MASS GENERAL RESEARCH INSTITUTE
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Labeling Guidelines and Recommended Expiration Dates for Research Drugs and Agents

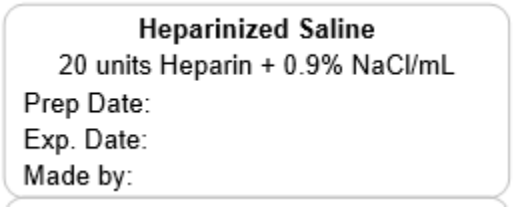
The purpose of this document is to provide guidance to researchers on the labeling and storage requirements when making reconstitutions, dilutions, or combinations of agents that will be administered to animals in research.

Labeling guidelines for each container include:

- Contents
- Concentration
- Date of reconstitution/preparation
- Expiration date
- Initials of preparer

Example 1: Controlled substances

Example 2: All other substances



Recommended shelf life/expiration date

Follow these guidelines unless the original label or packaging indicates something different.

- **Unopened drugs or agents in the original packaging:** expiration/use by date printed on the label or packaging
- **Opened multi-dose vials/bags of injectables**: a multi-dose vial/bag that has been opened or accessed (e.g., needle-punctured) should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial/bag.
- **Aliquots:** expiration date/use by date printed on the label or packaging of stock material.
- **Reconstituted solutions:** expiration date/use by date/instructions printed on the label or packaging. Reconstituted solutions must be stored under the conditions described in the packaging.
- **Dilutions:** discard 28 days after preparation
- **Mixtures / formulations:**
  (Note: any mixture that becomes clouded or precipitates should not be used in animals)
  - 28 days after preparation, sooner if the mixture becomes clouded or precipitates.
  - If the stability of an agent in formulation is unknown, prepare fresh prior to each use.

Definitions:

Aliquots: material transferred to secondary containers, and not diluted or mixed.
Reconstituted solutions: medication supplied in powder form mixed with liquid before administration.
Dilutions: stock material mixed with diluent/vehicle to produce required concentration.
Formulation: different chemical substances, including active drug, combined to produce a final product.
Diluent/vehicle: carrier or inert medium used as a solvent (or diluent) in which the medicinally active agent is formulated and or administered.

Recommended Storage Containers

All aliquots, dilutions, and formulations should be prepared using aseptic procedures and should be stored in sterile containers.

For drugs or agents that will be prepared and used on the same day, sterile screw cap vials or tubes like the ones pictured below may be used.

If drugs or agents will be used for more than one day, a sterile container with a rubber septum should be used. An additive free Vacutainer is an acceptable alternative.