

- **CCR 1735, regarding the possible exemption from the definition of compounding the mixing of ingredients from an FDA kit.**

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a compounded drug preparation from chemicals or bulk drug substances

(b) "Compounding" does not include any of the following:

- (1) The reconstitution of a drug pursuant to a manufacturer's direction(s), ~~nor does it include~~
- (2) The sole act of tablet splitting or crushing, or of capsule opening, ~~or~~
- (3) The addition of flavoring agent(s) to enhance palatability
- (4) The combining of nonhazardous ~~ingredients~~ FDA-approved medication from prepackaged kits supplied by a FDA-registered manufacturer for a topical or oral preparation completed in conformance with the manufacturer's instructions.

- **CCR 1735.1(e)(1), regarding pressure differential.**

(1) For nonhazardous compounding a minimum positive pressure differential of 0.02- ~~to 0.05-~~ inch water column relative to all adjacent spaces is required.

- **CCR 1735.1(r), regarding the board's definition of "hazardous drug."**

(r) Until ~~July-December 1, 2018~~2019, "Hazardous" means all anti-neoplastic agents identified by the National

Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge. Effective ~~July-December 1, 2018~~2019, "hazardous" means any drug identify by NIOSH and that exhibit as at least one of the following six criteria:

- (1) Carcinogenicity
- (2) Teratogenicity of developmental toxicity
- (3) Reproductive toxicity in humans
- (4) Organ toxicity in low doses in human or animals
- (5) Genotoxicity
- (6) New drugs that mimic existing hazardous drugs in structure or toxicity.

- **CCR 1735.2(a), regarding the requirement to document a prescriber's authorization to compound a product.**

~~(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.~~

- **CCR 1735.2(i)(2)-(4), regarding the BUD for sterile drug products.**

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

- (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
- (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) For compounded drug preparations not sterility tested ~~The the~~ beyond use date assigned for sterility in section 1751.8, and -
- (E) For compounded drug preparations that are sterility tested in accordance with section 1751.8 the beyond use dates in section 1735.2(i)(1)(D)(E)

(3) Extension of a beyond use date is only allowable when supported by the following:

- (A) Sterility testing that incorporates method suitability testing in accordance with USP Chapter <71>, ~~Method Suitability Test,~~
  - (B) Container Closure Integrity Test, and
  - (C) Stability ~~Studies~~Research and Analysis
  - (D) A pharmacist, using his or her professional judgment may establish an extended date as provided in (A), (B), and (C), if the pharmacist researches by consulting and applying drug specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation and research, analysis and conclusion. The factors the pharmacist must analyze include:
    - (i) the nature of the drug and its degradation mechanism,
    - (ii) the dosage form and its components,
    - (iii) the container in which it is packaged,
    - (iv) the expected storage conditions, and
    - (v) the intended duration of therapy.
- Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(4) In addition to the requirements of paragraph three (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.

- **CCR 1751.4(d), regarding where decontamination needs to occur.**

(d) Cleaning shall be done using a germicidal detergent ~~and sterile water~~. The use of a sporicidal agent is required to be used at least monthly. When hazardous drugs are being compounded decontamination with an inactivating agent shall take place before each cleaning. Any dilution of the germicidal detergent, sporicidal agent, or inactivating agent shall only be done with sterile water.

- **CCR 1751.4(d)(1), regarding the frequency of cleaning.**

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least every 48 hours, when open and daily when compounding, and at minimum must be cleaned each day prior to compounding. ~~at least daily~~. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters

- **CCR 1751.7(e)(1), regarding the allowance of alternative testing methods.**

*(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant unless a validated rapid microbial method (RMM) test is performed an alternative testing method is performed that results in at least as effective and reliable as the USP chapter 71 compliant sterility testing, per USP chapter 797, and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. Validation studies (method suitability) for each formulation using ~~a RMM test~~ an alternative testing method shall be kept in a readily retrievable form at the licensed location. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic, ~~and~~ inhalation preparations, and irrigation solutions.*

- **Adding new definition of batch**

"Batch" means more than 25 units.

- **Deleting CCR 1735.1(n), regarding the definition of "dosage unit"**

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.