

Center for Biomedical Research / IACUC Standard Operating Procedure - Guidelines

Use of Non-Pharmaceutical Grade Compounds in Animals

Guidelines:

- Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures.
- Medications and anesthetics/analgesics/euthanasia agents must be pharmaceutical grade.
- All injected compounds and diluents must be sterile when used for survival animal procedures.
- Diluents do not need to be pharmaceutical grade but must be sterile.
- Experimental compounds do not need to be pharmaceutical grade when used in research paradigms, as opposed to being used as therapeutic agents.
- Investigators should consider relevant animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of new variables when using non-pharmaceutical grade compounds.
- Exceptions to these guidelines must be justified and submitted to the IACUC for review and may be granted for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product.
- Cost savings alone are not an adequate justification for using non-pharmaceutical grade compounds in animals.

NOTE: "Recent exorbitant cost increases of pentobarbital have placed it logistically into the unavailable category. Pentobarbital from a reagent or analytical-grade powder, properly prepared by a pharmacist or other knowledgeable individual (e.g., chemist, veterinarian, researcher), with assurance of appropriate storage and handling, and approval by the IACUC, is acceptable." [March 2012 NIH/OLAW Webinar].

If you would like to use non-pharmaceutical grade pentobarbital but were previously approved for only pharmaceutical grade, please submit a Change in Protocol request, including your handling practices and a justification that quotes the pricing of pharm grade pentobarbital.

References:

USDA Animal Welfare Act:

http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy3.pdf

NIH Office of Laboratory Animal Welfare:

<http://grants.nih.gov/grants/olaw/faqs.htm#f4>