PHARM TECH BASICS · ONE-PAGER

Storage, Recalls, Returns and Disposal

USP storage temperatures, light and moisture, vaccine monitoring, in-use and expiration dates, recall classes, returns and reverse distribution, and federal disposal rules

33 sources + more detail

pharmtechbasics.com/sheets/pharm-storage-recalls-returns.html

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1 Storage temperatures (USP terms)

'Excursions permitted' covers brief swings, as in shipping, not a warmer place to keep stock.

LABEL TERM	CELSIUS	FAHRENHEIT
Freezer	-25 to -10 °C	-13 to 14 °F
Refrigerator (a cold place)	2 to 8 °C	36 to 46 °F
Cool	8 to 15 °C	46 to 59 °F
Controlled room temperature	20 to 25 °C; excursions 15 to 30 °C allowed	68 to 77 °F; excursions 59 to 86 °F
Warm	30 to 40 °C	86 to 104 °F
Excessive heat	Above 40 °C	Above 104 °F

- Light: keep the product in its carton or a light-resistant container until use. Latanoprost, insulin and many vaccines say 'protect from light'.
- Moisture and potency: dispense in a tight container when the label says so. Nitroglycerin sublingual tablets stay in the original glass bottle, capped tightly after each use, to keep their potency. Dabigatran capsules stay in the original bottle or blister to protect them from moisture, never a pill organizer.
- Restricted access: C-II to C-V go in a locked, sturdy cabinet, or a pharmacy may disperse them through the non-controlled stock (21 CFR 1301.75).

EXAM TIP Know two pairs cold: refrigerator 2 to 8 °C = 36 to 46 °F, and controlled room temperature 20 to 25 °C = 68 to 77 °F.

2 Vaccines and temperature monitoring (CDC)

- Ranges: refrigerator 2 to 8 °C (36 to 46 °F); vaccine freezer -50 to -15 °C (-58 to 5 °F); ultra-cold -90 to -60 °C. Check each package insert.
- Monitor with a digital data logger (DDL): buffered probe in the center of the vaccines, display outside the door, alarm, min/max display.
- At the start of each workday, check and record the min and max temperature, date, time and your name. Keep logs 3 years.
- Never use a dormitory-style or bar-style refrigerator-freezer. No food or drinks in the unit. Earliest expiration dates in front.

SAFETY On an excursion: tell the vaccine coordinator or supervisor at once, label the vaccines 'DO NOT USE', keep them at the correct temperature, apart from other stock, and do not discard them. Only the manufacturer or the immunization program can say they are still usable.

3 Expiration and in-use dates

A date given as month and year means the last day of that month: 12/2026 is good through December 31, 2026. An in-use or beyond-use date replaces the expiration date but never extends it: use whichever comes first.

PRODUCT (LABEL)	BEFORE OPENING OR MIXING	AFTER OPENING OR MIXING
Insulin lispro pen (Humalog KwikPen)	Refrigerate: good to the expiration date. Room temperature (up to 30 °C): 28 days	28 days at room temperature, counting any unopened days out of the refrigerator; do not refrigerate
Amoxicillin oral suspension	Dry powder at controlled room temperature	Discard after 14 days; refrigeration preferable, not required
Amoxicillin-clavulanate suspension	Dry powder at or below 25 °C	Refrigerate; discard after 10 days
Latanoprost eye drops (Xalatan)	Refrigerate 2 to 8 °C, protected from light	Room temperature up to 25 °C for 6 weeks
Dabigatran capsule bottle (Pradaxa)	Controlled room temperature, original bottle	Use within 4 months of opening

Rotate stock first-expired, first-out: shortest date to the front, newest delivery behind it. Pull expired product at once and set it apart for return or disposal.

4 Recalls and market withdrawals (21 CFR 7.3)

TYPE	HEALTH RISK	USUAL DEPTH
Class I	Reasonable probability of serious harm or death	Consumer (patient) level
Class II	Temporary or medically reversible harm; serious harm remote	Retail (pharmacy) level
Class III	Not likely to cause harm (for example a labeling error)	Wholesale level
Market withdrawal	Minor or no violation; FDA would not take legal action	Set by the firm

1. Match the notice to your stock by NDC and lot number (shelves, will-call, robots, the refrigerator).
2. Pull every matching unit, label it 'Recalled: do not dispense' and quarantine it.
3. Follow the firm's instructions (return or destroy), send back its response form even if you had none, and keep a record.
4. For a patient-level recall, the pharmacist decides who is contacted and answers questions about stopping the drug.

EXAM TIP Class I is the most dangerous. Class numbers rank the hazard; the recalling firm, not the pharmacy, decides what happens to the product.

5 Returns

PRODUCT	WHERE IT GOES
Saleable overstock or product ordered in error	Credit return to the wholesaler it came from, under the wholesaler's policy
Expired, damaged or recalled stock	Nonsaleable return: manufacturer, wholesaler, or a reverse distributor (returns processor) that arranges credit and destruction
Prescription filled but never picked up	Reverse the claim; return to stock only as state law and pharmacy policy allow, with the drug, lot and expiration still identifiable
Controlled substance from a patient	Never back to stock: only an authorized collection receptacle or mail-back package, then destruction

Non-returnable items are set by the wholesaler's or manufacturer's policy, not federal law. For vaccines, open or broken vials and syringes, activated manufacturer-filled syringes and predrawn doses cannot be returned (CDC). C-II returns need a DEA Form 222 (or CSOS order) from the receiver.

6 Disposal (federal rules)

WASTE	WHAT HAPPENS
Pharmacy's own controlled stock	Reverse distributor, return to supplier, or on-site destruction to non-retrievable with two employees witnessing, recorded on DEA Form 41
Patients' unwanted drugs	Authorized collector's receptacle, mail-back envelope or Take Back Day; if none, FDA flush list drugs are flushed, others mixed with litter or coffee grounds in a sealed bag in the trash
Hazardous waste pharmaceuticals (P- and U-listed, characteristic)	Never down the drain (EPA sewer ban since August 21, 2019); hazardous waste container, or a reverse distributor if potentially creditable
Sharps	Closable, puncture-resistant, leakproof, labeled or color-coded container, upright and not overfilled (OSHA)

SAFETY Never take a patient's controlled drugs back over the counter, and never pour hazardous drugs down a sink. States may be stricter than these federal rules.

7 Documentation

- Temperature logs with excursions and actions (CDC: 3 years).
- Recall notices, what was pulled and returned, and the response sent.
- Controlled substance returns, Form 222s and Form 41s (DEA: at least 2 years).
- Collection receptacle inner liner records, signed by the two employees.
- DSCSA transaction information and statements (6 years).

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