Purpose

To give clear guidance on the determination of the beyond use date (BUD) and availability of compounded medications.

Definition

Beyond use date (BUD) means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

Procedure

1. Non-sterile compounded drug preparations, the BUD shall not exceed any of the following:
    a. the shortest expiration date or BUD of any ingredient in the compounded drug preparation,
    b. the chemical stability of any one ingredient in the compounded drug preparation,
    c. the chemical stability of the combination of all ingredients in the compounded drug preparation,
    d. 180 days for non-aqueous formulations,
    e. 14 days for water-containing oral formulations, and
    f. 30 days for water-containing topical/dermal and mucosal liquid and semi-solid formulations.
2. Sterile compounded drug preparations, the BUD shall not exceed any of the following:
    a. the shortest expiration date or BUD of any ingredient in the sterile compounded drug preparation,

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b. the chemical stability of any one ingredient in the sterile compounded drug preparation,

c. the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

d. the BUD assigned for sterility in section 1751.8.

3. Extension of a BUD is only allowable when supported by the following:

a. Method suitability test,

b. Container closure integrity test, and

c. Stability studies

4. In addition to (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

5. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

6. Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

a. such ingredients cannot be used for any non-sterile compounded drug preparations more than three (3) years after the date of receipt by the pharmacy.

b. such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

7. Where any sterile compounded drug preparation was compounded either outside of an ISO Class 5 PEC or under conditions that do not meet all the requirements for any of the subdivisions, the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

8. Sterile injectable single-dose medications

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a. BUD within one hour when punctured in an environment with air quality worse than ISO Class 5.

b. Within six (6) hours when needle punctured in an environment with ISO Class 5 or better air quality.

c. If the puncture time is not noted on the container, the container must immediately be discarded.

9. Sterile injectable multi-dose medications. BUD is 28 days from initial opening or puncture unless otherwise specified by the manufacturer and stored according to the manufacturer's specifications.

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