



Secundum Artem

Current & Practical Compounding
Information for the Pharmacist.

PHARMACY COMPOUNDING EQUIPMENT

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INTRODUCTION

The "tools of the trade" for most professions have changed over the years. Physicians are now using computers, laser light, high technology communications systems and biotechnology-derived drug products; lawyers are extensively using computers and large database search methods in the courtroom and pharmacists are using computers for such applications as dispensing, patient monitoring, patient counseling, drug preparation activities, high technology communications, access to data bases and drug delivery (pumps).

As one observes the changes that have occurred over the past 25 years in the delivery of medical and pharmaceutical care, it is evident that the equipment and supplies that are handled on a daily basis have changed. It is also notable that in many state boards of pharmacy regulations, changes are being made to reflect current practice activities, especially as they apply to the preparation of drug products.

As one looks at change in pharmacy, it becomes apparent that the rate of change is increasing, especially with new technology. New methods and techniques must be learned and mastered as they replace older ones. However, many time-honored methods and techniques are still valuable and appropriate today and should be maintained as long as they are useful and contribute to patient therapy. It is imperative, as one looks at current and future practice activities in pharmacy, to be cognizant of the role that computerization and robotics play. These will impact counseling, drug utilization review, medication management and dispensing activities. As

pharmacists, it is important to know what equipment is available, how to use and maintain it, and to be aware of changing responsibilities and opportunities in health-care. As long as there is drug therapy, pharmacists must be involved in the preparation and/or provision and appropriate use of the product to meet the specific needs of the patient. This is especially true for the newer and biotechnology-derived medications and for providing patient-specific products which must be compounded.

PURPOSE

The purpose of this issue of Secundum Artem is to describe the different types of equipment and supplies that are now available for the compounding of drug products. Obviously, this will not be a complete list as there are differences in practices of pharmacy throughout the U.S. and many of these require different equipment and techniques. The intent is to present the more common items and to present novel uses for alternative equipment.

HISTORICAL REVIEW

Historical records reveal that apothecaries began by using very simple equipment and tools. Common dosage forms included ointments, oils, powdered extracts from plants, etc. Mortars and pestles were common, as were knives and axes for obtaining the plants and plant parts. Other equipment included mixing vessels and drying tables. Later, processes such as distillation and extraction were introduced, resulting in more complex equipment requirements.

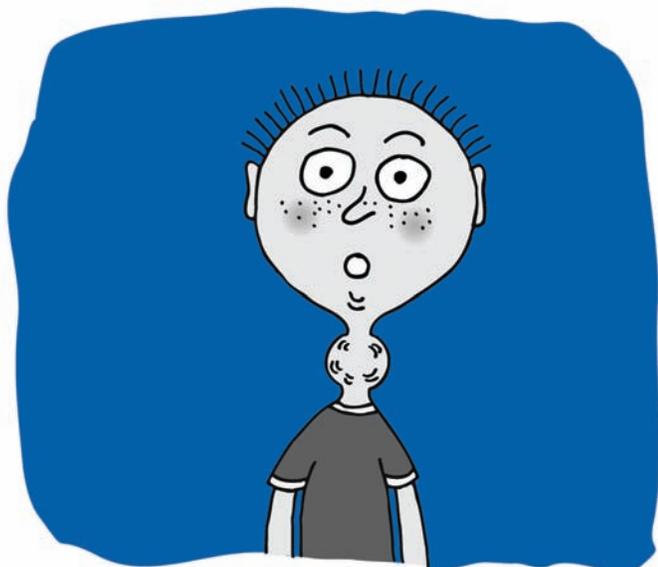
Equipment used by pharmacists for compounding during the 1940s, 1950s and 1960s was basic, consisting of mortars and pestles, beakers, conical graduates, prescription balances, hot plates, refrigerators, pill tiles and spatulas. During the 1970s, with the advent of pharmacist's responsibility for intravenous

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Pharmacists are becoming involved in a higher level of technology-based pharmacy.

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admixture services, additional equipment was introduced into the pharmacy, including laminar flow hoods, aseptic transfer devices/pumps and sterile filtration units.

In the 1980s and 1990s, the resurgence of compounding has resulted in a large increase in the diversity of equipment in pharmacies, depending upon the scope of practice. From traditional compounding activities in the preparation of syrups, suppositories, troches and ointments to the high-tech aseptic compounding of total parenteral nutrition solutions containing 20 or more ingredients and even the programming of ambulatory pumps capable of predetermined delivery of a weeks supply of drugs contained in a small reservoir, pharmacists are becoming involved in a higher level of technology-based pharmacy.

Despite the tremendous changes in the equipment requirements of today's practicing pharmacists, many regulatory agencies have not "kept up with the profession" in updating practice regulations. Since the practice of pharmacy is so diverse, we have probably passed the time in which a Board-defined single list of items will suffice for all practice settings; rather, different lists must be developed dependent upon the type of practice, i.e., community, hospital, home healthcare, nuclear, traditional compounding and aseptic compounding. Many regulatory bodies are now looking at this subject so we will probably see increased activity in the future. Until that time, this issue will serve as a reference for some of the equipment and supplies that pharmacists are using, depending upon their practice activities.

COMPOUNDING EQUIPMENT AND SUPPLIES

The approach taken in this presentation is to divide the equipment into four areas of pharmacist involvement, as follows:

1. General nonsterile product compounding equipment
2. Advanced nonsterile product compounding equipment
3. General sterile product compounding equipment
4. Advanced sterile product compounding equipment

The costs presented for some items are only approximate and will vary greatly depending upon their source, quality and design. Many routine items are simply listed without cost and discussion, as use of these has become common. Discussion will usually be limited to those items for which the applications and use may be unclear or for those in which there is an unusual application. Many items are actually used for both nonsterile and sterile product compounding.

NONSTERILE PRODUCT COMPOUNDING EQUIPMENT

General Nonsterile Product Compounding Equipment

Balance—Prescription, Torsion

Balance—Triple Beam

Beaker Hot Stand

Beaker Tongs

Beakers—50, 100, 150, 250, 400, 600,
1000 mL Glass/Plastic/Stainless
Steel

Beakers—With/Without Handles,
1000, 2000, 3000 mL Glass/
Plastic/Stainless Steel

Capsule Filling Equipment

Cylinders—Graduated 5 to 2000
mL—Glass/Plastic

Desiccators—Glass/Plastic

Desiccant (Drier-Rite®)

Dishes—Evaporating, Porcelain—
with/without Handles

Funnels—Glass/Plastic—2", 3", 4", 5", 6"
Graduates—Pharmaceutical/
Conical 10, 25, 50, 100, 250, 500
and 1000 mL, Glass/Plastic
Hotplates, Various Sizes and
Features
Glasses—Safety
Graters, Hand—Fine, Medium,
Coarse, Combination
Mortars/Pestles—Glass and
Porcelain—2, 4, 8 oz.
Openers—Jar/Bottle/Tube
Ovens—Drying
Pill Tiles—Glass, Frosted
Racks, Drying—Plastic or Epoxy
Resin Material
Refrigerator with Freezer
Spatulas—4", 6"—Plastic and
Stainless Steel, Assorted
Stir Plate—Magnetic with Stir Bars
Stirring Rods
Strainers—Small, Medium, Large
Suppository Molds (rectal, vaginal,
urethral)
Thermometers—Glass
Thermometer Clips
Troche Molds
Weighing Dishes—Plastic and
Aluminum
Weighing Papers
Weight Sets

Advanced Nonsterile Product Compounding Equipment

(in addition to those listed above)

Balance, Electronic—Minimum
sensitivity of 10 mg.
Balance, Electronic—Minimum
sensitivity of 1 mg.
Bath, Dry—Heater/Incubator
Beakers, Insulated
Beakers, Teflon
Beakers, Heat-resistant plastic
Blender
Liquefy, Puree, Mix
12 mL to 4,000 mL capacities
Temperature controlled, Foam
arrestor
Blender, Hand—Variable speed
Mixing container, stand, various
blades, at least 2 speeds.
Blender, Hand—Two speed Lab
Three blades, with stand
Boiling Chips or Beads
Bottles, Drop Dispensing—Plastic or
Glass
Bottles, Dispensing Fluid—Plastic or
Glass
Brushes, Cleaning—Nylon—Various
sizes/shapes to fit equipment
Buckets with Lids—Plastic
Burets, 10-50 mL
Burners, Bunsen or Similar (natural
gas or propane)
Carboys with/without spigots
Carts, Plastic/Metal

Centrifuge
Chopper/Grinder
Coffee Grinder
Crimper, Hand operated
Desiccator
Desiccator/MicroMarinader
Creates vacuum. . . desiccator
applications
Dispensing Pumps, Variable Speed
Pipet bulbs
Fat/oil separator (Gravy separator)
Food Processor
Slice, Grate, Chop, Puree, Mix,
Knead: various blades
Heat Gun, Variable Heat Outputs
Homogenizers, Hand operated
Lead Sticks, flexible
Light boxes
Magnetic Stirrers
Microspatulas, Stainless Steel, Teflon
Coated
Motorized Stirrer
Malt Shop Mixer (2 speed motor,
stainless steel cup 28 oz.)
Mixer—Orbital, Single/Variable
Speed
Mixer, Professional—Kitchen
Mortar/Pestle, wide shape
pH Meters, Variable Sizes/Styles
Pipets, 1-100 mL
Pipet Fillers, Hand Operated
Pipettors/Micropipettors—Variable
Size: 5-200 μ L, 200-1000 μ L
Pipettors—Multichannel
Pipettor, Motorized
Pitcher, Stirring
2000 mL capacity, Blades attached
to handle, plastic
Powder Blender
Blends powders in dust-free
environment and protects operator
from powder dust.
Repeating Dispensers for Liquids
Sealers, bag or suppository
Sealers, tube
Sieves, 3", 5", 7", various mesh sizes
Solvent Dispensing/Spray Bottles
Spatulas, Stainless Steel, Teflon-
coated, Porcelain, Plastic.
Sprayer Bottles
Tablet Press, single punch
Tea/Spice Ball
Thermometer, Hi-Lo Alarm
Thermometer, Digital Probe
Thermometers with alarm
Test-tube rack, four-sided
Tongs, Beaker/Flask/Tube
Tool Set, Cooks'
Heavy gauge stainless steel
Pasta fork, turner, solid spoon,
ladle, server, skimmer and hanging
rack.
Tubing, various sizes/types
Tubing clamps, various sizes/types
Vortex Mixers
Ultrasonic Cleaner, Various
Capacities

Workbench protector sheets (plastic,
rubber, absorbable paper, matted)
Wash Bottles
Water system

STERILE PRODUCT COMPOUNDING EQUIPMENT

General Sterile Product
Compounding Equipment
Laminar Flow Hood, Horizontal
(Class 100)
Laminar Flow Hood, Vertical (Class
100)
Refrigerator
Anemometer, Direct Reading
Ampule Openers, Disposable
Apparel for Clean Rooms (Class
10,000)
Aprons, Sleeves, Gloves, Hoods—
Open Face, Hoods—Face Mask,
Boot Covers, Shoe Covers, Frocks,
Coveralls, Head Coverings, Lab
Coats, Smocks, Shirts/Pants, Hats/
Caps, Facemasks, Beard Covers
Autoclave Tape
Biohazard Autoclave Bags
Biohazard Bag Holders
Autoclave Bags
Baggies/Pouches/Pouch Sealers
Cleaning Materials
Pickup Roller-Wall
Pickup Roller-Floor
Pickup Roller-Cabinet/Work
Space
Hazardous materials handling
equipment
Filter Units, Vacuum—Disposable
Filters, Sterilizing—Numerous types/
shapes/applications
Filter Unit—Repeating Syringe with
Three-Way connector and Check
Valve
Forceps
Impulse or Induction Sealer for plastic
overwraps
Needle Destroyer
Pumps, Vacuum
Pump-Vacuum, Hand Operated
Pumps, Pressure
Refrigerator with Freezer
Sharps Disposal Unit
Stainless Steel Pressure Filter Holders—
Various Capacities
Stainless Steel Pressure Vessels
Tacky Mats
Trash Container—Gowns/Apparel
Articles
Trash Container—Plastic/Paper Articles
Wire Racks/Shelving

Advanced Sterile Product Compounding Equipment

(in addition to the above)
Autoclave
Filtration, Sterile—Equipment
Cooler/Heater for medication transport
in automobile, 30 L

Crimper, Hand Operated
Decappers
Ice Replacement Gel—Various Forms/Types
Osmometers
Particle Counter
Particulate Testing Equipment
Pump, Pressure—Vacuum
Pyrogen Test Materials
Quality Control Equipment
Sample Transporter Coolant—Pouch
 Maintains sample at about 50° F (below 10° C
 for 30 minutes)
Smoke Sticks
Spatulas and Spoons, Sterile—Plastic for weighing
 and obtaining drugs
Sterility Test Equipment
Ultra-Freezer (Capable of about -80° C)

DISCUSSION

General Nonsterile Product Compounding Equipment

Beaker Hot Stand is a rubber or plastic molded hand protector that is convenient for picking up hot or very cold beakers, flasks, etc.

Capsule Filling Devices are available in numerous formats. From inexpensive plastic units (\$20) for 25 or 50 capsules to the more rugged 100-capsule machines (\$500-\$1500), these are timesavers if a large number of capsules is being prepared. The 100-capsule units can be used for preparing smaller numbers and work well with locking capsules.

Desiccators (\$50-100) containing a desiccant are important for storing drug products that require a very dry atmosphere. Desiccators are available in glass or plastic and may have a port for a vacuum.

Glass Pill Tiles (\$35) customarily are used for the preparation of many different dosage forms. Many come with graduated markings on one end for measuring lengths of suppositories, pill pipes, etc. Most glass pill tiles also have a "frosted" portion which is to be used as the primary work area. This area also provides a good working surface for comminution with a stainless steel spatula, and for mixing ointments.

Ovens-Drying (\$600-1000) are often required for the drying of various compounded products and for the drying of products that might have adsorbed or absorbed moisture over time. As the potency of drugs increases, the sorption of moisture will become even more dangerous due to weighing errors which may occur if the drug is not dried before weighing due to the apparently greater weight of the material.

Stir plates (magnetic with stir bars) are becoming commonplace in pharmacies involved in compounding a large number of fluid preparations. This frees up pharmacists time to do other duties while ingredients are dissolving and mixing. If the plate has a heating element, melted ointments and suppository bases will be more easily mixed to uniformity.

Suppository and Troche molds made of plastic are slowly replacing the older heavy metal molds. The molds may also serve as part of the dispensing package. Caution must be observed since these molds are available in different sizes, unlike many of the metal molds which were reasonably standardized at 2 mL each.

Weight sets (Brass, \$75) usually contain both apothecary and metric weights for use with prescription balances. The metric system is now the only official system in the U.S.P. XXIII.

Advanced Nonsterile Product Compounding Equipment

Balances (electronic) (\$850 to \$2500) are available to weigh quantities as low as 1 mg. These electronic balances are useful in compounding pharmacies to weigh small quantities of drugs very accurately and with a relatively low investment. They are easy to use, clean and calibrate. The cost of a balance is generally proportional to the lowest weight that can be measured.

Dry baths are alternatives to hot plates and are replacing water baths in many laboratories. A dry bath is essentially a heated chamber that can be filled with sand, salt or aluminum blocks designed to hold various sizes of glassware. For example, a beaker can be "wiggled" into the sand after the sand has equilibrated to the desired temperature for heating a preparation. These dry baths are easy to use and clean and are virtually maintenance-free.

Blenders (Cabinet top and hand held, \$50-\$300) are indispensable in the preparation of many products. Kitchen blenders are excellent for preparing solutions, suspensions, emulsions and even gels (if done properly). They are available in the standard kitchen size of about 28 ounces and in laboratory sizes with vessels ranging from 12 mL to about 4,000 mL. Hand-held blenders are excellent for preparing lotions, creams and other semisolid and liquid preparations. They are available as single, dual and variable speed.

Carts (plastic/metal-\$50-300) are items of equipment or furniture that can be very useful in compounding. They can serve to move supplies from one area to another as well as provide working surfaces when necessary.

Choppers/Grinders (\$30) and Coffee Grinders (\$15-25) are available in kitchen departments in large stores as well as in gourmet shops. They can be used for particle size reduction and even for blending small quantities of powders.

Crimper, hand operated (\$250) is used to attach aluminum tamper-evident safety caps on containers of prepared products. This is a very convenient system for packaging products where evidence of the package having been opened is desired and is similar to the seals used for injectables.

Dispensing pumps, (variable speed, \$1500-2000) are invaluable when the same volume of a liquid has to be measured and dispensed repeatedly. They are especially useful in packaging finished products into containers.

Pipet bulbs (\$10) can be used to aid in pipetting and eliminate many of the dangers associated with pipetting by mouth. There are numerous styles of these bulbs which may be used not only with measuring pipets but also with transfer pipets for moving small quantities of liquids from one vessel to another.

Fat/oil separators (\$10) can be used to obtain a foam-free liquid from an ingredient that has a foam on top which makes it difficult to measure. The spout originates at the bottom of the container so the liquid, not the foam, is dispensed. These are often referred to as "gravy separators".

Food Processors (\$200) capable of slicing, grating, chopping, pureeing, mixing and kneading, depending upon the various blades that are available, have many applications, including the preparation of ointments and pastes.

Heat guns (variable heat, \$50-65) can be used when heat is required in a situation where a hot plate is inconvenient. A heat gun can be used to direct the heat to a

specific area where it is needed, as in sealing plastic dose containers. It can also be used to apply gentle heat to beakers of liquids, etc.

Homogenizers (Hand operated, \$375) are available for assistance in the preparation of fine emulsions. They are easily disassembled for cleaning and work with as little as 60 mL. of liquid.

Lead Sticks (Flexible) are convenient for wrapping around beakers, flasks, and other pieces of equipment to prevent them from falling over. The sticks are made of soft lead with colorful plastic coatings and are available in many diameters and lengths. They easily may be shaped or formed to fit around almost any piece of laboratory glassware or equipment.

Light boxes are excellent aids to determining the completeness of solution when dissolving solids and for detecting precipitants when working with materials that may be incompatible or near the limit of solubility. A similar piece of equipment can be made by painting a piece of Masonite one-half black and one-half white, using "flat" paints. When this board is hung on a wall with a fluorescent light immediately above it, the dark and light backgrounds may be used to help determine the presence of particles in a solution.

Orbital mixers (\$300) can be used to mix a large number of beakers, bottles, flasks, etc. simultaneously. The containers are fixed in place on a platform that moves in a circular or orbital motion. These are very widely used in laboratories and can be used to advantage in compounding pharmacies where a large number of containers need to be mixed simultaneously.

Mixer (professional or kitchen, \$350-450) can be used for beating, mixing, whipping and kneading with flat beaters, dough hooks and wire whips. They can be used for the preparation of products ranging from liquids, including emulsions, to ointments.

pH Meters (\$50-2000) are now commonplace in compounding pharmacies. pH is critical for drug solubility and stability. Many products must be buffered, or the pH adjusted to a certain range that requires a greater degree of accuracy today than that provided by pH indicator papers.

Pipettors (micropipettors-variable sizes 5-200 μ L, 200-1000 μ L, \$175 each) are excellent for measuring small volumes of liquids accurately. They eliminate the need to prepare aliquots of drugs where only a very small quantity is required. Variable micropipettors are available so the investment can be kept to a minimum. For example, one micropipettor can be used for 200 to 1000 μ L and another one for 5 to 200 μ L. Multiple channel micropipettors are available for use where up to 12 channels must be delivered simultaneously; for example, when 0.5 mL is being placed in small vials/ampules and a large quantity are being prepared.

Powder blenders (\$2000-4000) enable pharmacists to blend powders in a dust free environment and protect the operator from powder dust. These blenders mechanically blend in enclosed plastic bags without allowing any of the powder to escape into the environment.

Sealers, bag or suppository (\$115) are convenient for sealing plastic bags or certain suppository molds.

Sealers, tube (\$800) are widely used for packaging large numbers of ointments, creams, or gels in plastic tubes. They are easy to use and provide reproducible results attractively packaged.

Tablet press (single punch, \$550) is an easy-to-use method of preparing individual tablets. A blend of the

active drug and excipients can be weighed and placed in the die, the handle lowered, and a tablet produced by compression.

Tea/spice balls (\$5-15) can be used to contain a flavoring ingredient while immersing it in a liquid until the desired strength is obtained.

Thermometers with alarm (\$60) can be used to provide an audible indication when a refrigerator or oven gets out of a preset temperature range. These are most often used on freezers and refrigerators, especially ultra-freezers.

Tool sets, cooks' (\$50) have some useful implements for compounding, often including a pasta fork, turner, solid spoon, ladle, server and a skimmer; complete with a hanging rack.

Ultrasonic cleaners, (\$175-1000) are useful for cleaning items but are also very useful for accelerating the dissolution of slowly dissolving drugs.

Water system (high quality, various prices) may be required if the Pharmacy is involved in preparing a large quantity of products requiring different grades of water.

Workbench protector sheets of plastic, rubber or absorbable paper are often convenient for defining a work area for a specific project. They can be cleaned or disposed of when finished.

General and Advanced Sterile Product Compounding Equipment

Many of the items listed in the categories of sterile product compounding and advanced sterile product compounding can be placed into one of four general categories. The first group includes those items that are used for the preparation of sterile products: ampule openers, impulse sealers, vacuum pumps, sterile filtration equipment, sterile spatulas and spoons. Second is a list of items for quality control, including an anemometer, particle counter, particulate testing equipment, pyrogen test materials and sterility test equipment. The third area is that of product storage and delivery, including such items as a refrigerator, cooler/heater for automobile, ice replacement gel, and an ultra-freezer. Fourth, we include those items used for maintenance of the clean room environment, such as apparel for personnel, cleaning materials, and HEPA filters.

SUMMARY

To invest or not to invest? This is an age-old question concerning business opportunities, both professional and vocational. Some pharmacists hesitate to invest hundreds or thousands of dollars in equipment necessary to become involved in compounding pharmacy. There is no question that taking the time and using the professional and scientific expertise of the Pharmacist in preparing specific dosage forms and strengths to meet the individual needs of patients is financially worthwhile. A first step includes informing local Physicians of the availability of compounding services to meet the needs of their patients and practice. This brief introduction often has resulted in new opportunities for professional activities. In times of shrinking fees and margins and increased demands on pharmacists time for patient counseling, investments in time-saving technologies should be considered, as should additional services to meet the demands of the marketplace for individualized patient care through compounded prescriptions.

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