

STANDARD OPERATING PROCEDURES
DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

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TITLE:	Test and Control Articles
SCOPE:	All GLP Testing Facility Personnel
RESPONSIBILITY:	All GLP Testing Facility Personnel, Study Sponsor
PURPOSE:	To Outline the Methods of Receipt, Identification, Storage, Handling and Disposition of Test and Control Articles for Use in Nonclinical Laboratory Studies.

I. PURPOSE

1. To outline procedures to ensure the identity and integrity of each test and control article are maintained through proper handling, storage, retrieval, and disposition procedures designed to protect the integrity of the test and control articles and the study data.

II. RESPONSIBILITY

1. It is the responsibility of the sponsor and/or Testing Facility Management of a nonclinical laboratory study to appropriately define and document the characteristics of test and control articles as to identity, strength, purity, composition, stability, and methods of synthesis, fabrication, and/or derivation for each batch.
2. The Director of the GLP Testing Facility (e.g., Center for Advanced Medical Learning & Simulation, CAMLS CEO) must identify an individual who is responsible for the receipt, storage, distribution, disposition, and maintaining documentation of the aforementioned, for all test and control articles when maintained by the testing facility.
3. All GLP testing facility staff contributes to the successful compliance with this policy.

III. PROCEDURES

1. When the GLP Testing Facility (e.g., CAMLS) is responsible for maintaining test and/or control articles for a study, the sponsor shall provide, in writing, instructions for test and control article handling and storage to the GLP testing facility prior to the receipt of the test and control articles, and in advance of the initiation of the study, to ensure the appropriate methods of handling, and conditions of storage are in place to maintain the identity, strength, purity, and composition of the test and control articles, when applicable.

2. Storage containers of test and control articles are labeled so that they clearly identify their contents and when applicable should include the name, chemical abstract or code number, batch number, and expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the article. Storage containers shall be assigned to a particular test article for the duration of the study.
3. Storage, distribution, and sampling of all test and control articles will be in a manner designed to preclude the possibility of contamination, deterioration, or damage to the article.
4. The receipt and distribution of each batch of test and control articles are documented to establish chain of custody, and shall include the date and quantity of each batch distributed or returned.
5. Proper identification of all test and control articles is maintained throughout the distribution process.
6. Reserve samples are retained for the period of time provided by Title 21 CFR Part 58.195 when studies of more than 4 weeks duration are conducted.
7. Where any of the components of the test and control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one compound has an expiration date, the earliest date shall be shown.

Approved:

Date: