

WVU IACUC Guidelines: Multi-Dose and Mixed-Substance Container Labeling, Use and Expiration Dates

Purpose

To describe how to properly label and use multi-dose and mixed-substance containers in order to prevent administering outdated or contaminated substances (i.e. drugs, biologics or reagents) to an animal that could have a negative impact on their health and /or wellbeing.

Definitions

Containers: include vials, bottles, bags (such as intravenous fluids), etc.

Multi-dose container: contains more than one dose of a substance. Drugs provided from manufacturer in multi-dose container typically contain agents to limit bacterial growth. *Example: 100 mL bottle of antibiotic drug.*

Single-dose vial: Labeled for single use by the manufacturer and is intended to not be maintained for extended period of time. If container states single use only, bacteriostatic agents are not present and special attention **must** be given to maintaining sterility of that compound.

Mixed-substance container: contains two or more active substances, mixed for convenience of administration. *Example: vial containing two anesthetic drugs, mixed so they can be administered in one injection; or diluted compounds.*

Secondary container: An alternative container which was not the original provided by the manufacturer. Commonly used when mixing or diluting compounds. All secondary containers used for compounds **must** be sterile and appropriate to prevent contamination of the compound.

Expiration date given by manufacturer as MONTH/YEAR: substance expires on the last day of that month.

Procedures

1. Single- Dose Containers (manufacturer):
 - a. It is best practice to use single dose compounds only once and then discard. Repeated use may result in contamination of the product.
 - b. If necessary, to maintain a single dose vial for multiple uses:
 - The open date should be written on the container.
 - Care **must** be taken to prevent contamination of the product.
 - c. Discard vial/bag 30 days after opening or immediately, if it becomes contaminated. *Any exception to this requirement **must** be requested and justified in the protocol.*
2. Multi-Dose Containers (manufacturer):
 - a. Container **must** be labeled with the date of first use or puncture. In order to indicate the meaning, this date should be labeled using the term “**Opened-on**”.
 - b. Some compounds (e.g., Rimadyl, Buprenorphine SR/XR, antibiotics) will have an abbreviated expiration date once the vial is punctured and opened (e.g. expires 30 days after opening).
 - The updated expiration date **must** be written on the vial using term “**Expiration**” or abbreviation “**Exp**”.
3. Mixed-Substance and Secondary Containers:
 - a. In some cases, compounds may need to be diluted or mixed with other compounds in a secondary container prior to administration.
 - b. All mixed substances **must** be labeled to indicate the name of the substance(s), the concentration(s), the date on which the container was mixed, and the date of expiration or the use-by date.

- c. The expiration date of all compounds used to mix **must** be evaluated prior to use.
 - d. All compounds **must** be sterile if they are to be used for parenteral administration. *Any exception to this requirement must be requested and justified in the protocol.*
 - e. Regardless of the manufacturer's expiration date, all mixed substances **must** be discarded 30 days from the date mixed. Label this date using the term "**Expiration**" or the abbreviation "**Exp**".
 - If the expiration date given by the manufacturer comes before that 30 days, label the container with whichever expiration date comes first.
 - f. Syringes
 - Compounds drawn up for immediate use do not require the syringe to be labeled.
 - Compounds drawn up ahead of time into syringes for use at a later timepoint **must** be labeled as indicated above.
 - ***Consider concerns with compound interactions with syringe material and light exposure if using this practice.***
4. Container handling practices:
- a. Prior to use, clean the septum or stopper on the container with a 70% isopropyl alcohol wipe, and let air dry for 10 seconds prior to piercing.
 - b. Use the smallest gauge needle possible and limit the number of entries.
 - c. Use a new needle and new syringe for each entry.
 - d. Do not leave open needles in the septum or stopper, to prevent contamination.
 - e. Discard if substance or sterility is compromised or questionable.
 - f. Discard container or replace label if it becomes illegible or is missing.

Reference

Adapted from: United States Pharmacopeia (USP) General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* (last revised 2008).