the use of non-pharmaceutical-grade compounds for reason of scientific necessity.
2. Acceptable veterinary or human pharmaceutical-grade products are not available or are not available in appropriate concentrations. (Most novel compounds are in this category.)
3. Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in animals.
4. For all species, any non-pharmaceutical chemical agents administered parenterally (by injection) in survival studies should be sterile, maintained in a sterile container, and labeled to provide the mixing date, name and concentration of the compound as well as its expiration date. Heat-stable compounds may be sterilized by autoclaving, and those that are not heat stable can be sterilized by microfiltration. The Investigator is responsible for determining the “shelf” life for the compound after being dissolved

in solvent. If the “shelf life” is not obtainable, it is recommended that the solution be prepared each day it is used.

References:

- AWA Section 13
- 9 CFR, part 2, Sections 2.31, 2.32, 2.33, 2.40
- 9 CFR, part 3, Section 3.110

Wolf, et al Frequently Asked Questions About the Public Health Service Policy on Humane Care and Use of Laboratory Animals, Lab Animal, Vol. 32, No.9, p32-36