Tips & Hints for Quality Compounding - Part III

**GOALS AND OBJECTIVES**

**Goal:** To provide tips and hints in the practice of pharmaceutical compounding that may save time, money and contribute to a more efficient workplace.

**Objectives:** After reading and studying the article, the reader will be able to:

1. Discuss the methods available to maintain the integrity of empty and filled gelatin capsules.
2. Describe some methods to enhance the effectiveness and compliance using quick dissolving tablets.
3. Discuss the advantages of a gel-cream over simpler gels or creams.
4. List precautions and procedures involved in packaging, labeling and shipping of compounded preparations.
5. Describe quality assurance practices and counseling activities that can aid the pharmacist to become more efficient and effective.

This is the third issue of *Secundum Artem* covering various tips and hints that can be used by compounding pharmacists. The first appeared in Volume 5 Number 1 (covering solutions, suspensions, emulsions, ointments, creams, pastes, gels, lotions-emulsion-type, powders, capsules, ophthalmics, suppositories, troches/lozenges, flavoring/coloring) and the second appeared in Volume 15 Number 4 (covering the facility, equipment, ingredients, procedures, sterile preparations, beyond-use dates, preservation, sterilization and depyrogenation). These are available for download at [www.perrigo.com/rx](http://www.perrigo.com/rx).

This issue will cover tips and hints involving tablets, capsules (additional tips), lollipops, gummy bears, patches, sticks, gel-creams, pastes (additional tips), otics, nasals, packaging and labeling, shipping and distribution, patient counseling and administration, sweeteners and quality assurance practices.

**Tablets**

- See also Vol. 5 Number 1 Tips and Hints on Powders, Capsules as some apply to Tablets.

**General**

- In working with tablet compositions, passing the blended powder through a sieve will aid in breaking up clumps, etc.
- For faster formulation development, determine the volume per tablet mold multiplied by the number of tablets to be prepared. Weigh the materials that are of fixed weight and place in a graduated cylinder. Add the desired diluent material to the calculated volume in the graduated cylinder; mix, check the volume again and adjust if necessary. Prepare the tablets. Check their final weights.

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**Disclaimer**

The content and opinions of this article are those of the author and are for educational purposes only. Although the material is based on review of multiple sources of information, it is not all inclusive of information available. Readers should review and consider other publications and materials on this topic and not rely solely upon the information in this article.
Sintered Tablets

Comp ressed Tablets available from different supply companies and will therefore empty capsules.

pH due to static electricity, which can generally be corrected by dehumidifier and conditioning and cooling if needed. If the preparation is made, then it can be cut into calibrated square space or stumped out using a calibrated "cutter" in various shapes.

A few small numbers of tablets, prepared then individually using a single punch machine and filling each portion individually.

For larger numbers of tablets, can be prepared using the heat and placing the powder in the bobber for a complete run.

Capsule (Additional Information)

The major cause of capsules, or other problems with capsules is generally traced to improper moisture loss or gain during storage or shipping to the fina- ginal packaging.

In an environment, empty gelatin capsules are often protected from moisture or from ex- posure to large variations in relative humidity by packaging in food grade antiseptic plastic bags inside daily-dosing carriages.

Ziploc® containers are great for skimming empty capsules, as they are easy to open and close. But when they are filled, keep capsules separated, closed and in a cool dark place.

"Tupperware®" also a good storage container for empty capsules.

It is generally best to dissolve the drug in a minimum of water-miscible or oil-miscible as this is important for the final container.

If using a microw ave, only use the "carousel applica- tion to Lollipops.

Use sucrose or other sweetener that increases the final concentration of the sugar.

When working, mixing, containers, soften the paste using low heat to aid in pouring into the final container.

Measure specific amounts of a paste for applications, a small calibrated bowl-scoop.

Some powders can be poured into a cylinder, molded and slurred into thin waters for application.

Gel-Creams

Fill capsules with liquid (such as gelatin suspension, etc.) and pour into capsules, then seal the final preparation as "drops" or "sprays".

Nasal preparations are generally solutions, suspensions, or solutions.

Sometimes a spray bottle can be converted for sterile preparations of other forms.

If a longer beyond-use date is needed for a compounded preparation, the pharmacist and the patient to remove one at a time to prevent mixing.

In nose drops, the drug should be considered as a nasal spray.

Sweeteners

Sweetener solutions can be used to transform bad-tasting drugs into acceptable preparations.

Dilution can help increase the preparation viscosity of a less desirable or residence time in the mouth.

If using a microw ave, only use the "carousel applica- tion to Lollipops.

The patient of whether the otic dosage form is compounded preparation.

Patient counseling should involve instructions to the patient to report any untoward or unexpected effects of the formulation.

Shipping and Distribution

Designate an area in the pharmacy for sterile preparation administration. A program of caregiver training; if possible, use "models" or actual examples.

Surveillance should include instructions to the patient for proper handwashing, aseptic technique, and the proper handling and disposal of the preparation.

If any device is used, proper use, care, cleaning and maintenance should also be discussed.

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  - Capsules are emphasized as the drug state to be used in the compound preparation.
  - The main advantage of capsules is that they can be made into various shapes and sizes.

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Capsules(AdditionalInformation)

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teration to nasals.
Use videotapes or DVDs that are commercially available.
Develop your own counseling aids, as appropriate.
Patient Advisory Leaflets must be developed cautiously as these may be used in the event of any litigation that may occur in the future.

Quality Assurance Practices

- One can start slow with a quality testing program and build as experience is gained.
- Start with basic techniques of weighing, volume determinations, pH, observation and supplement with outsourced testing. Incorporate more methods in the pharmacy as experience is gained.
- All personnel engaged in compounding must be adequately and thoroughly trained.
- Keep documentation of all training in personnel files.
- Incorporate and update SOPs for all procedures and equipment in the pharmacy.
- Document all activities as required in the SOPs of the pharmacy.
- Dilutions, concentrates and triturations should be tested for accuracy as they impact many preparations compounded from them.
- The compounding should develop an SOP of what to test, when to test, what methods to use, how to interpret the results, the limits of the tests, and what to do when a preparation is outside accepted limits.
- All equipment must be checked out and verified before use.
- When using an outsourced laboratory, it should be checked out using “split-samples” and other procedures.
- Select an analytical laboratory that is FDA registered and inspected.
- Samples should be obtained and handled properly for testing either in-house or if outsourced.
- All testing results should be filed for future reference. If outside of accepted limits, an explanation of the problem and corrective actions taken should be included.

Miscellaneous

- Take care with packaging organic solvents, strong acids, or caustic agents in dropper bottles with rubber tips…the rubber will deteriorate with potential loss and/or contamination of the contents.
- Geometric addition/dilution is the method of choice for incorporating active ingredients in a vehicle.
- When working with aqueous systems, use the minimum amount of heat for as short a time period as appropriate to minimize water loss and potentially, drug loss.
- To use as long a beyond-use date as possible, keep the preparation anhydrous.

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