



Animal Facility SOP 27.2 Pharmaceutical Drugs

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I. Purpose

This document describes guidelines for use, preservation, and disposal of pharmaceutical drugs in the BSSC Vivarium. These procedures will ensure adequate safety of staff, visitors, and researchers in the BSSC Vivarium.

II. Scope

Researchers are expected by regulatory authorities to use pharmaceutical grade compounds whenever possible. This document references the policies and guidelines of the major animal research oversight organizations.¹⁻⁶

III. Definitions

1. A pharmaceutical-grade compound (PGC) is defined as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by a recognized national or regional pharmacopeia (e.g., the U.S. Pharmacopeia (USP), British Pharmacopoeia (BP), National Formulary (NF), European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), etc.). These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy. The Food and Drug Administration (FDA) maintains a database listing of FDA approved commercial formulations for both FDA approved human drugs (the Orange Book) and veterinary drugs (the Green Book). Researchers must have authorization before use of non-pharmaceutical drugs

2. Availability: Refers to compounds that are commercially available from an active U.S. vendor.

3. New investigational compound: A compound supplied by its manufacturer for testing in an experimental setting only and for this reason would not have chemical purity standards established and by default is considered a *non-pharmaceutical-grade compound*.

IV. **Requirements:** When compounds are used for the clinical treatment of animals or to prevent or reduce animal pain or distress, PGCs must be used whenever possible.² When compounds are used to accomplish the scientific aims of the study PGCs must be used if available and suitable. ²

V. Responsibility

1. The facility manager monitors and documents use of Pharmaceutical drugs prescribed by the veterinarians Dr. Matthew Terzi, Dr. Julie Watson.
2. The Principal Investigator or his/her designee monitors and documents use of drugs that are part of an approved protocol.
3. All drugs used in the vivarium will be cataloged in the SDS folder kept in Tech room (116R) and online on the BSSC Vivarium Google Drive. Controlled drugs will be stored in a locked cabinet in the BSSC Vivarium along with a controlled drug use log.
4. PGCs must always be used when available. Use of non-pharmaceutical grade drugs is only permissible as part of an approved protocol where there are no alternative PGC's available. Cost savings alone is not an adequate justification for the use of Non-PGCs
5. When non-pharmaceutical grade compounds are used as part of a study precautions should be taken to ensure sterility and accurate dosage.

VI. Authorized Pharmaceutical Drugs for use in BSSC

Requisition of controlled pharmaceutical drugs must follow the [Access to Controlled Substances for Animal Care and Use SOP](#). The following pharmaceutical drugs have been accepted for use in the BSSC Vivarium. Pharmaceuticals must be either prescribed by the veterinarian or included in the approved ACUC protocol. Ketamine and buprenorphine are controlled drugs and must follow the controlled drug policy.

- Ketamine (injectable)
- Xylazine(injectable)
- Acepromazine(injectable)
- Buprenorphine (injectable)
- Isoflurane(gaseous anesthetic)
- Tobramycin (ophthalmic antibiotic)
- Triple antibiotic ointment (ophthalmic antibiotic)

References:

1. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care, Animal Care Policy Manual, [Policy #3 Veterinary Care](#), March 14, 2014. 2. AAALAC [Frequently Asked Questions: C. Institutional Responsibilities 9. Non-Pharmaceutical-Grade Compounds](#) 3. [OLAW Position Statement- Non-Pharmaceutical-Grade Substances](#) 4. [Transcript of OLAW On-line Seminar broadcast on March 1, 2012 - Use of Non-](#)

Pharmaceutical-Grade Chemicals and Other Substances in Research with Animals 5.
Transcript of OLAW [On-line Seminar broadcast on June 4, 2015](#) - Regulatory
Considerations for Using Pharmaceutical Products in Research Involving Laboratory
Animals 6. OLAW [Frequently Asked Questions – PHS Policy on Humane Care and Use of
Laboratory Animals, F. Animal Use and Management, 4. May investigators use
non-pharmaceutical- grade substances in animals?](#)