

Policy on Labeling and Dating of Compounded Pharmaceuticals

This document establishes the policy of the IACUC regarding pharmaceutical agents, including anesthetics and analgesics, that are commonly diluted, mixed, or aliquoted when used for work involving research animals at the University of Kentucky. Specific research requirements that deviate from this document must receive IACUC approval prior to initiating.

Policy

If drugs are placed in a container other than that supplied by the manufacturer (including addition to a container with other pharmaceuticals), or are altered by diluting or mixing, the new container must be labeled with the name of the substance(s), the concentration(s), and an expiration date.

If there is published data on the expected time of efficacy for a given drug combination or an expiration date is provided by the compounding pharmacy at which the compounded material was prepared, that anticipated expiration date must be used. The expiration date of mixed preparations for which published data is not available must be the earliest expiration date of the component drugs or 30 days from the day of mixing, whichever occurs first.

If there are any signs of a mixture being compromised, then it must be **discarded immediately**.

For Example:

Unanticipated change in color.

Abnormal precipitate or signs of vial/container contamination.

Loss of efficacy.

Approved and Adopted by the IACUC:
July 15, 2020