PHARM TECH BASICS · ONE-PAGER

Hazardous Drugs: Handling, Spills and Disposal

What makes a drug hazardous, the NIOSH 2024 tables, USP <800> in a pharmacy, gloves and gowns, spill steps, hazardous drug waste versus EPA hazardous waste, and safety data sheets

24 sources + more detail
pharmtechbasics.com/sheets/pharm-hazardous-drugs.html
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1 What makes a drug hazardous

NIOSH calls a drug hazardous when it is approved for humans by FDA's drug center (CDER), is not regulated by the Nuclear Regulatory Commission (radioactive drugs are), and either carries manufacturer's special handling information in its package insert or shows one of six toxicities: cancer, harm to a developing baby (including birth defects), harm to fertility, damage to genes, organ damage at low doses, or a structure and toxicity like an existing hazardous drug. About 8 million US healthcare workers may be exposed, pharmacy staff and receiving clerks among them.

EXAM TIP Three bodies, three jobs. NIOSH says which drugs are hazardous (advisory). USP <800> says how to handle them (enforced by state boards and accreditors that adopt it). EPA says which waste drugs are hazardous waste (federal law, run by the states). A drug can be on one list and not the other.

2 The NIOSH 2024 list: two tables

TABLE	WHAT PUTS A DRUG THERE	EXAMPLES ON THE 2024 LIST
Table 1	Special handling information in the package insert, and/or a known or probable human carcinogen (NTP, IARC Group 1 or 2A). Many are cytotoxic; not all are cancer drugs	Methotrexate, cyclophosphamide, hydroxyurea, tamoxifen, azathioprine, mycophenolate mofetil, valganciclovir; conjugated estrogens and estrogen/progesterone combinations
Table 2	Meets the NIOSH definition without the Table 1 features. Also holds drugs that are only a reproductive or developmental hazard (the old Table 3)	Anastrozole, letrozole, estradiol, carbamazepine, phenytoin, spironolactone. Reproductive or developmental only: finasteride, dutasteride, warfarin, valproate, testosterone, misoprostol, paroxetine

EXAM TIP The 2016 list sorted hazardous drugs into three tables and called Table 1 'antineoplastic'. The 2024 list has two, and some cancer drugs (anastrozole, letrozole) sit in Table 2. For USP <800>, 'antineoplastic' means a cancer drug in Table 1.

3 USP <800> in a pharmacy

STEP	RULE
List and assessment of risk	The pharmacy keeps its own hazardous drug list. Table 1 antineoplastics that need manipulation and any bulk ingredient (API) get full containment; for other drugs and dosage forms, a written assessment of risk, drug by drug, may set other controls
Receiving	Unpack Table 1 antineoplastics and APIs in a designated area at neutral or negative pressure, never in a positive-pressure or sterile compounding room, wearing at least one pair of chemotherapy gloves. A damaged box is handled as a spill
Storage	Table 1 antineoplastics needing manipulation and all APIs: separate from other stock, in an externally vented negative-pressure room with at least 12 air changes per hour (a dedicated refrigerator there for cold items). Final dosage forms may sit with other stock if policy allows
Counting and packaging	Dedicated tray and spatula, cleaned after use. Never put Table 1 antineoplastic tablets or capsules in an automated counting or packaging machine. Do not crush or split outside a containment hood
Compounding	Table 1 antineoplastics and APIs: in a containment hood (C-PEC) inside a negative-pressure room (C-SEC); other hazardous drugs as the assessment of risk sets. Closed-system transfer devices are recommended for compounding and required for giving Table 1 antineoplastics when the dosage form allows

4 Protective equipment

TASK	GLOVES	GOWN AND MORE
Receiving, storing, counting intact tablets	Chemotherapy gloves; one pair is usually enough for intact forms	Per SOP; gown and more if a leak is seen or suspected
Crushing, splitting, opening capsules, compounding	Two pairs of chemotherapy gloves	Protective gown shown to resist hazardous drugs, hair and shoe covers; eye, face and respiratory (N95) protection if not in a hood
Spill cleanup	Two pairs	Gown, goggles with face shield, shoe covers, and a respirator: N95, or a chemical cartridge respirator for a large liquid spill

- Chemotherapy gloves are tested to ASTM D6978, powder-free, never latex. Inner glove under the gown cuff, outer glove over it. Change about every 30 minutes, or at once if torn or contaminated.
- Gowns: disposable, closed in the back, long sleeves with tight cuffs, shown to resist hazardous drugs. Never a cloth lab coat. Never reused.
- A surgical mask is not respiratory protection. Use a fit-tested N95 for powders; a full-facepiece chemical cartridge respirator or PAPR for large liquid spills and volatile drugs.
- Wash hands with soap and water after removing gloves; NIOSH says not to use alcohol-based hand gel.

5 Spill steps

1. Stop, warn others, post a sign and keep people out of the area.
2. Get the spill kit. A trained person cleans; call for help if the spill is too large to contain.
3. Put on two pairs of chemotherapy gloves, gown, goggles and face shield, shoe covers, and a respirator (N95; a chemical cartridge respirator for a large liquid spill).
4. Liquids: cover with absorbent pads. Powders: cover with wet pads or towels so no dust rises. Glass: scoop into a puncture-proof container.
5. Work from the cleanest edge toward the center; bag all waste and PPE as hazardous drug waste.
6. Deactivate, decontaminate, clean and disinfect the area, then wash hands with soap and water.
7. Report and document: drug, amount, cause and everyone exposed.

SAFETY Drug on skin: wash at once with soap and water. In the eyes: flush with water or an eyewash for at least 15 minutes. Then report it.

6 Waste: hazardous drug versus EPA hazardous waste

STREAM	WHAT GOES IN	COMMON CONTAINER
Trace chemotherapy	Empty vials, syringes, gloves and gowns with only trace residue	Yellow
RCRA hazardous waste	P-listed, U-listed or characteristic (D-coded) drug waste; PPE visibly contaminated with drug; spill cleanup items the waste plan sends here	Black
Nonhazardous pharmaceutical	Drug waste that is neither	White or blue

DRUG	NIOSH	EPA WASTE CODE
Warfarin	Table 2 (reproductive)	P001 above 0.3 percent; U248 at or below
Nicotine	Not listed	P075, except FDA-approved OTC patches, gum and lozenges (once the state adopts the exemption)
Arsenic trioxide	Table 1	P012
Cyclophosphamide	Table 1	U058
Methotrexate	Table 1	Not P- or U-listed

SAFETY Never pour or flush hazardous waste drugs down a drain. EPA's sewer ban has covered every pharmacy and healthcare facility in every state since August 21, 2019. Colors are common practice, not federal law; follow the pharmacy's waste vendor.

7 Safety data sheets

OSHA's Hazard Communication standard requires a safety data sheet (SDS, formerly MSDS) for each hazardous chemical in the workplace, readily available to staff on every shift; electronic access is allowed. Drugs in solid, final form for direct administration (tablets, pills) and drugs packaged for retail sale to consumers (OTC) are exempt; hazardous liquid and powder drugs, bulk ingredients and cleaning chemicals are covered. Every SDS has 16 sections in a fixed order.

EXAM TIP Sections exams ask about: 2 hazards, 4 first aid, 6 accidental release (spills), 7 handling and storage, 8 exposure controls and PPE, 13 disposal.

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