Handling Hazardous Meds

USP provides guidance on safely handling hazardous meds (as defined by NIOSH) in all settings, including inpatient and outpatient sites (pharmacies, physician offices, etc). USP <800> addresses ALL aspects of handling hazardous meds, such as receiving, storing, compounding, transporting, administration, and disposal. The goal is to minimize the risk of contamination to the patient, the healthcare worker, and the environment.[1] The chart below reviews pertinent updates for the handling of hazardous meds including conducting an assessment of risk and use of proper personal protective equipment. The list of hazardous meds identified by NIOSH is available at https://www.cdc.gov/niosh/topics/hazdrug/default.html. Share our technician tutorials, *Hazardous Drugs 101* and *Medication Disposal in the Hospital* with your techs to keep them up to speed on the latest in handling and disposing of hazardous meds.

Question	Pertinent Information

What are the differences between USP <795>, <797>, and <800>?	• USP <795>: pharmaceutical compounding of NON-sterile preparations
	• USP <797>: pharmaceutical compounding of sterile preparations
	• USP <800>: handling of **hazardous drugs** in the healthcare setting
	• When compounding a product that includes a hazardous drug, both applicable chapters should be followed. For example:
	  o Follow USP <795> and <800> when compounding a **NON-sterile product containing a hazardous drug**.
	  o Follow USP <797> and <800> when compounding a **sterile product containing a hazardous drug**.
	• See our CEs, *USP 800 - Hazardous Med Handling* and *Sterile Compounding: Basics of USP Chapter 797* for more on hazardous meds and compounding.

How are hazardous meds defined?
 	
Continued…
	• Use NIOSH as a tool or aid when creating your facility-specific hazardous med list, as the NIOSH list is not comprehensive.[2]
	• The NIOSH list of hazardous meds includes drugs approved for use through the FDA Center for Drug Evaluation and Research (CDER). Drugs evaluated through the FDA Center for Biologic Evaluation and Research (CBER) are NOT included in the hazardous med list. These include vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins (e.g., Bacillus Calmette Guerin [BCG]).[3]
	• NIOSH defines a med as hazardous if it has one or more of the following characteristics in humans or animals:[3]
	  o **carcinogenicity** (cancer causing).
	  o **teratogenicity** or other **developmental** toxicity (causing harm to an unborn baby).
	  o **reproductive toxicity** (interference with normal reproduction such as effects on fertility in either sex).
	  o **organ toxicity** at low doses (harming organs, such as heart, liver, lungs, etc).
	  o **genotoxicity** (damaging the genetic information in a cell, which could lead to cancer).
	  o **similar structure or toxicity profile** to a med already determined to be hazardous

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defining hazardous meds, continued	• The NIOSH list of hazardous meds is periodically updated, therefore newer meds may not be included on the current list. The 2024 list only includes meds approved through December 2015. For newer drugs or drugs approved through CBER, consider the following as an indicator of their risk until further guidance is available: structure and toxicity profiles that are the same as existing hazardous drugs, information in product labeling, peer-reviewed literature about the hazard potential, or safety data sheets.[2,3] For investigational drugs, if the mechanism of action suggests there may be concern, treat these as hazardous drugs until data are available to exclude them.[3]
How are hazardous meds classified?	• Previously, hazardous meds were divided into THREE groups:[2] o Group one: **antineoplastic drugs** (per the American Hospital Formulary Service [AHFS] classification) o Group two: **NON-antineoplastic drugs** o Group three: **meds with primarily reproductive risk** (i.e., to males and females who are trying to conceive and persons who are either pregnant or breastfeeding). • These three groups of hazardous meds may have led to some confusion because categorizing a med as "antineoplastic" doesn't tell the whole story. For example, meds used to treat cancer aren't all cytotoxic. Plus, some antineoplastics have non-cancer indications. • There are TWO groups or tables in the 2024 NIOSH list:[2] o **Table 1**: **Known or probable carcinogens** according to the National Toxicity Program (NTP) or International Agency for Research on Cancer (IARC) or hazardous meds with special handling instructions in their product labeling. o **Table 2**: Meds not thought to be carcinogens according to NTP or IARC, but are **defined as hazardous by NIOSH** due to other adverse effects (e.g., developmental toxicity, organ toxicity, reproductive effects). o **Antineoplastics can be included in Table 1 or Table 2**, but only those in **Table 1** are known or probable carcinogens. • You can access the full NIOSH list of hazardous meds at https://www.cdc.gov/niosh/docs/2025-103/pdfs/2025-103.pdf?id=10.26616/NIOSHPUB2025103.
What training is required for staff who work with hazardous meds?	• Designate one or more persons to be responsible for and oversee compliance with hazardous meds.[4] • Tailor training to the applicable job functions of personnel (receiving, compounding, dispensing, administering).[1] • All staff involved with hazardous meds must be fully trained prior to working with hazardous meds independently.[1] • Training and demonstration of competency are required ANNUALLY and must include:[1] o overview of the facility's designated list of hazardous drugs and their risks and labeling requirements. o review of all policies and procedures related to hazardous drugs. o proper use of devices, equipment, and PPE. o what to do in case of exposure or a spill. o proper disposal of hazardous meds and contaminated materials.

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What containment strategies and/or work practices should be followed when handling hazardous meds?	USP <800> containment strategies and work practices to limit exposure to hazardous meds must always be adhered to for:[4] • hazardous med active pharmaceutical ingredients (APIs) • antineoplastics (per Table 1 of the most recent NIOSH list)[5] requiring manipulation. Facilities are allowed to customize their containment strategies/work practices based on an "assessment of risk" for some individual hazardous meds to determine how best to protect their employees (see the **requirements for assessment of risk** in the next section).[1] These risk assessments can be done for the following types of NIOSH hazardous med classifications:[1] o antineoplastics that DO NOT require manipulation (e.g., only packaging, counting) o NIOSH table 2 antineoplastics o NON-antineoplastics o final dosage forms of compounded hazardous meds Some **example containment/work practice strategies to limit exposure** to hazardous meds include: • Use disposable or dedicated equipment (e.g., counting trays, spatulas) for counting hazardous meds that only require counting or repackaging of final dosage forms.[1] Use wipes (wetted with an appropriate solution), instead of spray bottles to decontaminate reusable spatulas and counting trays after EACH use. Spray bottles could spread hazardous residue.[1] • Regardless of risk assessments, DO NOT USE automatic counting or packaging machines for any **NIOSH Table 1 antineoplastic** tablets or capsules.[1] Use of these machines can create residue that could contaminate both the machine and potentially other medications used in these devices.[1] • If your facility compounds sterile and non-sterile hazardous meds, it may be easier to maintain the sterile environment if these compounding areas are separated. Sterile and non-sterile containment primary engineering controls (C-PECs) can be located in the same room AS LONG AS sterile requirements are maintained. However, this is not recommended.[1] • Crushing or splitting hazardous meds is considered compounding. Where and how this is done may depend on the assessment of risk. For example, NIOSH Table 1 antineoplastics must be crushed in a chemo hood. However, based on the assessment of risk, crushing of other hazardous meds may be allowed on the floor in a containment device (e.g., *RxCrush*).[1]
What are the assessment of risk requirements? *Continued…*	For hazardous meds that meet the appropriate criteria (see above), an assessment of risk can be performed to determine the containment strategies/work practices needed to protect employees. This assessment will be based on the medication's risk and how it will be used in the facility. • The following must be included in the assessment of risk:[1] o hazardous med classification (i.e., based on the current NIOSH list) o dosage form (How can the hazardous med potentially enter the body: skin, inhalation, ingestion, etc?) o risk of exposure (What PPE is available? What engineering controls are available?) o manipulation (How is the med handled? How often is the med handled?) o packaging (description of packaging in which hazardous med is received)

Question	Pertinent Information

assessment of risk requirements, continued	• Documentation must include the alternate containment strategy/work practice that will be used to minimize exposure.[1]
	  o For example, alternate containment strategies/work practices could include:[6]
	  ▪ purchasing unit-dose or unit-of-use product to eliminate need for manipulation or compounding.
	  ▪ package all liquid doses in patient-specific oral syringes
	  ▪ labeling lidded automated dispensing cabinet bins so anyone who accesses or administers these meds is reminded of necessary PPE to use when administering or handling.
	• Assessments of risk for hazardous meds must be reviewed (and documented) at least once yearly.[1] Examples of hazardous drug assessment of risk templates can be found online at various websites (e.g., ASHP, CriticalPoint).[6,7]

What are the cleaning requirements with hazardous meds?	• All areas and equipment where hazardous meds are handled need to be deactivated, decontaminated, and cleaned. In addition, areas where hazardous drugs are involved in **sterile compounding** must be disinfected.[1]
	• Follow policies and procedures for deactivation, decontamination, cleaning, and disinfecting. The requirements will vary based on the situation.
	  o Two pairs of chemotherapy gloves and disposable impermeable gowns are required for these activities.[1]
	  o Eye protection may be needed if splashing is expected.[1]
	  o Respiratory protection may be needed if dust particles are expected.[1]
	  o Use wipes (wetted with an appropriate solution), instead of spray bottles. Spray bottles could spread hazardous residue.[1]
	• See our CE, *USP 800 - Hazardous Med Handling*, for information on surface sampling.

What personal protective equipment (PPE) should be used?	• USP <800> and NIOSH both provide recommendations on the use of PPE (e.g., gloves, gowns, head, hair, shoe, and sleeve covers; eye and face protection; respiratory protection).[1-3] For example:[1,3]
	  o Single gloves are appropriate for **unpacking or receiving orders** of hazardous meds, unless a spill occurs (then double gloves are needed).
	  o Double gloves and two pairs of shoe covers are appropriate for **sterile** and **non-sterile compounding** of hazardous meds.
	  ▪ The outer pair of gloves must be sterile for **sterile compounding**.
	  o Eye /face protection is appropriate when using liquids that can splash.
	  o Gowns are appropriate for sterile and non-sterile compounding. Gowns must be **impermeable and disposable**.
	  o For more details and additional practical examples concerning PPE use, refer to chapter 8 of the 2023 NIOSH Managing Hazardous Drug Exposures: Information for Healthcare Settings guidance (https://www.cdc.gov/niosh/docs/2023-130/2023-130.pdf?id=10.26616/NIOSHPUB2023130).[3]
	• For medications that undergo an assessment of risk, follow your facilities policies and procedures for PPE requirements.
	  o Single gloves may be deemed appropriate for counting some hazardous meds in capsule form, but double gloves may be required for prepping an intravenous dose of the same med.
	• See our CE, *USP 800 - Hazardous Med Handling*, for specific requirements on spill kits and use of PPE during spills.

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What are specific pregnancy- and conception-related considerations?	• Always follow policies and procedures when handling hazardous meds. However, consider additional precautions during pregnancy, while breastfeeding, or if trying to conceive. Note that it is appropriate for persons who are pregnant or breastfeeding, or males or females who are trying to conceive, to work with their supervisor on possible alternative work assignments (i.e., involving no or less handling of hazardous meds).[8] • Refer to product labeling to see if there are specific recommendations for pregnant or breastfeeding persons, or for males or females trying to conceive. For example (**note this list is NOT inclusive**), product labeling states pregnant persons (or persons who may become pregnant) should: o not handle **dutasteride capsules** (*Avodart*, *Jalyn*). If contact is made with leaking capsules, wash the area immediately with soap and water.[9] o not handle **crushed or broken finasteride tablets** (*Propecia*, *Proscar*). Finasteride tablets are coated and will prevent contact with the active ingredient during normal handling provided that the tablets have not been broken or crushed.[9] o generally avoid direct care of patients who are receiving **aerosolized ribavirin** (*Virazole*). Refer to US product labeling for specific recommendations if direct care cannot be avoided.[10,11] o avoid exposure to patient's **testosterone gel application sites**, as well as **used testosterone packets, patches, or pumps** (*AndroGel*, *Testim*, etc).[9] If unwashed or unclothed skin to which gel has been applied (or unwashed clothing exposed to testosterone gel) comes in direct contact with the skin of a pregnant person (or any non-patient), wash the general area of contact on the person with soap and water as soon as possible.[9]
What medical surveillance is recommended for healthcare workers who handle hazards drugs?	• Medical surveillance is used in conjunction with exposure control programs, engineering controls, safe work practices, and PPE to minimize adverse effects to staff who could be exposed to hazardous drugs.[1] Expect to be involved in a medical surveillance program if you handle hazardous drugs.[1] • See our CE, *USP 800 - Hazardous Med Handling*, for facility and employee involvement and responsibilities in medical surveillance programs.
When and how will USP <800> be enforced?	• USP <800> has been enforceable as of November 1, 2023.[4] • See our CE, *USP 800 - Hazardous Med Handling*, for what USP <800> recommends to be included in policies and procedures related to hazardous meds. • Enforcement of compliance with USP <800> is the responsibility of regulators (e.g., The Joint Commission, state boards of pharmacy). USP has no role in enforcing USP <800>.[4]

Abbreviations: NIOSH = National Institute for Occupational Safety and Health; PPE = personal protective equipment; PPPM = Pharmacy Purchasing & Products Magazine; USP = United States Pharmacopeia.

Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

Levels of Evidence

In accordance with our goal of providing Evidence-Based information, we are citing the **LEVEL OF EVIDENCE** for the clinical recommendations we publish.

Level	Definition	Study Quality
A	Good-quality patient-oriented evidence.*	1. High-quality randomized controlled trial (RCT) 2. Systematic review (SR)/Meta-analysis of RCTs with consistent findings 3. All-or-none study
B	Inconsistent or limited-quality patient-oriented evidence.*	1. Lower-quality RCT 2. SR/Meta-analysis with low-quality clinical trials or of studies with inconsistent findings 3. Cohort study 4. Case control study
C	Consensus; usual practice; expert opinion; disease-oriented evidence (e.g., physiologic or surrogate endpoints); case series for studies of diagnosis, treatment, prevention, or screening.	

***Outcomes that matter to patients** (e.g., morbidity, mortality, symptom improvement, quality of life).

[Adapted from Ebell MH, Siwek J, Weiss BD, et al. Strength of Recommendation Taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. Am Fam Physician 2004;69:548-56. https://www.aafp.org/pubs/afp/issues/2004/0201/p548.html.]

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Cite this document as follows: **Clinical Resource,** ***Handling Hazardous Meds. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber Insights.*** **February 2025. [410269]**