



Secundum Artem

*Current & Practical Compounding
Information for the Pharmacist.*

General “Good Compounding Practices” for Nonsterile Products

INTRODUCTION

Pharmacists are the only health professionals formally trained in the art and science of compounding medications. Consequently, they are expected to possess the knowledge and skills necessary to compound extemporaneous preparations. The percentage of compounded prescriptions represented 11% of all prescriptions dispensed in 1994 (Drug Topics, July 10, 1995), which is a great increase over the 1970s and 1980s. It is evident that the need for individualized drug therapy for patients has been realized and is resulting in patient-specific prescriptions and the compounding of medications that are not commercially available.

Accompanying this increase in compounded prescriptions is the need for Good Compounding Practices to guide the compounding activities of pharmacists and pharmacist-supervised personnel. The purpose of this edition of *Secundum Artem* is to provide some general guidelines as Good Compounding Practices for Nonsterile Products. Many states have modified and adopted state-specific Good Compounding Practices developed by the National Association of Boards of Pharmacy (NABP). Further pharmacists engaged in the compounding of drugs must operate in conformance with applicable state law regulating the practice of pharmacy.

Compounding is an integral part of pharmacy practice and is essential to the provision of health care. Compounding can be simple, such as the addition of a liquid to a manufactured drug powder; or complex, such as the preparation of a multicomponent parenteral nutrition solution. Compounding basically differs from manufacturing in that compounding involves a specific practitioner-patient-pharmacist relationship, a relatively small quantity of medication prepared, and the conditions of sale (specific prescription order).

The pharmacist is responsible for compounding preparations of acceptable strength, quality, and purity with appropriate packaging and labeling in accordance with good pharmacy practices, official standards and current scientific principles. Pharmacists should expand their compounding knowledge continually through participation in seminars, literature study, and consultation with colleagues.

A few general guidelines should be mentioned before beginning the specific detailed discussion.

- Pharmacists may compound, in reasonable quantities, drug products that are commercially available in the marketplace based upon the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription.
- Pharmacists may compound over-the-counter medications in commercially-available dosage forms or in alternative dosage forms to accommodate patient needs.
- Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products dispensed at the pharmacy.
- Pharmacists should not offer compounded medications to other pharmacies for resale; however, a practitioner may obtain compounded medication to administer to patients but it should be labeled with the following: “For Office Use Only”, date compounded, “beyond-use” date, and name, strength and quantity of active ingredients.
- Compounding pharmacists/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services. (Currently, pharmacists should not solicit business by promoting the compounding of a specific drug product).

Other activities related to compounding and communications are involved; in general, the pharmacist may:

1. Present the fact that prescription and over-the-counter compounding services are provided. These services may be, but are not limited to: chemicals, devices, and alternative dosage forms.
2. Provide drug searches on specific chemicals in different dosage forms, strengths, bases, etc., to accommodate physicians’ specific needs.
3. Provide follow-up information as a result of a practitioner’s request of information regarding a compounded medication.
4. Have discussions with practitioners regarding a particular dosage form when discussing services with a health care provider.

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DEFINITIONS

Compounding is the preparation, mixing, assembling, packaging, and/or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

Manufacturing is the production, preparation, propagation, conversion and/or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

FACILITY

Pharmacies engaging in compounding should have a designated area with adequate space for the orderly placement of equipment and materials to be used to compound medications. The compounding area for **sterile drug products** should be separate and distinct from the area used for the compounding or dispensing of **non-sterile drug products**. The area(s) used for the compounding of drugs should be maintained in a good state of repair and in a clean and sanitary condition. It should be free of infestation by insects, rodents, and other vermin.

The compounding area should be free of dust-collecting overhangs such as ceiling pipes, hanging light fixtures, and ledges. The actual work area should be level, smooth, impervious, free of cracks and crevices, and non-shedding. Surfaces should be cleaned at the beginning and completion of each compounding operation. The entire compounding area should be cleaned daily or weekly but not during the process of compounding. Prior to each compounding activity, pharmacies engaged in occasional compounding should prepare an area adequate for the safe and orderly compounding of the prescriptions received.

Bulk drugs and other materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or under proper refrigeration as required. Drugs should be removed from cartons and boxes before being stored in the compounding area.

Adequate lighting and ventilation should be provided in all drug compounding areas. Potable water should be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, other than restrooms, must be easily accessible to the compounding area(s) of the pharmacy. These facilities should include, but not be limited to, hot and cold water, soap or detergent and air-dryers or single-source towels. Trash should be held and disposed of in a timely and sanitary manner. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) should be disposed of in a safe and sanitary manner.

PERSONNEL

The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription and compounding practice.

Pharmacists should possess education, training, and proficiency properly and safely to perform compounding duties at the level with which they are involved. All pharmacists who engage in compounding of drugs should be proficient in the art and science of compounding and should maintain proficiency through current awareness and continuing education.

Personnel engaged in the compounding of drugs should wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, or hand or arm coverings, should be worn as necessary to protect drug products from contamination. A clean laboratory jacket generally is considered appropriate attire for nonsterile compounding procedures. Work with hazardous materials, such as chemotherapeutic agents, may require the use of goggles, gloves, masks/respirators, double gowns, foot covers, and the availability of showers and eyewash stations.

Only personnel authorized by the pharmacist-in-charge should be in the immediate vicinity of the drug compounding operation. Any person with an apparent illness or open lesion(s) that may adversely affect the safety or quali-

ty of a drug product being compounded should be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel to not jeopardize the safety or quality of the product(s) being compounded. All personnel who assist the pharmacist in compounding procedures should be instructed to report to the pharmacist any health condition that may have an adverse effect on drug products.

Instruction for compounding pharmacists should include, but not be limited to, the following:

1. Proper use of compounding equipment such as balances and measuring devices, including guidelines for selecting proper measuring devices, limitations of weighing equipment and measuring apparatus, and the importance of accuracy in measuring.
2. Pharmaceutical techniques needed for preparing compounded dosage forms (*i.e.*, comminution, trituration, levigation, pulverization by intervention, and geometric dilution).
3. Properties of dosage forms to be compounded and related factors such as stability, storage considerations, and handling procedures.
4. Literature regarding stability, solubility, and other physicochemical properties of the ingredients.
5. Handling of nonhazardous and hazardous material in the work area, including protective measures for avoiding exposure, emergency procedures to follow in the event of exposure, and the location of Material Safety Data Sheets (MSDSs) in the facility.
6. Use and interpretation of chemical and pharmaceutical symbols and abbreviations in medication orders and in product formulation directions.
7. Pharmaceutical calculations review.

EQUIPMENT

The pharmacist is responsible for the equipment in the compounding process. A suggested equipment list was published in *Secundum Artem* (Volume 4, Number 3). Equipment used in the compounding of drug products should be of appropriate design, adequate size, and suitably located to facilitate operations for the dosage forms to be prepared. It should be of a neutral and impervious composition so that components, in-process materials, or drug products will not react with, add to, or be absorbed by it in such a way that the safety, identity, strength, quality, or purity of the drug product is altered beyond the desired composition.

Equipment and utensils used for compounding should be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the desired results. Clean equipment and utensils must be protected from contamination prior to use. Immediately prior to compounding operations, all equipment must be inspected by the pharmacist and determined to be suitable for use.

If drug products which require special precautions to prevent contamination are involved in a compounding process, appropriate precautions must be taken to prevent cross-contamination. These include dedication of equipment for the operations or meticulous cleaning of the contaminated equipment.

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems that will perform a function satisfactorily may be used in the compounding of drug products. If such equipment is used, it should be routinely inspected, calibrated or checked to assure proper performance. The maintenance of the equipment should be documented.

Balances:

In addition to Class A torsion balances, many compounding pharmacies also have electronic balances, most with a capacity of about 300 g and a sensitivity of about 1 mg. Balances should be situated in areas of low humidity and placed on flat, nonvibrating surfaces away from vents, fans, and other currents of moving air. The performance of the balances should be checked at least monthly and the performance documented.

Measuring Equipment:

In addition to the customary measuring equipment consisting of graduated cylinders, pipets, calibrated syringes, etc., it is becoming more commonplace to use micropipets for measuring very small quantities of liquids. Micropipets should be checked frequently to determine their accuracy in the volume of liquid delivered. This can be accomplished easily by weighing the volume of Purified Water delivered onto a tared receptacle on a balance. Their performance should be documented. Ordinarily, two or three pipets can cover the range of about 10 μ L to about 5 mL.

INGREDIENT SELECTION

Pharmacists should receive, store, and use drug substances for compound-

ing that meet official compendial requirements. If this is not possible, then pharmacists should use professional judgment to procure alternatives, such as analytical reagent (AR), or certified American Chemical Society (ACS) grades. If a desired substance is not an official preparation or substance, additional information, such as a certificate of analysis, should be obtained by the pharmacist to ensure its suitability by comparison with general USP/NF standards. It is the responsibility of the pharmacist to select the "most appropriate" quality of chemical for compounding. USP/NF would be the first choice; if it is not available, descend the list of purity grades using professional judgment and discretion to choose the appropriate source.

Chemicals should be stored according to the manufacturers' directions or the USP/NF monographs, generally in tight, light-resistant containers at room temperature. Temperature requirements for storage of substances are detailed in the USP/NF. The temperatures of the storage areas, including refrigerators and freezers, should be monitored and recorded at least monthly. Flammable or hazardous products should be stored appropriately in safety storage cabinets and containers which are available from many laboratory suppliers.

THE COMPOUNDING PROCESS

Questions to be considered prior to compounding a prescription include the following:

1. What are the physical and chemical properties and medicinal and pharmaceutical uses of the drug substance?
2. Is the quantity and quality of each active ingredient identifiable?
3. Will the preparation and route of administration, provide adequate absorption, either locally or systemically, according to the purpose of the prescription?
4. Are any excipients present from any source (manufactured products) that may be expected to cause an allergic reaction, irritation, toxicity, or an undesirable organoleptic response from the patient?
5. For orally administered products, are the active ingredients stable in the normal gastric pH range or are they subject to extensive hepatic first-pass metabolism?

The compounding process may include the following steps:

1. Judging the suitability of the prescription in terms of its safety and intended use and the dose for the patient.
2. Performing the calculations to determine the quantities of the ingredients needed.
3. Selecting the proper equipment and making sure it is clean.
4. Donning the proper attire and washing hands.
5. Cleaning the compounding area and the equipment, if necessary.
6. Assembling all the necessary materials/ingredients to compound and package the prescription.
7. Compounding the prescription according to the Formulary record or the prescription, according to the art and science of pharmacy.
8. Checking, as indicated, the weight variation, adequacy of mixing, clarity, odor, color, consistency and pH.
9. Entering the information in the compounding log.

10. Labeling the prescription.
11. Signing and dating the prescription, affirming that all the indicated procedures were carried out to ensure uniformity, identity, strength, quality, and purity.
12. Cleaning and storing all equipment.
13. Cleaning the compounding area.

Continuous Quality Improvement:

The pharmacist reviews each step in the compounding procedure to assure accuracy, and completeness before dispensing the prescription to the patient. The steps to be reviewed include a (1) preparatory step (2) final check, and (3) sign off by the pharmacist. A pharmacist may also use professional judgment and discretion to complete analytical testing of the dissolution rates and concentrations of compounded medications.

The preparatory step includes, but is not limited to:

1. Appropriate ingredients, adjuvants, and equipment selected for the specific preparation.
2. Correct calculations.
3. Accurately performed measurements using properly functioning equipment.
4. Appropriate formulation for the intended use and stability limits of the preparation.

The compounding step includes, but is not limited to:

1. Accurately following and documenting procedures and techniques used in preparing the product.
2. Obtaining a reasonably esthetic product and ensuring content uniformity.

The final check includes verifying that:

1. The calculated yield is consistent with the actual yield.
2. The tolerance for individual dose weight variation has been met by a sampling technique when appropriate (*i.e.*, capsule weight).
3. The physical characteristics (clarity, color, odor, etc.) of the preparation are consistent with those predicted for the preparation.
4. Physical tests were performed when appropriate and the preparation meets those test limits.
5. The preparation is suitably labeled and the contents have been verified with the prescription order. All legal requirements have been imprinted on the label and in the compounding record.
6. The preparation is suitably packaged for patient use and a container has been selected which will protect the preparation from undue environmental exposure at least until the "discard after" date.
7. There is documentation as listed in the section entitled "Records and Reports".
8. Patient or caregiver has been adequately informed about ways to identify obvious evidence of instability in the compounded preparation.
9. The preparation is labeled with explicit storage and administration instructions.

Analytical testing may include:

1. Additional tests, assays, or visual observations of samples of the preparation to assure the content, stability, pH, etc.
2. The pharmacist may use an analytical testing laboratory to perform testing of certain processes or products that are compounded. This does not include each and every prescription that is compounded by that process,

but testing of "samples" that have been compounded.

PACKAGING AND STORAGE

The pharmacist should inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process. Materials used in the compounding of drugs should be handled and stored in a manner consistent with contamination avoidance and prevention. These materials should be stored off the floor, preferably on shelves in a clean environment.

Compounded preparations should be packaged in containers meeting USP standards. The container employed depends on the physical and chemical properties of the compounded preparation and the intended use of the product.

Materials used should not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the specifications for an acceptable product. Materials, ingredients and supplies should be rotated to use the oldest stock first. Packaging specifications as described in the current edition of the USP/NF should be consulted and followed. If no expiration date is provided on the chemical/materials used, a system of monitoring should be provided, such as placing the date of receipt of the materials on the label of the container.

To help maintain potency, materials used for packaging should not interact physically or chemically with the product. Container characteristics of concern include inertness, visibility, strength, rigidity, moisture protection, ease of reclosure, and economy of packaging. Plastic containers have increased in popularity and use because they are less expensive and lighter in weight than glass. Only plastic containers meeting USP/NF standards should be used.

Labeling should be done according to state and federal regulations. Usually, this includes the generic or chemical name of the active ingredients, the strength or quantity, pharmacy lot number, beyond-use date and any special storage requirements. When a commercial drug product has been used as a source of the drug, only the generic name of the drug product should be used on the label, not the proprietary name. Inactive ingredients and vehicles should also be listed on the label. The use of specialty "coined" names or short names for convenience should be discouraged. This can cause difficulty in emergency rooms in case of an overdose, accidental poisoning, or for health professionals treating the patient who require knowledge of the patient's medication. When preparing batch quantities of products, a lot number should be assigned and should be placed on the labels. If extra labels are prepared but not used, they should be destroyed.

CONTROLS

The pharmacist should review all compounding records for accuracy and conduct in-process and final checks to assure that errors have not occurred in the compounding process. Written procedures for compounding of drugs should be available and followed to ensure the identity, strength, quality, and purity of the finished product. Such procedures should include a listing of the ingredients, quantities, order of mixing/preparation and a detailed description of the compounding process. The equipment and utensils should be listed as well as the container/closure packaging system. Information concerning stability and compatibility should be included, as well as any documentation related to the product.

Ingredients should be weighed, measured, or subdivided accurately as indicated. These operations should be checked and rechecked by the compounding pharmacist at each step in the compounding process to ensure that the correct weight or measure is obtained.

Written procedures (Standard Operating Procedures, SOPs) should be available describing tests or examinations to be conducted on the finished product. The tests could include physical examination, pH determinations, weight, volume, etc. These procedures are established to monitor the output of the compounding pharmacy and to validate the performance of those compounding processes that may cause variability in the completed drug product.

LABELING OF EXCESS PRODUCTS

If excess product is prepared or if quantities of product are prepared in anticipation of prescriptions within a reasonable time, written procedures should be available for the proper labeling of the excess product. Included should be the complete list of ingredients, preparation date, the assigned expiration date, appropriate testing/published data, and control numbers. The product should be stored and inventoried to help ensure its strength, quality, and purity. At the completion of the compounding process, the excess product should be examined once more for correct labeling and contents.

STABILITY, EXPIRATION, AND BEYOND-USE DATING

The USP/NF defines "stability" as the "extent to which a dosage form retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of its preparation". There are five types of stability described in the USP/NF: chemical, physical, microbiological, therapeutic, and toxicological. A number of factors influence stability, including the properties of each ingredient, environmental factors (temperature, light humidity, air), particle size, pH, properties of water and other solvent used, nature of the container and the presence of other substances resulting from contamination or purposeful mixing of ingredients.

"Discard after" dating is a period determined during which a compounded product may be usable after dispensing. This period should be based on available stability information and reasonable patient needs with respect to the intended drug therapy. When a commercial drug product is used as a source of active ingredient, its expiration date often can be used as a factor to determine "discard after" dating. When determining "discard after" dating, a pharmacist may consider:

1. The nature of the drug and its degradation kinetics.
2. The container in which it is packaged.
3. The expected storage conditions to which the preparation may be exposed.
4. The expected length of therapy.
5. The expiration date of similar commercial products for guidance, if the active ingredient is a USP or NF product.
6. Published literature.
7. The manufacturer, if no information is available.

The beyond-use date assigned to a specific product should be based upon the following:

1. Physical and chemical properties of the ingredients.
2. Use of preservatives and/or stabilizers.
3. Dosage form prepared.
4. Storage conditions.
5. Scientific, laboratory or reference data.

The assignment of a beyond-use date is a very difficult activity. All the available stability information should be consulted and a conservative estimate made for the product. General guidelines that may be considered are as follows:

1. When a manufactured commercial product is used as the source of the active ingredient, the beyond-use date should be no more than 25% of the manufacturer's remaining expiration date or six months, whichever is less.
2. When a USP or NF pure chemical is used, no more than six months, for dry products.

*In cases that do not fall within the guidelines above, use 30 days or the intended period of therapy, whichever is less.

The compounding pharmacist must avoid formulation ingredients and conditions that could result in a subpotent product, leading to poor clinical results. A knowledge of the chemical reactions by which drugs degrade often provides a means of establishing conditions under which

the rate of degradation is minimized. At all steps in the compounding, dispensing and storage process, the pharmacist should observe the compounded drug preparation for signs of instability.

All compounded products should be observed periodically for signs of physical instability, including observations for microbiological and fungal contamination for all products that do not have preservatives in their formulas. If large quantities of any one product are legitimately prepared, it may be advisable to conduct potency and stability assays on the product to provide the compounding pharmacist with the assurance of product potency to the assigned beyond-use date.

RECORDS AND REPORTS

Pharmacists should maintain at least four sets of records for compounding.

Formulation Record (Master Control Record):

The formulation record provides a consistent source document for preparing the formulation, a "recipe", and the compounding record documents the actual ingredients in the preparation and the person responsible for the compounding activity.

The formulation record is a recipe file. It lists the name, strength, and the dosage form of the preparation, the ingredients and their quantities, calculations regarding dilutions/aliquots, equipment needed to prepare the preparation and mixing instructions. Mixing instructions include the order of mixing and any other environmental conditions that should be monitored, such as the temperature, duration of mixing, etc. An assigned "beyond-use" time, dispensing container, storage requirements and any quality control procedures must be included. When formulas originate from published articles, copies of these should be duplicated and attached to or filed with the written procedures. Computerized records are appropriate. Records should be in sufficient detail that preparations can be duplicated.

Compounding Record:

The compounding record contains the name and strength of the compounded preparation, the formulation record reference for the preparation and the sources and lot numbers of the ingredients used in the preparation. It also must include information such as the total number of dosage units compounded, the name of the person preparing the product, the name of the pharmacist approving the preparation, the date of preparation, the assigned internal identification number, an assigned beyond-use date, and the prescription number. The results of the quality control procedures should also be recorded, *i.e.*, weight range of filled capsules.

A summary of example contents of compounding records for two different situations follows:

- A. Compounding records for products prepared in anticipation of orders:
 1. Date of preparation.
 2. Facility lot number.
 3. Manufacturers' lot numbers and expiration date of all components or source if no number is available.
 4. Complete formula, including complete methodology and necessary equipment.
 5. Signature or initials of the pharmacists or supportive personnel performing the compounding function.
 6. Signature or initials of the pharmacist-supervisor.
 7. Package size and the number of units prepared.
 8. Documentation of the Quality Control procedures used.
 9. Criteria used to establish the "beyond-use" date.
- B. Compounding records for products prepared on individual prescription:
 1. Date of preparation.
 2. Complete formula.
 3. Signature of pharmacist or supportive person performing the compounding function.
 4. Signature or initials of the pharmacist responsible for supervising the supportive personnel and conducting in-process and final checks of the compounded products if supportive personnel perform the compounding function.
 5. Quantity in units of the finished products or grams of raw materials.
 6. The package size and the number of units prepared.
 7. Documentation of performance of quality control procedures. These are not necessarily required if two or more commercially available oral liquids are mixed, or the products are intended for external use.

Equipment-Maintenance Records:

Equipment-maintenance records include documentation of checks of balances, refrigerators, freezers, mixers, and all equipment. Equipment files should be organized and routinely updated. Calibration check records should be maintained documenting the performance of the equipment. Refrigerator and freezer thermometers should be checked and documented routinely. Temperatures should be recorded on a regular basis to document the performance of these pieces of equipment.

Ingredient Records:

Records of ingredients purchased should include certificates of purity or certificates of analysis for chemicals and Material Safety Data Sheets (MSDSs). There should be an MSDS file for any bulk drug or chemical substance located in the pharmacy. MSDSs should be requested from the chemical supplier and kept on file in the pharmacy. Employees should be instructed as to the location of the file and its format.

Records and reports should be retained for the period of time indicated in state laws and regulations for the retention of prescription files. All records and reports should be readily available in the pharmacy for authorized inspection during the retention period. These records should be retained as original hard copy, true copies such as photocopies, microfilm, microfiche, or other accurate reproduction of the original records. Computerized records also can be utilized.

PATIENT COUNSELING

Compounded prescriptions provide an excellent opportunity for patient counseling and to explain to the patient that this particular prescription has been prepared especially for him/her. If further steps are required prior to administration, this should be explained in detail to the patient, as well as the other items on which patients routinely are counseled.

REFERENCE LIBRARY

Compounding pharmacists must have ready access to reference materials on all aspects of compounding. This may involve on-site books, reprints, journals, etc. as well as telephone access to information from a compounding or drug information center. Computer access also is acceptable.

A suggested minimal library includes at least the following items:

- Remington's *Practice of Pharmacy*
- Secundum Artem*
- Pharmaceutical Dosage Forms and Drug Delivery Systems* (Allen, Popovich, Ansel)
- Pharmaceutical Calculations* (Stoklosa, Ansel)
- Handbook of Pharmaceutical Excipients*
- American Hospital Formulary Service: *Drug Information*
- Martindale's *The Extra Pharmacopoeia*
- The Merck Index*
- USP PHARMACIST' PHARMACOPEIA
- USP-DI

Specific reference to the following USP Reference monographs:

- <41> Weights and Balances
 - <661> Containers
 - <671> Containers — Permeation
 - <795> Pharmaceutical Compounding - nonsterile preparations
 - <797> Pharmaceutical Compounding - sterile preparations
 - <1176> Prescription Balances and Volumetric Apparatus
 - <1191> Stability Considerations in Dispensing practice
- Compounding monographs as they are published in the USP/NF.

Information contained herein is a general guide. Pharmacists should consult applicable state laws and regulations for specific requirements of their respective practice settings.

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