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IG005: USE OF NON-PHARMACEUTICAL GRADE SUBSTANCES IN RESEARCH

Investigators are required to use pharmaceutical-grade substances* whenever they are available, to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and/or interfere with the interpretation of results. Cost savings alone are not an adequate justification for not using pharmaceutical-grade compounds in animals.

The IACUC is responsible for evaluating the potential adverse consequences of **non-pharmaceutical grade substances** when used for research. Non-pharmaceutical grade chemical substances can only be used in animals after specific review and approval by the IACUC for reasons such as scientific necessity, investigational need, pharmacy-compounded materials or unavailability of an acceptable veterinary or human pharmaceutical-grade product.

Drugs that are **non-pharmaceutical grade** should be identified on the animal use protocol. The use of non-pharmaceutical grade compounds must be scientifically justified. In addition, if non-pharmaceutical grade compounds are to be used, the PI should take precautions to maintain aseptic conditions and the drugs should be:

- of the highest purity available
- adjusted to ensure a pH level as close to neutrality as possible
- constituted in a filtered sterile solution for administration to the animal
- kept in a sterile, sealed container after constitution until expiration date (see below)
- administered using sterile techniques to avoid unintended contamination

The expiration date of non-pharmaceutical grade substances will be the manufacturer's date printed on the label/package for materials. For dilutions, preparations, reconstitutions or mixtures of drugs or fluids prepared using sterile technique and under proper storage conditions, **an expiration date of six (6) months from the date of preparation, or the earliest expiration date for any single component (if < 6 months)**, is recommended unless otherwise scientifically justified in the protocol. An item is considered expired the day *after* the month or date indicated on the label.

(Example: Item labeled Aug. 2025 would be considered expired on Sept. 1, 2025)

**Pharmaceutical-grade substance: any active or inactive drug, biologic, reagent, etc., manufactured under Good Manufacturing Practices (GMP) which is approved, conditionally approved, or indexed by the Food and Drug Administration (FDA) or for which a chemical purity standard has been written or established by a recognized compendia (e.g., United States Pharmacopeia-National Formulary; USP (<https://www.uspnf.com/>), British Pharmacopeia (<https://www.pharmacopoeia.com/>)).*

For additional information see Section F. Animal Use Management, Question #4: [National Institutes of Health Guidance and FAQs](#)