

UMSL IACUC POLICY

Pharmaceutical-Grade Compounds in Research (USDA Policy #3)

To ensure humane care and proper use of laboratory animals in research, The UMSL IACUC is obligated to provide policies that notify and train personnel concerning the appropriate techniques, equipment, and agents in agreement with the policies and procedures set forth by USDA and OLAW.

USDA policy #3: Pharmaceutical-Grade Compounds in Research is as follows:

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 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.

The 8th Edition of the Guide for the Care and Use of Laboratory Animals and the NIH Office of Laboratory Animal Welfare has issued the following guidance regarding the use of non-pharmaceutical grade 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:*

1. *Scientific necessity,*
2. *Non-availability of an acceptable veterinary or human pharmaceutical grade product, and*
3. *Specific review and approval by the Institutional Animal Care and Use Committee (IACUC).*

Definition:

Pharmaceutical grade compound is any active or inactive drug, biologic, reagent, etc. which is approved by the FDA or for which a chemical purity standard has been written / established by any recognized pharmacopeia (book / compendia) such as the US Pharmacopeia (USP) and the National Formulary (NF).

Procedures:

A. Pharmaceutical Grade Compounds-

- i. Define within the applicable animal use protocol whether or not all compounds being administered to research and teaching animals are pharmaceutical grade.
- ii. Search FDA databases to determine if compounds are pharmaceutical grade,
 - The “Orange Book” is a reference for FDA-approved human drugs.
 - The “Green Book” is a reference for FDA-approved veterinary drugs.
 - Pharmaceutical grade compounds occasionally may not be listed in the Orange or Green book. These compounds should be labeled with a New Animal Drug Application/Abbreviated New Animal Drug Application (NADA/ANADA) or with a National Drug Code (NDC).

iii. UMSL's IACUC considers dilutions and or mixtures of compounds to be equivalent to pharmaceutical grade so long as all ingredients within the solution/mixture are pharmaceutical grade

B. Non-pharmaceutical Grade Compounds

- i. The use of non-pharmaceutical grade compounds in animals must be described and justified in an animal use protocol and approved by the IACUC
- ii. Take precautions to ensure a reasonable degree of safety when preparing and using a non-pharmaceutical grade compound in regards to:
 - (a) Grade
 - (b) Purity
 - (c) Sterility
 - (d) pH
 - (e) Pyrogenicity
 - (f) Osmolality
 - (g) Stability
 - (h) Site/route of administration
 - (i) Compatibility of components
 - (j) Adverse reactions
 - (k) Pharmacokinetics
 - (l) Storage of drug

Applicable To:

All UMSL faculty, staff, employees and students involved in the care or use of animals owned by the UMSL.

Revisions to the Policy:

This policy is intended to be flexible and readily adaptable to changes in regulatory requirements. It is reviewed as part of the semiannual program review to ensure regulatory compliance. The UMSL IACUC has the authority to amend this policy.

References:

- FDA Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>
- FDA Green Book, Animal Drugs: <http://www.accessdata.fda.gov/scripts/animaldrugsatfda/>
- OLAW, FAQs, PHS Policy on Humane Care and Use of Laboratory Animals: <http://grants.nih.gov/grants/olaw/faqs.htm>
- USDA Animal Care Resource Guide Policies, Policy #3, Veterinary Care, Pharmaceutical-Grade Compounds in Research; March 25, 2011: http://www.aphis.usda.gov/animal_welfare/downloads/policy/Policy%20Manual%2003-25-2011.pdf
- United States Pharmacopeia-National Formulary (USP-NF): <http://www.uspnf.com/uspnf/login>
- Brown P, Clarke C, and Newcomer C. OLAW, Educational Resources, "Use of Non-Pharmaceutical-Grade Chemicals and Other Substances in Research with Animals – March 1,

- Cornell University Institutional Animal Care and Use Committee, “ACUP 413 Use of Non-Pharmaceutical Grade Compounds in Animal Research.”
<http://www.research.cornell.edu/care/documents/ACUPs/ACUP413.pdf>
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