



University of Michigan Policy On The Use of Non-Pharmaceutical Grade Drugs

The *Guide for the Care and Use of Laboratory Animals*, the Office of Laboratory Animal Welfare (OLAW), and the United States Department of Agriculture (USDA) all state that pharmaceutical-grade chemicals, biologics and other substances, when available, must be used in laboratory animals¹⁻⁴. This includes anesthetics, analgesics, and any substances administered experimentally, and apply to non-survival as well as long-term studies.

To meet this requirement, the use of **non-pharmaceutical grade substances** in animal-based research requires **prior IACUC approval** and must be based on either:

- (1) Unavailability of an acceptable veterinary or human pharmaceutical-grade compound
- (2) Scientific necessity

Additional factors the *Guide* and OLAW state that must be addressed include:

- (1) Stability, potency, and sterility of formulation;
- (2) The storage and preparation procedures;
- (3) How expiration or beyond use dates will be determined.

By definition, a pharmaceutical grade substance is an FDA-approved veterinary or human drug. A database is available at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>. **NOTE:** Drug compounds sold by chemical manufacturers (e.g., Sigma-Aldrich®) are typically reagent grade and **NOT** pharmaceutical grade.

Any non-FDA approved substance is therefore considered to be non-pharmaceutical grade and requires justification in the IACUC application. These substances are available in a spectrum of quality and consistency. The following order of choice should be applied:

- (1) Drug compounded from an FDA-approved drug or an active pharmaceutical ingredient manufactured in conformance with current Good Manufacturing Practice and meeting United States Pharmacopeia/National Formulary/British Pharmacopeia (USP/NF/BP) standards. This includes drugs acquired from a Pharmacy Compounding Accreditation Board or FDA-registered compounding pharmacy.
- (2) USP-grade chemical or substance used to formulate a needed dosage form (e.g., electrolytes, amino acids, DMSO, dextrose, or methylcellulose powder).
- (3) Non-pharmaceutical grade or non-USP grade compounds: (e.g., analytical, or reagent grade chemicals, such as those from Sigma-Aldrich®; peptides; or oligonucleotides used to compound or formulate a needed dosage form).

NOTE: Dilutions or formulation modifications to an FDA-approved veterinary or human drug or biologic also require IACUC approval to ensure safety, efficacy, proper storage, and assignment of expiration dates.

For additional information on the rationale behind these guidelines, aspects to be considered in scientific justification, additional definitions of terms, and the list of references, please see the supporting document: [Additional Information for PIs and Committee Members regarding Non-Pharmaceutical Grade Drugs](#).