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of the University of Connecticut School of Pharmacy and Pharmaceutical Sciences

EDUCATIONAL OBJECTIVES

After completing the continuing education activity, pharmacists and pharmacy technicians will be able to

- LIST the reasons why a compounding lab might consider purchasing machinery and the steps in the evaluation process
- IDENTIFY the purpose and function of common compounding equipment (e.g., balances, mixers, mortars and pestles, capsule fillers, ointment mills)
- DESCRIBE the principles of accuracy, precision, and calibration as they relate to compounding tools
- EXPLAIN regulatory expectations for equipment use, cleaning, and maintenance (USP <795>)

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Pharmacists and pharmacy technicians are eligible to participate in this application-based activity and will receive 0.2 CEU (2 contact hours) for completing the activity, passing the post-test with a grade of 70% or better, and completing an online evaluation. Statements of credit are available via the CPE Monitor online system and your participation will be recorded with CPE Monitor within 72 hours of submission

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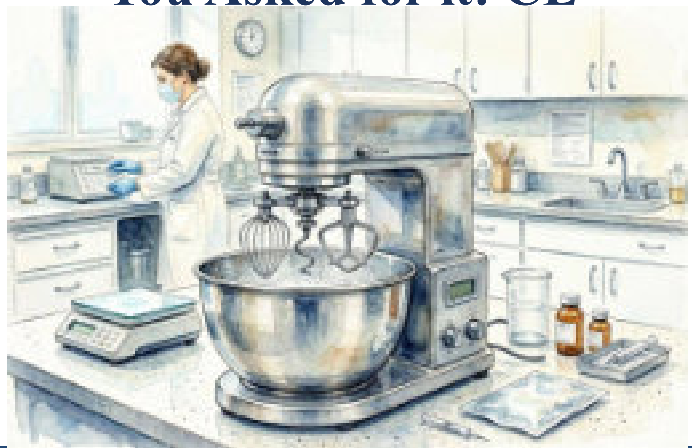

Equipment to Make Non-Sterile Compounding A Breeze

TARGET AUDIENCE: Pharmacists and pharmacy technicians who need continuing education credits in compounding.

ABSTRACT: As interest in specialized compounding, veterinary preparations, and cannabidiol (CBD)-related products grows, pharmacy compounding laboratories increasingly face decisions regarding automation and equipment acquisition. Although compounding equipment can improve efficiency, reduce repetitive manual labor, enhance dosing accuracy, and potentially decrease contamination risk, selecting appropriate equipment requires a structured and data-driven needs assessment. This continuing education activity reviews the major considerations involved in choosing compounding equipment. Decision makers must evaluate the pharmacy's scope of services, compounding volume, formulation complexity, regulatory obligations, facility limitations, staff training needs, ergonomic concerns, and financial constraints before investing in equipment. They must consider the United States Pharmacopeia chapters <795>, <797>, and <800>, workflow integration, maintenance requirements, and vendor support. Ergonomics and repetitive strain prevention are also critical factors, noting that automation may be justified even when time savings are modest if employee injury risk can be reduced. This CE covers commonly used compounding equipment categories. For each category, it summarizes mechanisms of action, advantages, limitations, regulatory implications, and practical considerations affecting equipment selection. Ultimately, successful equipment selection depends on aligning technology with the pharmacy's actual compounding needs rather than purchasing equipment based solely on novelty or perceived efficiency. A thoughtful needs analysis can help pharmacies avoid costly purchasing errors while improving product quality, workflow efficiency, and employee safety.

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FACULTY DISCLOSURE: Ms. Nolan has no financial relationships with an ineligible company.

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INTRODUCTION

With the increased interest in specialized, veterinary, and cannabidiol (CBD) compounds, pharmacy staff who work in academia and specialize in compounding occasionally field questions from start-up companies that need help selecting the best equipment for their needs. Most compounders who have these questions are aware of compounding equipment's advantages; the machines are semi-automatic or automatic, streamlined, safe, and more efficient and faster than humans.[1,2] Saving time means saving money! When used according to the directions, they also produce products with accurate dosing.[1,2]

Pharmacy compounders who are considering the purchase of machines always have additional questions. They want to know if specific equipment will decrease human exposure to medications and decrease the likelihood of human error. They also ask if machines can decrease repetitive motions. What is the likelihood of cross contamination? And will the finished products be pharmaceutically elegant? Unfortunately, compounding experts will not have a one-size-fits-all answer. Each compounding lab will need to conduct a needs analysis before considering new equipment. Choosing compounding equipment without a needs analysis is how pharmacies end up with very expensive dust collectors.

PAUSE AND PONDER: Other than the "cool factor," why might your compounding pharmacy benefit from a new machine?

CONSIDERATIONS FOR SELECTION

Before purchasing any machine, decision makers need to ask, "What specific problem does this solve, and how often will we have that problem?" The answer to that question must be data driven.

First, decision makers need to define the scope of services the pharmacy provides.[3] It's critical to choose equipment based on type of medications being compounded now (see **Table 1**), and to also consider how the business may grow in the next few years. When looking at the compounded product types, the employee or employees doing the analysis need to augment the data with the volume or frequency that the pharmacy compounds each type of product.[3] Things to think about include peak and average workload, batch compounding as opposed to one-off prescriptions, and the patient's or customer's typical turn-around expectations. The goal is to determine which compounds the staff makes often enough and in large enough quantities that automation would be a reasonable consideration.

Table 1. Types of Compounded Products

Nonsterile	Capsules Creams Gels Gummies Ointments Solutions Suspensions Troches
Sterile	Intravenous Ophthalmics
Hazardous drugs (e.g., oncology)	

Second, decision makers need to look at the various formulations they compound and assess their complexity. They need to look at each formulation and determine if it requires some kind of special approach. It might be high shear mixing, precise particle size reduction, or homogeneity testing. The high-shear mixing process involves using shear to emulsify, homogenize, disperse, or reduce particle size. This shear force occurs when part of the mixture is pushed in one direction, while the other part is pushed in the opposite direction simultaneously. If the shear force is higher, the particles mix more evenly due to the particle size reduction outcomes, which assists in homogenization. An example of this would be creating a cream or lotion with an oil and water base.[4] These compounds tend to be more complex than other compounds, and if they are produced in large enough batches, the decision makers may need to look at mixers, electronic mortars and pestles, or homogenizers. Concurrently, they need to look at each compound and ask, "What level of dosing accuracy is required?" If any of these products include drugs with narrow therapeutic indexes or are destined for pediatric or neonatal patients, it's possible that automated dispensing systems, precision balances, or capsule filling machines could be helpful.

Third, it's always important to look at regulatory and compliance considerations.[5] People who make these decisions need to be fully educated about the United States Pharmacopeia (USP) chapters <795>, <797>, and <800>.[6-8] In addition, they need to be aware of their State Board of Pharmacy rules. This means that they should determine if any environmental monitoring, documentation systems, or closed system transfer devices are needed. (A closed system transfer device is a drug transfer system designed to prevent hazardous drugs from escaping into the environment and to block contaminants from entering the system during preparation and administration.) Any equipment that they purchase must be in compliance with the rules and not purchased just to improve production. This is also the time to also ask if the specific piece of equipment will provide traceable documentation. If batch-to-batch consistency is imperative, documentation is an indispensable element of the pharmacy's quality assurance program. [6-8]

Fourth, space and facility constraints are very important.[3,5] Before purchasing any machine, pharmacy staff should look at their available square footage and cleanroom requirements to determine if the machine will even fit.[5] A good way to do this is to determine the equipment's size and construct a dummy out of cardboard. Placing it in the workflow will help determine if the machine will work for the specific pharmacy. Many machines are large and will require dedicated space or specific ventilation. A **PRO TIP** is to ask, "Does it integrate with your existing equipment?"[5] Integration means that the new machine may need to be able to "talk" to the pharmacy's software, labeling systems, and barcoding.[5]

Fifth, decision makers need to assess the pharmacy team's current skill levels and determine if the staff will need additional or extensive training.[3,5] If the team's skill level is only basic, or if the pharmacy experiences high employee turnover, it might be important to look for simpler equipment rather than fancier equipment. While conducting this part of the needs assessment, decision makers also need to determine if manufacturer support and training is available and included in the purchase price. If it is not included in the purchase price, the budgeting process will need to reflect the additional cost.

A related concern is how the physical work of compounding affects employees' bodies over time, referred to as ergonomics. Many compounding tasks—grinding powders with a mortar and pestle, mixing thick creams by hand, filling capsules, drawing up liquids into syringes by the hundreds, and even keyboard strokes—are very repetitive.[9] Small, precise motions repeated hundreds of times can be more damaging than heavy lifting—because they never give muscles a break.[10,11] Over time, drawing 0.5 mL 300 times is more straining than lifting a heavy box 10 times. Employees may develop wrist pain, hand fatigue, shoulder or neck strain, or long-term injuries that require workman's compensation.[9,10] A **PRO TIP** is to replace the question, "Can an employee do this task?" with, "Can an employee do this task all day, every day, without risk of injury?" If a machine can save employees from strain or injury, it might be worth it—even if it doesn't save much time.

PAUSE AND PONDER: A technician draws up small volumes (0.5–1 mL) into syringes for 2–3 hours straight. Why is this more tiring than it sounds? What small muscles are being overused? What could reduce strain *without* full automation?

Repetitive hand motions could cause carpal tunnel syndrome, which is caused by compression of the median nerve. This causes pain, numbness, and tingling in the hand.[12]

Sixth, developing a budget isn't as simple as just determining how much money is available.[3] Two questions should drive budgeting:

- "Will this machine pay for itself?"
- "What happens if it breaks?"

The answers to these questions emanate from an analysis of upfront costs and the long-term anticipated return on investment.[3] Sometimes, decision makers overlook hidden costs like maintenance and calibration costs, consumables and proprietary supplies (supplies that are only available from the manufacturer), and service contracts.[5]

During the budgeting process, decision makers should delve into some additional concerns listed in **Table 2** (on the following page). A snazzy machine with poor vendor support becomes useless quickly.

A final and seventh step is to ask, "What specific problem does this solve, and how often will we have that problem?"

Heads = Machine, Tails = Employee

After completing the seven steps described above, it may be clear that the pharmacy has the volume, money, and justification to purchase a machine.[3] However, it's a good idea to play devil's advocate and think about ways to reduce strain without full automation. This is a good brainstorming activity for the entire staff.

Some ways to reduce strain include rotating tasks every 30 to 60 minutes, so that staff members alternate fine motor tasks and non-fine motor tasks, and scheduling micro breaks.[9] It's also possible to tweak equipment so that there's less strain on employees. Using larger syringes when possible uses less force per draw. Choosing low resistance syringes can decrease strain because they have smoother plunger actions. Employees can also use a syringe holder, or a stabilizing device and training should emphasize ensuring proper hand positioning.[9]

Regardless of the type of equipment being used, compounders should use disposable products when applicable (i.e. weigh boats [a small, shallow, disposable container used in laboratories to hold solids while they are being weighed on a balance], or single use oral syringes) in conjunction with their equipment. They increase infection prevention and patient safety by avoiding cross contamination; they save time and labor by not having to clean and sanitize in between compounds; and there is no

Table 2. Vendor Support & Reliability[5]
• Is technical support readily available? What is the typical or guaranteed response time? • What is the process for machine cleaning and calibration? • Does the vendor supply replacement parts or can they be purchased elsewhere? • Does the vendor provide training? If so, is it free or associated with a charge? • What happens if the machine fails? What is the backup plan or work-around process? • What is the cost of the service contract and does it include replacement parts?

maintenance involved. There may also be potential for bulk buying discounts.

Decision makers need to keep one more thing in mind when they select equipment. USP <795> requires compounding pharmacies to clean and maintain the equipment according to written procedures.[8] The **PRO TIP** here is that as soon as equipment is purchased, the pharmacy needs to establish and follow such procedures.

Let's look at the types of available equipment.

PAUSE AND PONDER: Take a moment and think of all the ways that machines can help you do your work.

EQUIPMENT TYPES AND PURPOSES

Weighing and measuring equipment in compounding ensures accurate quantities, which are critical for safety and effectiveness. This includes balances for weighing powders and volumetric measuring devices (e.g., graduated cylinders, syringes) for liquids. Selection depends on the required precision—small volumes or potent drugs demand higher accuracy. Employees must calibrate equipment and use it properly to avoid dosing errors. Inaccurate measurement can lead to subpotent or toxic preparations, making proper technique and maintenance essential in both sterile and nonsterile compounding.

Choosing the right scale depends on the pharmacy's specific compounding needs. Most quality scales range from $500 to $2,000. Scales come in two types: analogue and digital.

The USP discusses and requires **Class A prescription scales** on compounding pharmacies.[13] All state laws require a Class A scale or a scale that is more sensitive in licensed pharmacies, too. This level of mechanical balance is sensitive enough to detect small weight changes, with a sensitivity requirement of 6 mg or less and a minimum weighable quantity of 120 mg (to ensure error will be 5% or less). This means adding 6 mg will move the pointer one division on the scale. Because of this level of precision, Class A balances are considered appropriate for accurately weighing ingredients used in compounded preparations. A Class A balance is defined by how little weight it can detect (again, 6 mg or less)[13]; in case you are wondering, there are no official Class B or C balances in USP compounding—just balances that either meet the standard or don't.

An **analogue scale** is a mechanical device that uses physical weights, springs, or balance beams and does not need electricity. It uses the principle of equilibrium, comparing the unknown weight with standard weights.[14] Analogue scales are less costly than digital scales. All older pharmacies had torsion balances, which are a form of analogue scale, which did not require electricity. They were extremely durable and highly accurate when used correctly. In the "old days," schools of pharmacy taught students how to use these scales. Many schools no longer teach this, considering these scales old-fashioned. Yet a survey that received 372 responses from pharmacies in Missouri found that almost half of those pharmacies (46.8%) owned a torsion balance.[15] Almost 60% of pharmacists-in-charge recommended continuing to teach how to use torsion balances.[15] Do you still have a torsion balance in your practice?

Over time, mechanical parts may loosen and analogue scales will need recalibration using certified weights. Ideally, a compounder should test the balance with a standard weight set before the scale is used each time and should arrange to have the scale calibrated professionally every one to two years, depending on its amount of use. In addition, parallax error—error that occurs when someone reads a scale or measurement from the wrong angle, rather than looking at it straight on—is possible. The compounder must look at the measurement mark at eye level . Because analogue scales are slow to use and require manual skill and calibration, human reading errors are possible, and today's compounding pharmacies tend to use digital scales.[14] (But having an analogue scale is handy if the power goes out or a digital scale breaks.)

Digital scales use electronic sensors to measure weight and display the result numerically.[16,17] Usually, these scales use a load cell to convert force (weight) into an electrical signal. A highly sensitive analog-to-digital converter changes the load cell's electrical signal into a digital value. Next, a microcontroller is a calculator of sorts, changing the signal into an LCD display and telling the user what the item's weight is. They are fast and easy to read, highly precise (often to milligrams or better), and sometimes include features like taring (resetting the scale to zero after placing a container on it, so employees only measure the substance they add—not the container), calibration alerts, and unit conversion. These features reduce human error. More costly than analogue scales, digital scales need a power source and can be sensitive to environment (vibration, airflow, static).[16,17]

SIDEBAR: Stop Calling It Personal Protective Equipment![6-8]

Experts now discourage the term "personal protective equipment" (PPE) in cleanroom settings because it implies protection of the worker, while the primary goal is protection of the product from contamination. Cleanroom standards (e.g., USP <797>) emphasize garbing to maintain aseptic conditions. Using "PPE" can lead to incorrect practices, such as prioritizing self-protection over sterility, potentially increasing the risk of microbial contamination in compounded sterile preparations.

And the USP documents themselves are confusing! USP <800> uses PPE but <795> and <797> used the preferred term "garb"!

PAUSE AND PONDER: Say it 10 times! In compounding we garb!

However, most new balances have a battery backup so they can still be used in case of a power outage.

When choosing scales, pharmacy staff should start by considering how precise their measurements must be (e.g., 1 mg vs. 1.001 g) and the typical quantity—small amounts or several kilograms. Space may matter, so a compact design can help. Many modern scales offer digital features like battery backup, USB, or Ethernet connectivity for data recording, and automatic internal calibration. Analog scales are more affordable and suitable for basic tasks, while digital scales provide greater precision and reliability, making them ideal for more demanding environments.[10,11,14,16]

Other types of weighing scales include bench scales, truck scales, pallet scales, floor scales, and dynamic weighing systems.

PAUSE AND PONDER: You in your workplace is responsible for calibrating your scales?

Mixing and blending equipment ensures ingredients are evenly distributed so each dose is consistent and effective. This includes manual mortar and pestles, electronic mortar and pestles (EMPs), ointment slabs, electronic mixers, and homogenizers. The choice depends on the formulation—thick creams may require more force, while suspensions need uniform particle distribution. Proper mixing prevents "hot spots" (too much drug in one area), "cold spots" (areas with little to no drug), or separation.[18] Equipment should be easy to clean and appropriate for the product to maintain quality and avoid contamination.

Using the **traditional mortar and pestle,** compounders crush and mix various ingredients to create a fine mixture by hand.[19] They place the ingredients in the mortar (the sturdy bowl made of hard materials) and rub it with the pestle (the club-shaped implement used to pound or grind substances). The process can be time-consuming, and the final product may differ in consistency depending on who wields the mortar! Proper hand positioning in holding the pestle will reveal how skilled the compounder is.[19]

EMPs generally retail at about $2,000 to $4,000 each. They increase the potential output of topical compounds.[20] Employees can use them to make multiple compounds in small, personalized batches using single use plastic jars and small plastic mixing discs, which remain in the final product jar. Often, topical compounds produced using EMPs have better product quality than those produced by hand.[19] Considered a closed system, these machines also prevent cross contamination. EMPs use a circular or S-shaped blade that spins inside the jar, pushing the cream outwards (toward the jar's wall). The paddle on each end of the blade creates a forceful, shearing effect and delivers a homogenous and smooth mixture as the process is repeated.[20] One limitation to EMPs is they may generate heat during the process, which introduces the possibility that the heat will degrade the active pharmaceutical ingredient (API).[19] This outcome is highly unlikely because these machines are FAST—they can mix in three to five minutes depending on the product.

A **planetary mixer** is a closed mechanical mixing device used to blend creams, ointments, gels, and viscous formulations.[19] They produce less heat than EMPs. The name comes from the motion of the mixing blade, which rotates on its own axis while traveling around the bowl, similar to a planet orbiting while spinning. Its dual movement provides thorough, uniform mixing and reduces unmixed areas. These mixers are also very fast. Planetary mixers are especially useful for thicker preparations and larger batches, improving consistency and reducing manual effort.[19] However, they require cleaning between batches and may be less practical for very small quantities.

In the compounding lab, student Carli is watching a demonstration of the planetary mixer. Several of her classmates are bored and visibly distracted, but she is intrigued. At the end of the demonstration, she stays behind and tells her instructor that she found the whole concept interesting. She says that her classmates often make cupcakes for a fundraising event, and when they make buttercream frosting, the powdered sugar goes everywhere. She likes the idea of a closed system that would incorporate butter, sugar, flavoring, and milk with no mess. She says, "Too bad these are so expensive. They'd be great for frosting!" The instructor asks her to think about it and identify the reason why the planetary mixer would make terrible frosting. It takes a minute, but Carli says, "Ah! It's because when making buttercream frosting, you need to whip air into it. Planetary mixers press all the air out." The instructor says, "Correct." Carli's friend Sydney is nearby and says, "I guess you can't make meringue from egg whites in a planetary mixer either!" The instructor nods.

SIDEBAR: The EMP to Ointment Mill Switcheroo!

Kyle is a pharmacy student taking an advanced compounding class. A proctologist has ordered a 20% benzocaine ointment for a patient who has anorectal pain. He has laid out his components and has the EMP ready to mix the ointment. He asks the instructor to check his work. She approves his calculations, but says, “You would be better off using the ointment mill. He says, “Why? I didn’t see anything about this in the USP. Is this some kind of FDA regulation?”

She replies, “No universal USP or FDA rule dictates using an ointment mill instead of an EMP if a topical contains more than 10% API. Compounders often switch to an ointment mill at higher API loads to improve pharmaceutical quality and address rheology issues. Rheology is the science of how materials flow, spread, deform, or resist movement under force.)”

She goes on to summarize this way:

- At low API concentrations, an EMP can usually generate enough shear and mixing energy to disperse powder uniformly.
- At higher concentrations (especially insoluble powders such as urea, salicylic acid, ketoprofen, zinc oxide, etc.), the formulation behaves more like a dense suspension than a simple cream.
- High solids loading increases
  - agglomeration (the situation in which mall powder particles stick together and form clumps)
  - grittiness
  - poor wetting
  - nonuniform particle distribution
  - risk of dose variability,
  - instability/separation

An ointment mill produces much higher and more controlled shear forces than an EMP. The rollers physically reduce particle size and break agglomerates, improving

- content uniformity
- smoothness/elegance
- skin feel
- reproducibility
- and potentially, drug release characteristics.

An EMP mainly homogenizes and mixes; an ointment mill both mixes and reduces particle-size.

Most ointment mills use three rollers that rotate in different directions and at different speeds, creating shear forces that break down particles and blend them thoroughly.[22] This process, related to particle size reduction, enhances drug absorption and ensures stable, professional-quality ointment. Using an ointment mill is definitely faster them mixing an ointment by hand.[22]

Homogenizers create a uniform mixture by reducing particle or droplet size and evenly dispersing ingredients throughout a preparation.[23] They are especially useful for emulsions, suspensions, and creams, where consistent distribution of components is critical for accurate dosing and stability.[23]

Homogenizers work by applying intense mechanical forces—such as pressure, turbulence, or shear—to break down particles and droplets.[23] By forcing mixtures through narrow channels at high pressure, homogenizers decrease particle size and increase uniformity, leading to better bioavailability. This process improves texture, enhances absorption, and prevents separation over time. The result is a smooth, stable product with consistent therapeutic properties, achieved through principles related to homogenization.[23]

Capsule filling machines efficiently fill empty capsules with precise amounts of powdered or granulated medication.[24] They help ensure consistent dosing and uniformity across multiple capsules, which is especially important when preparing individualized prescriptions.[24] Capsule filling machines may be manual, semi-automatic, or fully automatic.[25]

These machines typically align empty capsules, separate the caps from the bodies, fill the bodies with the prepared formulation, and then reassemble the capsules.[24] By improving speed and accuracy compared to manual filling, they reduce variability and enhance workflow efficiency. Proper use supports uniform drug distribution and dose accuracy, key aspects of content uniformity. Traditionally, compounders use hard or soft gelatin capsules, which remain widely available and inexpensive. They are not vegetarian, however, as gelatin is a meat byproduct, but there are vegetable-based capsules available. In addition, some gelatin capsules are kosher, but some are not. To be kosher, the gelatin capsules must be made from a kosher source and in a supervised, certified process. Capsules that meet vegetarians’ needs and the needs of people who keep kosher are available and made of cellulose. They tend to be more costly than gelatin capsules.[24]

Of note, 21 U.S.C. § 830 (Controlled Substances Act [CSA] – recordkeeping & reporting) and 21 CFR Part 1310 (DEA regulations on “regulated transactions”) require reporting of certain transactions involving encapsulating machines. These laws define an encapsulating machine as any equipment that will be used to fill capsules with powder, liquid, and others, regardless of the alleged purpose. The CSA legally classifies anyone who sells or distributes these machines as a regulated person and any sale of an encapsulating machine—domestic, import, or export—triggers the requirement to file Form 452 and keep sales records. The purpose of these laws is to scrutinize sales that may be linked to illicit drug production. Note that owning such machines is not illegal; selling them is if the seller does not file a Form 452.

Infuser machines ($100 to $400) extract active ingredients from raw materials into a liquid or oil base.[26,27] The term "infuser machine" is colloquial, meaning that's what just about everyone calls them, mainly because they have been used heavily by the emerging cannabis industry. The scientific names for these machines include[27]

- solid–liquid extractors
- botanical extraction systems
- maceration/percolation systems
- dynamic extraction devices

The infusing procedure extracts compounds from the solid material to the outlet (the liquid in which it is infused), creating a solution that contain colorants, bioactive compounds, and/or fragrances.[27] Compounders use these machines to prepare infused oils or solutions by combining heat, time, and controlled mixing to transfer desirable compounds into the final product.[26]

These machines work by maintaining consistent temperatures and agitation, which helps improve extraction efficiency and uniformity.[26] This process relies on principles of solid-liquid extraction, including diffusion and osmosis, ensuring that the active components are evenly distributed throughout the preparation for consistent potency and quality. They can infuse a variety of flavors and aromas like milk, honey, butter, oil, or glycerin. They are popular with herbalists and THC/CBD manufacturers.[26]

Interestingly, infusion techniques have become a mainstay of valorization—taking something that would otherwise be considered waste, low-value, or underused and turning it into something more useful or economically valuable.[27] In doing so, the process must extract the desirable component while discarding the constituents that are less desirable.[28] Some examples include extracting antioxidants from orange peels that would otherwise be discarded; converting agricultural waste into biofuels; using spent grain from breweries to make protein ingredients; and the ever-popular recovering cannabinoids, terpenes, or polyphenols from plant material. Infusion techniques are also very often used in herbal medicine.[28]

Compounders need to appreciate that extraction efficiency increases as particle size decreases because surface area increases.[27] That principle is exactly why many infusion machines grind material finely, heat the oil, stir continuously, or cycle between pressure and vacuum.[27]

Molds and presses constructed of silicone or stainless steel ensure uniform shape and size. Many are available in standard sizes, but some can be custom-made. They are employed in both manual and automated compounding. They enhance efficiency with regulated compression force-dosage uniformity. They must be cleaned regularly and thoroughly to meet quality assurance standards.

Magnetic stirrers mix liquids using a rotating magnetic field.[29-31] The compounder places a small, coated magnet ("stir bar" or "flea") in the liquid and then places the container on a plate that has a magnet below it. The stir bar is polytetrafluoroethylene-coated (PTFE which means it is coated in the chemically inert substance we usually know as Teflon). A motor rotates the magnet. The stir bar spins as the field rotates, creating a vortex that mixes the solution uniformly. Some units also include a hot plate for simultaneous heating and mixing. These devices mix the solution consistently, so the final product has uniform dosing and the results are reproducible. Adding heat can make solids dissolve faster and reduce the likelihood of hot spots.[29,30]

Magnetic stirrers work best with low- to moderate-viscosity liquids.[30] They mix creams, ointments, gels, and high-solid suspensions poorly, so for these, a planetary mixer or overhead mixer (a motorized mixer much like a stand mixer in a home kitchen) are better choices. They are also limited to batches of 2 to 4 liters. In addition, if used improperly (at high speeds or improper conditions) they are prone to stir bar decoupling, meaning the stir bar may fail to respond to the magnet

Table 3. Types of Filling Machines[35,36]

- **Volumetric liquid fillers** would be best for low- to moderate-viscosity liquids or well-mixed suspensions; they deliver a fixed volume per cycle. These may be piston fillers—which are very accurate and widely used—or peristaltic pump fillers when sterile or clean products are needed.
- **Peristaltic fillers** move fluid through a tub using rollers that compress the product. The fluid has contact with the tubing only so contamination is unlikely and cleaning is simple—just replace the tubing. These are less precise if the product is viscous, and the tubs may show wear and tear with use.
- **Auger fillers** are used for creams, ointments, and gels. In these devices, a rotating auger screw displaces a controlled amount of the product. These are able to handle higher viscosities than liquid fillers, and they're good for use with jars or wide mouth containers.
- Some **piston fillers** are used for viscous products, especially topicals, and in these machines, a high force piston pushes the product through a nozzle. Piston fillers have better control than augers for some formulations.
- **Tube filling machines** are used for ointments or creams, and they push the product into an aluminum or a plastic tube. The process is to fill, crimp or seal, and then trim the tube.

SIDEBAR: What is pH? The pHacts![37,38]

pHunny you should ask! pH is a way to describe how acidic or basic (alkaline) a pHluid is.

- It is measured on a scale from 0 to 14
- A pH of 7 is neutral (like pure water)
- A pH below 7 means the substance is acidic (like lemon juice or stomach acid)
- A pH above 7 means it is basic or alkaline (like soap or baking soda solution)
- The pH of most body fluids is 7.4

A straightforward way to think about it is this: pH tells you how "sour" or "soapy" a liquid would be if you could taste or touch it safely. And not all flavoring can affect pH. Most flavors are acidic and contain citric acid (i.e., lemon or orange), malic acid (apple), or tartaric acid (grape). So flavoring is an active excipient, not just a good taste. Compounders should remember that pharmaceutical-grade flavoring systems are often buffered and standardized.

Slight changes in pH can have remarkable effects on drug dissolution, stability, and propensity to be irritating or gentle.

completely.[32] In addition, compounders need to be certain that their containers are not too narrow or irregularly shaped.[33] And, magnetic stirriers do not reduce particle size.[30] Finally, the PTFE coating can chip or degrade over time and the magnet may weaken, potentially compromising mixing and introducing contamination.[31-34]

Filling machines accurately dispense a defined volume or mass of a preparation into containers (bottles, jars, tubes, syringes).[35] Compounders usually use them for oral liquids (solutions, suspensions), topical products (creams, gels, lotions), and occasionally syringes or unit-dose containers. **Table 3** (on the previous page) lists the several types of filling machines.

When using any type of filling machine, compounders need to be aware of some limitations. Filling machines can be influenced by the product's viscosity, air bubbles, or equipment calibration.[35,37] Of these factors, viscosity is the single most important driver of equipment choice.[37] Some machines may develop calibration drift that leads to dosing errors. A **PRO TIP** is to use gravimetric checks (weight verification) to ensure that their filling machines are accurate.

Compounders need to realize that they need to continuously stir suspensions when using filling machines to ensure that the product is evenly distributed. They must also premix creams in an appropriate mixer like a planetary mixer before using the machine. Another limitation is air incorporation. If for some reason the filling machine is incorporating air into the product, the fills will be inaccurate and the product's stability uncertain; air incorporation is most likely to occur with foaming liquids, gels, or creams. Finally, each of those machines needs to be cleaned thoroughly in accordance with the device's manual directions between all formulations.

Some ophthalmic preparations, oral solutions, and suspensions are only stable within a narrow pH range (see the **SIDEBAR**).[37,38] **pH meters** are electronic instruments that measure the acidity or alkalinity of a solution by detecting hydrogen ion activity. The typical device has a glass electrode (sensing element), a reference electrode, and a digital meter that converts voltage into pH units. The measurement the device produces uses electrochemical principles described by the Nernst equation, which relates voltage to ion concentration. Compounders need to know that with some devices, pH readings can change with temperature. (Those that have automatic temperature compensation are less likely to have this problem, but the manual will describe the temperature excursions window in which the device is reliable.) Most machines require thorough cleaning and electrode storage in a potassium chloride solution. They are less reliable in viscous solution, non-aqueous, or solution of low-ionic strength. An example of a low-ionic strength solution is preservative-free artificial tears. They have few dissolved ions (like sodium, chloride, potassium) compared with normal saline or buffered IV fluids, which makes them low ionic strength.

CONCLUSION

Overall, an efficient compounding company needs well-organized workspaces with designated zones for weighing, mixing, and packaging. Its work areas should be streamlined and well thought out to decrease excess motions and to reduce cross contamination. It is important to follow USP standards closely, and to conduct performance testing. Use best practices with quality assurance checks and regular sanitization and perform maintenance checks regularly and don't forget to fill out those training, cleaning, and maintenance logs.

When considering a certain machine, managers should ask the manufacturer of the machine for names of companies who have recently purchased the product. Reach out to those companies for feedback on the device. It is also important to let the compounders who are going to use the machine in your compounding company have an opinion.

Automated machines eliminate human error and can reduce cross contamination. They can produce compounds which have better consistencies that can increase absorption and enhance comfort. Most importantly, they allow the compounder to create specialized/customized vehicles with adjusted strengths, which opens up more treatment options for our patients.

Figure 1 summarizes key points.

Figure 1. Selecing, Using, and Maintaining Compounding Machines

Best

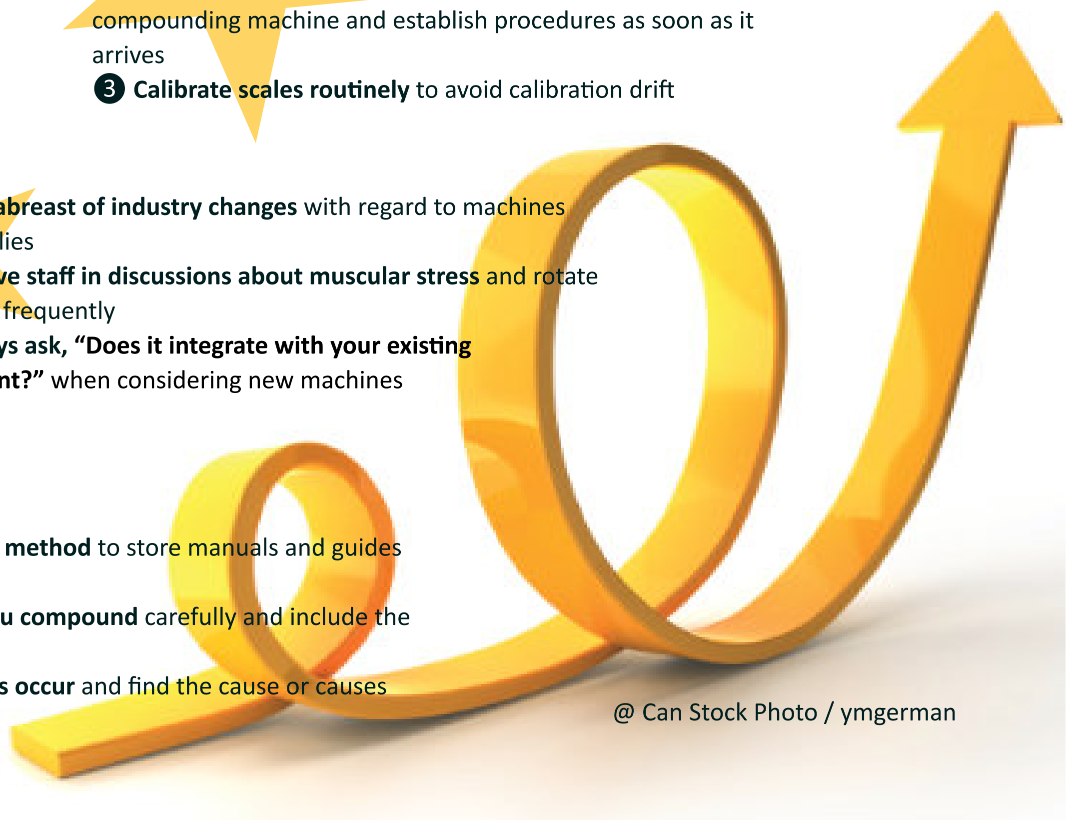
❶ **Be COMMUNITY CHAMPIONS** and talk about the ways that compounders can address challenging medication issues
❷ **Encourage discussion** with staff about any purchase of a compounding machine and establish procedures as soon as it arrives
❸ **Calibrate scales routinely** to avoid calibration drift

Better

❶ **Stay abreast of industry changes** with regard to machines and supplies
❷ **Involve staff in discussions about muscular stress** and rotate positions frequently
❸ **Always ask, "Does it integrate with your existing equipment?"** when considering new machines

Good

❶ **Establish a consistent method** to store manuals and guides for every machine
❷ **Track the products you compound** carefully and include the volume and frequency
❸ **Document if variances occur** and find the cause or causes



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