University of Louisville
Institutional Animal Care and Use Committee
Policies and Procedures

Use and Labeling of Drug Compounds, Dilutions,and Chronic-Use Fluids

Policy: This policy establishes the standards and expectations regarding the formulation, safety, and efficacy of drug compounds, dilutions, and chronic-use fluids for administration to laboratory animals. This policy does *not* apply to topical applications to fish. The use of adulterated drugs produced by compounding (combining two or more drugs), or by the dilution of drugs can introduce unexpected or even toxic effects, and should be avoided whenever possible. When compounding or diluting agents is necessary, aseptic technique must be employed and sterile, pharmaceutical-grade agents must be utilized. All agents administered to animals, as well as the dose and routes of administration, must be approved on the IACUC *Proposal* prior to use.

Rationale: The Institutional Animal Care and Use Committee recognizes that agents may need to be diluted, or compounded for use in laboratory animals. The stability and efficacy of many adulterated drugs is not well established, and may present risks to animal welfare. It is essential to ensure that all drugs used in laboratory animals are safe and efficacious.

Procedures, Guidelines, and Exceptions:

1. All in-house made compounds and diluted medications must use sterile, pharmaceutical-grade compounds (unless justification has been provided and approved for the use of non-pharmaceutical-grade drugs in a UofL IACUC *Proposal*[5]), must be combined using sterile technique, and must be stored in a sterile vial in a cool place and away from light. Appropriate storage necessitates the use of a secondary containerand methods which maintain sterility yet allow repeat withdrawals (e.g., use of a sterile injection vial with a rubber stopper). Sterile injection vials with rubber stoppers are available for purchase from the Comparative Medicine Research Unit (CMRU). The top of the container should be disinfected with 70% alcohol on clean gauze or cotton prior to accessing with sterile needle and syringe. Alternatively, for single use purposes a ***sterile*** microfuge tube can be used.
2. All adulterated drugs (compounds and dilutions) must be labeled with the drug names, diluent, final concentration of each component, date prepared, expiration date,and the initials of the person preparing the compound. All agents stored within CMRU vivaria must also be labeled with the Principal Investigator's name.

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Example:

Ketamine 10 mg/ml Xylazine 1 mg/ml in sterile saline
Date prepared / / by ____ Expires / /
Mouse dose: K 100 mg/kg and Xylazine 10 mg/kg
Directions: Give 0.2 mls per 20 grams body weight IP Do not redose.

3. All adulterated drugs (compounds and dilutions) must be prepared aseptically and stored in sterile vials and must be discarded within 30 days of preparation or the expiration date of the original stock, whichever is earlier.
    a. In the case of published data indicating a particular cocktail is stable for longer than 30 days, that published time period may be used provided the reference is readily available at all times.
4. Fluid bags (ex: NaCl, LRS) for chronic use must be labeled with the date opened/date of first puncture and discarded within 30 days of opening/first puncture. All fluids stored within the Comparative Medicine Research Unit (CMRU) vivaria must also be labeled with the Principal Investigator's name.
5. Fluid bags with added agents must be labeled to indicate any agents added. If agents are light sensitive, bags should be protected from direct light exposure using black plastic bags or other means. Fluids with added agents must be discarded according to the expiration of the added agent or within 30 days of opening/puncturing the fluids whichever comes first. All fluids/agents stored within the Comparative Medicine Research Unit (CMRU) vivaria must also be labeled with the Principal Investigator's name
6. If compounds or dilutions display cloudiness, particulate matter, or bacterial/fungal growth, they must be discarded immediately and not used for animal procedures.
7. If drugs, compounds, dilutions or fluids are found within the CMRU vivaria without appropriate labelling, they will be discarded by CMRU staff as they are found or the IACUC during inspections.
8. All substances should be discarded in compliance with the Department of Environmental Healthand Safety standards. Contact DEHS to arrange for proper disposal of controlled and hazardous substances (https://louisville.edu/dehs/contact-us).

References

1. Taylor BJ, Orr SA, Chapman JL, and Fisher DE . J AALAS 48:718-726, 2009.
2. Papich MG. Drug compounding for veterinary patients. AAPS J 7:E281–E287, 2005.
3. Kohn DF, Benson GJ, Wixson SK, White WJ. Anesthesia and Analgesia in Laboratory Animals;Academic Press, New York, 1997; Chapter 15.
4. Matthews KA and Taylor DK. Assessment of Sterility in Fluid Bags Maintained for Chronic Use. JAALAS 50:708712, 2011.
5. UofL IACUC Policy "Use of Pharmaceutical Grade Medications and Outdated Drugs or Supplies" https://louisville.edu/research/iacuc/policy-files/UseofPharmGrade