Use of Non-Pharmaceutical Agents in Animal Experimentation at the University of Pittsburgh

Regulations: USDA Policy 3 states the following regarding use of non-pharmaceutical grade drugs in animal experimentation:

> *Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical-grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC 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 regulated animals.*

Although the NIH *Guide* does not explicitly discuss the use of non-pharmaceutical compounds in animal research, the NIH Office of Laboratory Animal Welfare has made the following statements about such agents:

> *The use of non-pharmaceutical grade chemical compounds in experimental animals under certain circumstances has been, and will continue to be, a necessary and acceptable component of biomedical research. Their use should be based on:*
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> 1. *Scientific necessity*
> 2. *Non-availability of an acceptable vet*erinary or human pharmaceutical *grade product, and*
> 3. *Specific review and approval by the Institutional Animal Care and Use Committee (IACUC).*
>
> *In preparing and reviewing proposals to use non-pharmaceutical grade products, investigators and IACUCs should consider a number of related animal welfare and scientific factors including safety, efficacy, and the inadvertent introduction of research complicating variables. While issues such as sterility, pyrogenicity, stability, pharmacokinetics and quality control can be assumed to have been addressed during the course of producing pharmaceutical grade drugs, the same can not always be said for substances produced in the research laboratory using non-pharmaceutical grade chemical compounds. Cost savings alone is not an adequate justification for using non-pharmaceutical grade compounds in animals.*

University of Pittsburgh IACUC's Policies Regarding Use of Non-Pharmaceutical Grade Drugs.

In keeping with Federal regulations and policies, the University of Pittsburgh's IACUC has adopted the following standards regarding the use of chemical compounds administered to animals:

1) There is a strong preference that all chemical compounds administered to any animal species be of pharmaceutical grade, if that agent is available in pharmaceutical grade. Lists of chemical compounds available in pharmaceutical grade can be found in either the human or veterinary PDR. Copies of the PDRs are available in the DLAR library.

2) For USDA-regulated species, specific permission must be obtained from the IACUC to administer any non-pharmaceutical chemical compounds. Justification

for the use of non-pharmaceutical agents may include availability of suitable pharmaceutical grade drugs or scientific necessity. Cost in itself is not typically considered an adequate reason to employ non-pharmaceutical chemical compounds.

3) For non-regulated animals (rodents and birds), the IACUC requires that specific permission be obtained to use non-pharmaceutical agents for veterinary therapeutics or relief of pain or distress (including anesthetics, analgesics, sedatives, antibiotics, or paralytics). Justification for the use of non-pharmaceutical agents in these categories may include availability of suitable pharmaceutical grade drugs or scientific necessity.

4) For all species, any non-pharmaceutical chemical agents administered in survival studies must be sterile, maintained in a sterile container, and labeled to provide the 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 drug solution be re-prepared each day it is used.