THE BOARD OF REGISTRATION IN PHARMACY

ADVISORY ON LEVELS OF NON-STERILE COMPOUNDING

The Board of Registration in Pharmacy (The Board) defines simple, moderate, and complex non-sterile compounding as follows:

**Simple non-sterile compounding**: Making a preparation that: (1) is the subject of a United States Pharmacopeia (USP) compounding monograph; or (2) appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs. (USP <795>)

**Please note carefully, the Board does not consider reconstitution of commercially available FDA approved preparations to be “compounding.”**

**It is highly recommended that pharmacies maintain a reconstitution log for the preparation of commercially available products (e.g., antibiotic suspensions, erythromycin-benzoyl peroxide gel, etc.) If utilized, any flavoring agents should be recorded either on this log or a compounding log.**

Examples of simple non-sterile compounding (non-inclusive):

- allopurinol oral suspension
- captopril oral solution
- ursodiol oral suspension
- coal tar ointment
- some commercially manufactured prescription compounding kits (i.e. vancomycin compounding kit)

**Moderate non-sterile compounding**: Making a preparation that requires special calculations or procedures to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. (USP <795>)

**The Board considers the preparation of suppositories and troches to be complex compounds as these preparations require special equipment and training.**
Examples of moderate non-sterile compounding (non-inclusive):

- mixing two or more commercially manufactured creams, ointments, or liquids when the stability of mixture is unknown (i.e. Magic or Miracle Mouthwash)
- topical preparations intended for local effects
- omeprazole suspension when mixed from capsules or active pharmaceutical ingredients (API) since a pH meter is required
- preparations requiring special calculations (e.g. salt conversions like valproic acid to sodium valproate)

**Complex non-sterile compounding**: compounding of drug preparations which require special training, a special environment or special facilities or equipment or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient. (MGL 112 section 39D)

Examples of complex non-sterile compounding (non-inclusive):

- NIOSH drug containing preparations or other hazardous agents (does not include simple reconstitution of commercially available FDA approved products if prepared as directed by the manufacturer)
- radiopharmaceutical preparations
- transdermal dosage forms
- capsules
- suppositories
- troches
- lollipops
- sublingual dosage forms
- tablets
- tablet triturates
- modified-release preparations
- other dosage forms intended to deliver systemic effects (inserts, nasal sprays, nasal irrigations, certain gels, etc.)

Non-sterile compounding regulation 247 CMR 18.00:

Compounding definition MGL c. 112 section 39D:
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section39D

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