PHARM TECH BASICS · ONE-PAGER

Compounding and Beyond-Use Dates

Non-sterile tools and techniques (USP <795>), hoods, ISO classes, garbing and CSP categories (USP <797>), needles and syringes, repackaging and unit-dose labels, and compounding records

23 sources + more detail

pharmtechbasics.com/sheets/pharm-compounding-bud.html

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1 Non-sterile tools and techniques (USP <795>)

ITEM	USE IT FOR
Wedgwood mortar	Grinding (trituration): rough, porous surface; never for dyes, which stain it
Glass mortar	Drugs that stain, and dissolving crystals in a liquid; smooth, so not the usual choice for grinding
Porcelain mortar	Emulsions and solutions that do not stain
Spatula and ointment slab	Stainless steel or hard rubber spatula; ground glass or porcelain slab for mixing ointments
Balance and weigh boats or papers	Weigh on a fresh boat for each ingredient; tare first; Class III (Class A) torsion balance: 6 mg sensitivity, 120 mg least weighable
Graduated cylinder	Smallest size that holds the volume; read the bottom of the meniscus at eye level; cylindrical beats conical

TECHNIQUE	WHAT IT IS
Trituration	Grinding a powder fine, or mixing powders, with mortar and pestle
Levigation	Making a paste of a powder with a liquid it does not dissolve in (mineral oil, glycerin) to shrink particles
Geometric dilution	Mix the small-quantity drug with an equal amount of base, then keep adding amounts equal to the mixture
Spatulation	Mixing with a spatula on a slab or paper

2 Default BUDs for non-sterile preparations (2023 <795>)

Used when no USP monograph or formulation-specific stability study applies. Never later than the earliest expiration date of any ingredient.

PREPARATION	DEFAULT BUD
Aqueous (water activity 0.60 or more), no preservative	14 days, refrigerated
Aqueous, preserved	35 days, room temperature or refrigerated
Nonaqueous oral liquid (water activity below 0.60)	90 days, room temperature or refrigerated
Other nonaqueous forms (capsules, tablets, powders)	180 days, room temperature or refrigerated

EXAM TIP Older books show 14 days (water-containing oral), 30 days (water-containing topical) and 6 months (nonaqueous). Those are the pre-2023 values; the 2023 chapter adds 35 and 90 days and sorts by water activity.

3 Sterile compounding (USP <797>)

HOOD (PRIMARY ENGINEERING CONTROL)	AIRFLOW AND USE
Horizontal laminar airflow workbench (LAFW)	HEPA air blows from the back toward you: protects the product only; never for hazardous drugs
Biological safety cabinet (BSC), Class II	Vertical, inward and downward air, HEPA-filtered exhaust: protects product, worker and room; used for chemotherapy
Compounding aseptic isolator (CAI)	Closed glove box, ISO 5, for non-hazardous CSPs
Compounding aseptic containment isolator (CACI)	Closed glove box, ISO 5, for hazardous drugs: also protects the worker

SPACE	ISO CLASS (LOWER NUMBER = CLEANER)
Inside the hood (direct compounding area)	ISO 5 (old 'Class 100')
Buffer room, where the hood sits	ISO 7
Anteroom (hand washing, garbing)	ISO 8, or ISO 7 if it opens to a negative-pressure hazardous drug room
Segregated compounding area (SCA)	Unclassified space with a hood: Category 1 CSPs only

1. Remove jewelry, makeup, nail polish and artificial nails.
2. Shoe covers, then head and facial hair covers, then mask (dirtiest to cleanest).
3. Wash hands and forearms to the elbows for at least 30 seconds; dry with low-lint towels.
4. Gown.
5. Alcohol-based surgical hand rub; let it dry.
6. Sterile gloves last, then sanitize them with sterile 70% isopropyl alcohol.

TYPE	WHERE AND HOW LONG
Immediate-use	No more than 3 sterile products; administration starts within 4 hours of starting preparation
Category 1	SCA or cleanroom; 12 hours room temperature or 24 hours refrigerated
Category 2	Cleanroom suite only; about 1 to 90 days, by sterility method, testing, ingredients and storage
Category 3	Cleanroom suite plus extra testing and garb; 60 to 180 days

SAFETY A single-dose vial punctured inside ISO 5 air is good for 12 hours at most; an opened ampule is used at once and never stored; a multiple-dose vial lasts 28 days after first entry unless the label says less.

4 Needles, syringes and filters

ITEM	KEY POINT
Needle gauge	Higher number = thinner needle (about 13 to 27 in the IV room); use a wider needle for thick fluids
Luer-Lok tip	Threaded collar locks the needle on
Slip tip	Needle held by friction; can pop off under pressure
Catheter tip	Large tapered tip for irrigation and feeding tubes, not for needles; ENFit tips cannot fit IV Luer connectors
Filter needle (5 micron)	Draw up from a glass ampule, then change to a new needle before pushing the drug out
Vented needle	Lets air in to equalize vial pressure and reduce blowback; the maker says never for hazardous drugs
0.22-micron membrane filter	Sterilizes a solution as it is pushed out of the syringe

5 Repackaging, labels and records

- Unit-dose label (typical state rule): drug name, strength, dosage form, manufacturer, lot number (or one that traces to it), and BUD or expiration date.
- Repackaged solid (nonaqueous) BUD: FDA's pharmacy guidance (2017) allows up to 6 months, never past the original expiration date; commercial unit-dose repackagers (FDA 2020, USP <1178>) use 6 months or 25% of the time left to the manufacturer's expiration, whichever is shorter. State rules can differ; follow your SOP.
- Master formulation record (MFR): the recipe. How to make the preparation, ingredients and amounts, equipment, steps, BUD and storage with its reference, label, container, quality checks.
- Compounding record (CR): what was made this time. Each ingredient's lot and expiration, amounts weighed, who compounded and who checked, date, internal ID, BUD.

EXAM TIP Label a compounded preparation with a beyond-use date (BUD), not an 'expiration date'. The BUD counts from the date and time it was compounded.

6 Exam pearls

- Dyes and staining drugs: glass mortar. Hard crystals to grind: Wedgwood.
- Small amount of potent drug into a large amount of base: geometric dilution.
- Less than 120 mg on a torsion balance: make a trituration or liquid aliquot first.
- Horizontal hood blows toward you, so no chemotherapy in it; chemotherapy goes in a Class II BSC or a CACI.
- Gloves are mandatory for all non-sterile compounding; sterile gloves go on last for sterile compounding.
- USP chapters bind a pharmacy through its state board; states may add stricter rules.

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