Georgia State University  
Institutional Animal Care and Use Committee (IACUC)  

It is the responsibility of the Georgia State University (GSU) Institutional Animal Care and Use Committee (IACUC) to ensure judicious and humane use of animals used in its teaching and research programs that is consistent with federal requirements.*

Use of Non-Pharmaceutical Grade Substances (Injected Substances)

The use of pharmaceutical-grade substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals and ensures the health and welfare of the animals. One Federal regulations require that investigators use pharmaceutical-grade substances in live animals being used in research and teaching whenever they are available, even in acute procedures. Pharmaceutical-grade substances are ones which are approved by the U.S. Food and Drug Administration or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary or the British Pharmacopeia.

It is understood that the administration of non-pharmaceutical-grade substances may be necessary in order to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is not available. For instance, in studies seeking to test novel compounds, no pharmaceutical-grade compound would be available. In addition, it is recognized that, in some cases, the available human or veterinary drug is not concentrated enough to meet experimental requirements. The use of non-pharmaceutical-grade substances should be based on 1) scientific necessity, 2) non-availability of an acceptable veterinary or human pharmaceutical-grade compound, and 3) specific review and approval by the IACUC. Cost savings is not a justification for using non-pharmaceutical-grade compounds.

Preparation of Non-Pharmaceutical Grade Substances

- Filtering - filter through a 0.2μm membrane filter
- pH - the pH should be between 6.8-7.4.
- Osmolarity – the final solution should be isotonic, with an osmolarity around 300 mOsm.
- A sterile diluent should be used (e.g. sterile physiological saline or other appropriate diluent)
- The substance should be stored in a sterile injection vial, following standard sterility practices
- The injection vial must indicate the name of the substance(s), the concentration(s), the date of compounding, and the date of expiration.
- Regarding date of expiration, please note the following**:  
  - Single substances: The date listed on the original bottle or box or 30 days from the date of compounding, whichever occurs first  
  - Mixtures of substances: The earliest date listed on the original bottle or box of any substance or 30 days from the date of compounding, whichever occurs first. Multiple-dose injectable vials should not be used if they contain particulate matter, precipitates, turbidity, or discoloration.
• Sterile fluids (with no drugs added after opening) that are intended to be accessed multiple times to obtain small volumes for administration and drug mixing can be used for 30 days beyond initial opening if accessed in an aseptic manner.

** Please note that, when one compounds pharmaceutical substances (e.g. as occurs when one mixes substances together and/or dilutes the substance(s) from the standard concentration(s) then the duration of efficacy of the compounded substance is unknown and this also presents concerns regarding sterility over time (e.g. due to the dilution of preservatives). Accordingly, the above expiration parameters have been established by the GSU IACUC.-

• Multiple-dose injectable vials should not be used if they contain particulate matter, precipitates, turbidity, or discoloration.

References

Pertinent Regulations*
U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
Public Health Service Policy
Guide for the Care and Use of Laboratory Animals
Animal Welfare Act (AWA) and AWA Regulations

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Signature IACUC Chair: 
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