A Simple Introduction to

Compounding

Many students studying for the Pharmacy Technician Certification Exam forget about this crucial component.
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Introduction to Compounding

There are two types of Compounding:

- **Extemporaneous** – The preparation of a medication or dosage form that is not commercially available (by manufacturers).
- **Sterile** – The preparation of any dosage form that is intended to be used as a sterile dosage form (for injections, or ocular use)

In this E-Book, we’re going to focus on Extemporaneous (Non-Sterile) compounding governed by USP 795 Guidelines.

*Why do Pharmacies compound medications?*

- **Children and the Elderly:** Many people have great difficulty swallowing a tablet or capsule, Pharmacy personnel can compound an alternative dosage form for them – Suspension or Cream.
- **Veterinary Use:** Many animals will refuse traditional dosage forms of medications. The compounding of creams and ointments to apply on vascular regions (like the inside of an ear) is common.
- **Flavoring:** Even if a dosage form is acceptable for a child or animal, quite often the taste will prevent them from accepting a medication. For instance, cats prefer the taste of fish, we can dissolve a tablet in a type of *fish slush*, that is irresistible for cats.
Guidelines

USP 795

The United States Pharmacopeia provides guidelines for good Pharmacy Practice by Pharmacy Personnel when compounding a medication that will be used by both humans and animals.

USP 795 governs the practice of Non-Sterile Compounding, some highlights are below:

• **Beyond Use Dating:** The date in which a compounded prescription should not be used, determined by the dosage form and date that the compound was prepared. (exact dating on the next page)

• **Compounding Facility Requirements:** Equipment, Heating, Ventilation, Water Used, Lighting, and Medication Storage.

• **Documentation:** Formulation Records, Compounding Records, Standard Operating Procedures, & Material Safety Data Sheets.

• **Quality Control:** Check and Re-Check every procedure at every stage in the process to ensure the product compounded is done so in a manner consistent with the formulation record.

• **Compounding Personnel Requirements:** The compounding is responsible for adhering to any and all local, state, and federal requirements, as well as preparing medications in the same strength, quality and purity as the prescription order requires.

• **Labeling:** The compound must be labeled with the Medication Name, Strength, Beyond Use Date, Date Compounded, Appearance, and assigned lot number consistent with the formulation record.
Beyond Use Dating

• No Beyond Use Date should be assigned that exceeds the expiration date of the Active Pharmaceutical Ingredients (API) involved in the compound.

• If the compound has been submitted for testing, the beyond use date (as a result of the test) may be used in place of the information below.

• The Beyond Use Date must be made conservatively, meaning that the earliest date must be chosen.

<table>
<thead>
<tr>
<th>Non-Aqueous Solutions</th>
<th>Water Containing Oral Formulations</th>
<th>Water Containing Topical and Semisolid Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months OR The earliest expiration date of any API in the compound</td>
<td>14 days at refrigerator temp. OR The earliest expiration date of any API in the compound</td>
<td>30 days OR The earliest expiration date of any API in the compound</td>
</tr>
</tbody>
</table>
Techniques: Trituration, Levigation, & Ungulation

The three most common techniques performed during Extemporaneous Compounding are Trituration, Levigation and Ungulation.

**Trituration:** The grinding of solid dosage forms in a mortar using a pestle, reducing particle size. Commonly used when creating solutions, suspensions, creams, ointments, and pretty much any dosage form that begins with tablets or capsules.

**Levigation:** The wetting of pure powders or triturated powders in the preparation of almost every semi-solid or liquid dosage form.

**Ungulation:** The creation of an ointment or cream by distributing the active ingredient within a base. This can be accomplished with an Ungulator or an ointment slab.
Topical Dosage Forms
Creams, Lotions, & Ointments

In order to create any topical dosage (semisolid) dosage form:
1. Weigh/Measure all of the ingredients
2. Triturate any solid dosage forms reducing to a fine powder.
3. Levigate all powders using a wetting agent such as Aloe Vera or Glycerin.
4. Add the Levigated powders to the topical base (ex. Vanicream)
5. Blend the mixture together with an Ungulator or using an ointment slab.
When creating a liquid dosage form:
1. Weigh/Measure all of the ingredients
2. Triturate any solid dosage forms reducing to a fine powder.
3. Levigate all powders using a wetting agent such as Polyethylene Glycol or Glycerin.
4. Add the Levigated powders to the liquid medium 
   Ex. 1:1 Ora-Plus & Ora-Sweet
5. Blend the mixture together with an Magnetic Spinning Plate and Magnetic Spinner.

Magnetic Spinning Plate with Spinner in action
Packing Capsules

The process to pack capsules is quite involved. This specific process utilizes the Pro-Fill Capsule Filling System®:

1. Pour 50+ capsules onto Orientor and shake back and forth moving capsules into slots.
2. Lift gate and pour off excess capsules.
3. Open Filler locking plate and place the Orientor locating feet in the holes on the Filler marked "I".
4. Push the sliding portion of the Orientor to the left to drop capsules into the Filler.
5. Remove Orientor. Capsules are in every second row of the Filler.
6. To fill remaining rows, repeat steps 1-4 except this time align the Orientor locating feet in the holes marked "II".
7. Close the Filler locking plate and slide clamp to secure. Squeeze the cam lever to secure capsule bodies in the Filler.
8. To separate capsules, press palms down on Filler handles while lifting capsule tray up with fingers. After separation, release cam lever to drop capsule bodies flush with Filler.
9. Place powder tray* on Filler using locating pins and pour out pre-measured powder.
10. Use the powder spreader to move powder so it falls into the capsule bodies. Push excess powder onto reservoir.
11. Use tamper to compress powder into the capsule bodies. Spread the remaining powder from reservoir into bodies. All the bodies are now filled. Remove powder tray*.
12. Place capsule tray back onto Filler. To lock capsules, push down on locking plate with thumbs while pulling up on lifting plate (not visible) with fingers.
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