Best Practice Handling Hazardous Drugs Tablets, Capsules, Oral Solutions, Topicals

United States Pharmacopeia Chapter:
USP <800>: Hazardous Drugs—Handling in Healthcare Settings

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During her pharmacy career, she served as the Director of Pharmacy for a number of hospitals and health systems throughout California before joining ARxIUM. In that time she also, designed and built a number of hospital pharmacies, including her seventh pharmacy, an off-site central fill automated production pharmacy that include a state of the art non-hazardous and hazardous cleanroom, supplying the UCSF Medical Center Health System.

Backed by more than 35 years of experience, Scarlett has extensive knowledge of medication management and safety, compliance and regulatory issues. She is well versed in the most recent versions of USP 797, USP 800 and the National Association of Pharmacy Regulatory Authorities (NAPRA): Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations and Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. Scarlett specializes in working with individual hospitals or large health systems in understanding and how to implement USP 797, USP 800 and/or NAPRA with their current cleanroom space and/or to help them re-design or build a new cleanroom.

OBJECTIVES

- Identify Hazardous Exposure Risks in Handling of Hazardous Drugs and identify appropriate process for containment of hazardous residue
- Recognize how to complete the Assessment of Risk (AoR) of NIOSH listed drugs
- Identify the proper handling of Hazardous consumables: receiving, storage, dispensing, delivery, and waste; recognize the proper use of personal protective equipment
- Summarize cleaning, deactivation, decontamination, containment and personnel safety in handling hazardous drugs
- Identify appropriate cleaning process including: deactivation, decontamination, containment and personnel safety in handling hazardous drugs.

United States Pharmacopeia (USP)

United States Pharmacopeia (USP)

A scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries.

Chapters < 1000 are requirements and legally enforceable
Chapters > 1000 are recommendations

USP <800>:
Hazardous Drugs—Handling in Healthcare Settings

http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf

Enforceable Agencies

Inspectors from CMS, the state boards of pharmacy, and accreditation surveyors (e.g., The Joint Commission,) as well as federal agencies (e.g., OSHA) will be heavily involved in surveying for <800> compliance.

- The Joint Commission (TJC)
- Centers for Medicare and Medicaid Services (CMS)
  - conditions of participation
- State boards of pharmacy.
- State agencies: Office of Statewide Health Planning and Development
- United States Department of Labor. Occupational Safety and Health Administration (OSHA)

UTAH Pharmacy Law

Utah Code, Pharmacy Practice Act, Chapter 17b, Part 6, Section 618: Compliance with state and federal laws.

Index Utah Code
Title 58 Occupations and Professions
Chapter 17b Pharmacy Practice Act
Part 6 Regulation of the Practice of Pharmacy Operating Standards
Section 618 Compliance with state and federal laws.

58-17b-618. Compliance with state and federal laws.
The entities licensed under Sections 58-17b-301 and 58-17b-302 shall comply with all state and federal laws and regulations relating to the practice of pharmacy.

Enacted by Chapter 280, 2004 General Session

https://le.utah.gov/xcode/Title58/Chapter17b/58-17b.html

OSHA

- ***Employer programs should attend to several critical elements, including the infrastructure program and management requirements outlined in the U.S. Pharmacopeial Convention General Chapters 797 and 800***; the Oncology Nursing Society guidelines, now available free of charge; and staff work assignments and ***management to reduce/ remove hazards to conception, pregnancy, and breastfeeding arising from exposures to hazardous drugs***.

Overview of USP <800>

This chapter describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection for both sterile and nonsterile products and preparations.

Includes, but is not limited to:

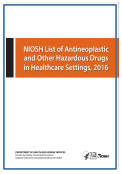
- ✓**receiving,**
- ✓**storage,**
- ✓**compounding,**
- ✓**Dispensing**
- ✓**Delivery/transporting**
- ✓administration,
- ✓**disposal.**

Overview of USP <800>, cont.

- Applies to all healthcare personnel who handle HD preparations, and entities which store, prepare, transport, or administer HDs: **pharmacies**, **hospitals, other healthcare institutions**, patient treatment clinics, physicians' practice facilities, veterinarians' offices.
- Personnel who may potentially be exposed to HDs include, but are not limited to: **pharmacists, pharmacy technicians**, nurses, home healthcare workers, physicians, physician assistants, veterinarians, and veterinary technicians.
- Entities that handle HDs must incorporate these standards into their **occupational safety plan**. At a minimum, include:
  - **Engineering controls**
  - **Competent personnel**
  - **Safe work practices**
  - **Proper use of appropriate Personal Protective Equipment (PPE)**
  - **Policies for HD waste segregation and disposal**

Overview of USP <800>, cont.

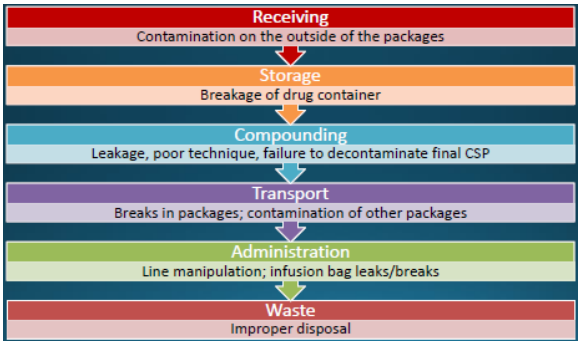
- Effective federally December 1st 2019
  - (exception – state can make effective immediately: example CA)
- Applies to **all** healthcare personnel that handle and / or work around HDs
- Applies to all entities: hospital, retail, doctor offices
- Includes all drugs listed by NIOSH



Possible Exposure Activities

- **Receiving and unpacking HD consumables**
- **Compounding CSP,**
- **Counting, cutting, crushing capsules/tablets**
- Expelling air from syringes filled with HDs
- Administering HDs
- **Contacting residue on drug container exteriors, work surfaces, floors and final drug preparations**
- Contacting or inhaling HD residue or aerosolization from another patients medication
- Surgical procedures on patient receiving HDs
- Handling body fluids, contaminated clothing, dressings, linens
- **Handling HD waste, including containers**
- **Deactivating, decontaminating, cleaning and disinfecting areas containing HDs or where HDs have been**
- Maintenance activities for HD equipment and devices
- **Spills – generation, management, and disposal**

Sources for Potential Contamination



Surface Areas for HD Contamination

- C-PECs, BSCs, CACIs
- **Floors/counters inside and outside of drug preparation areas**
- IV bags / syringes
- Vials
- **Consumable containers (tablets or capsules bottles/vials)**
- **Transport containers – for delivery personnel**
- Chairs
- **Waste containers**
- Elevator buttons
- Door handles
- **Pencils / pens**
- **Keyboards**
- **Touch screen on computer**

Types of Exposure

- Routes of unintentional entry of HDs into the body include:
  - Dermal and mucosal adsorption
  - Inhalation
  - Injection
  - Ingestion either of contaminated foodstuffs or mouth contact with contaminated hands

- Clinical and Non-clinical personnel maybe exposed:
  - Aerosols or generated **dust**
  - Spills
  - Touching a contaminated surface – receiving, administration, cleaning or disposal

Dermal Exposure / Ingestion

Dermal Exposure:

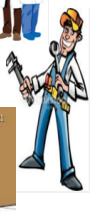
- Touching contaminated surfaces
- Improper donned PPE
- Improperly doffing and disposal of PPE
- Touching vials/bottles without PPE
  - vial/bottle surfaces are contaminated with HD residue
- Wearing non-tested gloves may be permeable to HDs
  - Wear only ASTM Standard 6978-05 tested gloves

Ingestion:

- Outside surfaces contaminated with HD residue
- Do not eat or drink where HDs are prepared or stored.

WHO is at risk of exposure

- **Pharmacists**
- **RX Technicians**
- **Receiving area workers**
- **Inventory – stocking, control**
- **Housekeeping / Environmental Services**
- **Trash collectors**
- Administration
- Patients
- **Visitors**
- **Family members at home for all of the above**
- **General public**
- Laundry service staff
- Unit Secretary
- Nursing
- Physicians
- Maintenance



Do you see the possible contaminated points / objects?

Exposure Control / Safe Handling

Exposure Control

- Good Policy and Procedure
- Signage
- Identifying Hazardous Containers

- Areas to Consider:
  - Receiving
  - Pharmacy
    - Storage (shelves)
    - Dispensing area (counting trays, counter tops)
  - Transport / Delivery
  - Housekeeping/Laundry
  - Waste management

Safe Handling Practices

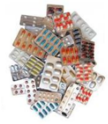
- *Wash hands for at least 20-30 seconds with warm water and soap* prior to handling, preparing, administering, transporting, disposing of, or managing spills of hazardous drug or waste.
- *Wash hands before and after working in any area where hazardous drugs are handled, prepared, administered, or disposed.*
- Do NOT eat, drink, chew gum, apply cosmetics or store food in areas where hazardous drugs are stored, handled, prepared, administered or disposed.

Mind the "dust!"

Dosage forms of drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulations.

Solid Tablets or Capsules

❖Mind the "dust!"



❖ Consider alternative containment strategies / work practices
  ❖ Including Personal Protective Equipment

Personal Protective Equipment

Personal Protective Equipment (PPE)

- Compounding sterile and nonsterile antineoplasatic HDs
  - ✓ Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required
- Administering antineoplastic HDs.
  - ✓ Two pairs of chemotherapy gloves are required.
  - ✓ Gowns shown to resist permeability are required when administering injectable antineoplastic HDs.

For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used).
The entity must develop SOPs for PPE based on the risk of exposure (see *Types of Exposure*) and activities performed.

Appropriate PPE must be worn when handling HDs including during:

- **Receipt**
- **Storage**
- **Transport**
- **Compounding** (sterile and non-sterile)
- **Packaging / Counting**
- Administration
- **Deactivation/decontamination, cleaning, and disinfecting**
- **Spill control**
- **Waste disposal**

PPE – HD GLOVES

USP <800>:

- Chemotherapy gloves should be worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs.
- Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs.
- Gloves must be inspected for physical defects before use.
- Do not use gloves with pin holes or weak spots.
- When used for sterile compounding, the outer glove must be sterile.

PPE – HD GLOVES

- ASTM gloves required for:
  - ✓ Unpacking
  - ✓ Compounding / Cutting / Crushing
  - ✓ Cleaning and disinfecting the HD exposed area
  - ✓ Decontaminating hazardous exposed areas
  - ✓ Transport/delivery
  - ✓ Spills
  - ✓ Disposal of HD products

❖ SHOULD CONSIDER FOR:
- ✓ Counting and Repackaging

PPE - Gowns

- Non-permeable, polyethylene coated polypropylene or laminated material
- Do NOT wear outside compounding/packaging area.
- May NOT be re-used.

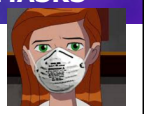
PPE – Bonnet, Booties, Head Covers.

- **HEAD, BEARD, SHOE COVERS:**
  NOT required for SOLID HD handling but if worn:
  - head, beard, shoe covers changed after removal or if contaminated
  - Shoe covers should be worn to contain HD residue to specific area
  - Shoe covers recommended to be coated
  - Do NOT wear shoe covers outside HD area,

If packaging in a non-classified 'cleanroom' should be donned.

- **EYE and FACE PROTECTION:**
  - Optional for compounding / cutting /crushing depending on HD drug
  - Required for
    - ✓ **Cleaning**
    - ✓ **Spills**
    - ✓ **Unpacking damaged HD items**

PPE –Respiratory Protection - MASKS



All Hazardous Masks must be fit-tested:
- ❑ N95 or N100 (NIOSH approved):
  - ✓ Compounding – cutting, crushing
  - ✓ Receipt of, unpacking and decontamination of HD intact items not in impervious plastic
- ❑ Half Mask with Multi-gas Cartridge and P100-filter:
  - ✓ receipt of, unpacking and decontamination of HD materials not contained in plastic.
- ❑ Full-face piece, chemical cartridge respirator with a pre-filter + shield or eye protection
  - ✓ If splash Risk during compounding / preparation
  - ✓ Spill management
  - ✓ Cleaning a Contained Vented Enclosure (CVE) or Containment Primary Engineering Control (C-PEC)
  - ✓ Known or suspected airborne exposure to powders, vapors or gases.

PPE – other requirements

- **PPE Disposal:**
  - All HD exposed PPE should be disposed in Trace Hazardous Waste bin – **NEVER REUSED**
    - ❖*If PPE saturated – then RCRA waste*

HAZARDOUS

Garbing of cleaning and disinfecting personnel

- Cleaning and disinfecting personnel must comply with the pharmacy's PPE garbing procedures for hazardous areas and performing housekeeping duties.
- Housekeeping personnel is responsible to clean Hazardous Exposed Area (CVE, C-SCA,) they must don ASTM International–approved gloves before starting work.

HD PPE DOFFING ORDER

Doffing of HD PPE is **very IMPORTANT**, *proper doffing will mitigate exposure risk to employee and possible spread of HD residue.*

HANDLING CONSUMABLES

RECEIVING Hazardous Consumables

- Must be received in a "neutral" or "negative" pressure area relative to adjacent spaces

Should be a dedicated receiving area.

- Must have appropriate/adequate personal protective equipment available:
  - ❖ Gloves
  - ❖ Gowns
  - ❖ Respirator
  - ❖ Eye Protection
  - ❖ Spill Kit

- ***All HD containers MUST be decontaminated upon receiving***
  - ***Mitigates HD residue movement within the pharmacy***
    - ***Wiper saturated with H2O***
    - ***Wiper saturated with a Deactivating agent for antineoplastic HD***

Received Intact

Non-antineoplastic HDs are not likely to arrive in separate packaging.

- Each facility must evaluate and determine how to handle:

Receiving and Handling Damaged HD Containers

If container is damaged:

- Seal the container and contact the distributor
- If the container is to be returned, place it inside of an impervious container that is marked "hazardous"
- Place in appropriate "quarantine" area (negative pressure best)
- Dispose of items sealed in container in Hazardous Waste if distributor will not accept returns

If damaged container must be opened:

- Don 2 pairs ASTM approved gloves and gown
- Don chemical cartridge respirator mask
- Place in impervious container
- Transport to C-SEC, first wiping down the outside with a decontaminate and sIPA
- Follow cleanroom gowning procedure
- Place absorbent pad inside the C-PEC
- Wipe down the container with sterile 70% IPA and place inside C-PEC
- Carefully remove usable items; decontaminating each item with a separate wipe
- Seal impervious container with damaged item(s) and dispose of in Hazardous Waste

Report and manage Damaged Containers as a Spill

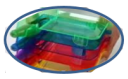
Counting or Repackaging of Hazardous Drugs

Counting or repackaging of HDs must be done carefully.

- PPE determined by Assessment of Risk – or follows USP <800> for all drugs.
  - Entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure (see *Types of Exposure*) and activities performed.

- Tablets and capsules of antineoplastic HDs must not be placed in automated counting or packaging machines - creates powdered contaminants.

- Consider dedicated equipment: counting trays, spatulas, funnels, etc.
- Consider Cross-contamination when packaging NISOH Table 2 and 3 drugs.



Solid Manipulation and Compounding

- Equipment for compounding:
  - **PPE to protect against occupational exposure**
    - **Double gloves required**
    - **FULL PPE when cleaning area and equipment.**
  - **Plastic backed preparation mat in C-PEC or CVE**
  - ***Equipment, mortars, pestles, spatulas, must be dedicated for HD***
  - Prepare liquids, cut or crush tablets, open capsules in a CVE or C-PEC to protect against occupational exposure.

- Deactivation/decontamination, cleaning and disinfecting – routinely
  - Area, Room,
  - C-PEC / CVE
  - Equipment

CVE= Contained Vented Enclosure
C-PEC= Containment Primary Engineering Control

Containment-Segregate Compounding Area: Solid Manipulation and Compounding

- USP <800>: manipulation of HD Table 1 anti-neoplastic solid form, tablet, capsule and Table 2 and 3 dependent on Assessment of Risk.
  - within negative pressure non-sterile C-PEC,
    - ✓ Unidirectional air not required
    - ✓ No ISO classification needed
    - ✓ preferred external vented, can be redundant HEPA filtered
      - BSC class I or II, CACI, CVE (containment ventilated enclosure)
  - C-PEC within negative pressure C-SCA
    - ✓ Area has fixed walls,
    - ✓ Is negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas,
    - ✓ Has minimum of 12 ACPH.
    - ✓ Must be externally vented.
    - ✓ LOD for doffing of HD PPE must be outlined at exit door.

If prepared in sterile compounding C-PEC, the C-PEC MUST be decontaminated and cleaned before using for sterile preparation

Containment-Segregate Compounding Area: Storage of HDs

HD in ready-to-dispense form may be stored within inventory – SHOULD BE CLEARLY MARKED per NIOSH Table Classification

- ***Not*** *in ready-to-dispense* form must to be stored separately from other inventory, includes refrigerated and frozen items:
- C-SCA:
  - Negative pressure
  - External exhaust ventilation
  - At least 12 air changes per hour
  - Storage temperature should be equal or less than 20° C, not to exceed 25°C
  - Does allow of HD sterile consumable storage in cleanroom (Containment- Secondary Engineering Control: C-SEC)
  - Consumables should be stored in containers/bins to help with chemical containment and to prevent consumable falling from shelves.
  - All shelving and storage bins needs to be easily decontaminated and cleaned
  - *Entry to storage requires proper donning and doffing of PPE.*

Transporting of Hazardous Drugs

- PPE determined by Assessment of Risk – or follows USP <800> for all drugs.
  - Entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure (see *Types of Exposure*) and activities performed.
- Use packaging containers and materials that maintain physical integrity, stability, and sterility (if needed) of the HDs during transport.
  - Packaging materials must protect the HD from damage, leakage, contamination, and degradation, ***while protecting healthcare workers who transport HDs.***
  - Written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.
- HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.

Transporting of Hazardous Drugs, cont.

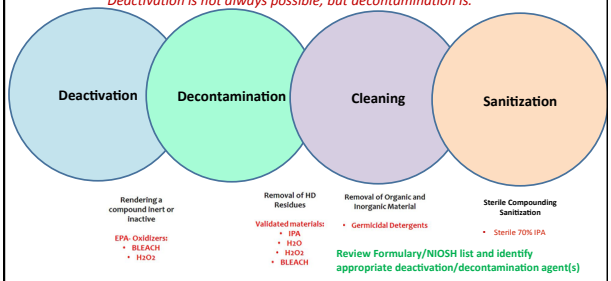
- Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.
- When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS.
  - Labels for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.

CLEANING UP

Deactivation, Decontamination, Cleaning, Sanitization

Use disposable wipers

Deactivation is not always possible; but decontamination is.



Review Formulary/NIOSH list and identify appropriate deactivation/decontamination agent(s)

Selecting Agents

- No single agent can deactivate all HDs
- Specific chemicals deactivate some HDs – check MSDS
- Most HDs are water soluble, using a cleaning agent that has surfactant allows the HD to transfer from the inanimate surface to the wet wiper

Agents for Deactivation/Decontamination

- Solution considered effective with HDs:

EPA-registered oxidizing agents (Environmental Protection Agency)

- Should have documented effectiveness in decontaminating surfaces
- Check expiration dates of product
- *Products not registered as EPA disinfectant should NOT be:*
  - *used as a decontamination, cleaning or sporicidal agent*

➢ 2% sodium hypochlorite (Bleach diluted)
- ***Mind the surface cleaning, and clothes exposed to solution.***
- Mix daily
- This is stronger concentration than when used as sporicidal

➢ Products containing 80% 10mM Sodium Lauryl Sulfate and 20% Isopropyl alcohol

➢ **Peroxyacetic Acid and Hydrogen Peroxide**

➢ Hydrogen Peroxide at a variety of concentrations

Cleaning and Disposal

- Policies and procedures for cleaning and disinfecting tasks must be developed,
  - Cleaning and disinfecting personnel must be trained and assessed on correct application of these policies and procedures.
- Only trained and qualified cleaning and disinfecting personnel may be allowed to clean the hazardous exposed area.
- To avoid cross-contamination and to protect cleaning and disinfecting personnel:
  - ❖Separate designated equipment for Hazardous cleanup
  - ❖Should be disposable
- Equipment (mop heads, towels, etc.) should be disposable and disposed in trace hazardous waste

Disposal of Hazardous Drugs

- All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination.
- Disposal of all HD waste must comply with all applicable federal, state, and local regulations. Items include, but not limited to:
  - unused HDs, expired etc.
  - trace contaminated PPE
  - other materials – empty HD bottles, wipers

Hazardous Drug Disposal Bins

- Hazardous waste must be stored in containers that comply with the RCRA (Resource Conservation and Recovery Act) rules
- PPE, Cleaning wipers, empty consumable bottles and/or drugs must be disposed of in the appropriate hazardous drug disposal bin
- Trace Waste: Yellow Bin
- RCRA Waste: Black Bin

Empty hazardous consumable bottles should be disposed into hazardous trace waste or RCRA if P-list drug

P-listed

- **P-listed** wastes are "acutely toxic", **meaning** that they **can** cause death or irreversible illness at low doses.

Common P-Listed Pharmaceuticals:

Name	No.
Arsenic trioxide	P012
Epinephrine[1]	P042
Nicotine	P075
Nitroglycerin[2]	P081
Physostigmine	P204
Physostigmine salicylate	P188
Warfarin >0.3%	P001

[1] Does not include epinephrine salts.

Unused smoking cessation aids (e.g., patches and gum) that contain nicotine as the only ingredient are classified as listed hazardous waste P075

U-Listed

- U-**listed** wastes are "toxic": they are still regarded as hazardous, but some of the more stringent regulations that apply to the **P**-list **do** not apply to U-**listed** wastes.

Common U-Listed Pharmaceuticals:

Name	No.	Name	No.
Chloral Hydrate (CIV)[2]	U034	Mitomycin C (chemo)	U010
Chlorambucil (chemo)	U035	Paraldehyde (CIV)2	U182
Chloroform	U044	Phenacetin	U187
Cyclophosphamide (chemo)	U058	Phenol	U188
Daunomycin (chemo)	U059	Reserpine	U200
Dichlorodifluromethane	U075	Resorcinol	U201
Diethylstilbestrol	U089	Saccharin	U202
Formaldehyde	U122	Selenium sulfide	U205
Hexachlorophene	U132	Streptozotocin (chemo)	U206
Lindane	U129	Trichloromonofluromethane	U121
Melphalan (chemo)	U150	Uracil mustard (chemo)	U237
Mercury	U151	Warfarin <0.3%	U248

Hazardous Waste Disposal Bins

- BLACK RCRA DISPOSAL BINS
- The EPA has identified several drugs as hazardous waste due to their toxicity. They require disposal in a separate bin (BLACK)

Example Hazardous drugs that require disposal in the black RCRA bins:
Chlorambucil
Cyclophosphamide (Cytoxan)
Chloral hydrate
Diethylstilbesrol
Reserpine
Warfarin

http://www.hercenter.org/rmw/ut-rmw.cfm

Hazardous Drug Disposal Bins

- Trace Waste Bin:
  - PPE
  - Wipers, used to decontaminate
  - Protective work space mats
  - Empty bottles non-P-listed drugs
  - Empty P-listed drug bottles tripled rinsed and/or deactivated / decontaminated inside and outside

Hazardous Waste Disposal Bin

- Does my empty bottle of P-listed Pharmaceutical go in RCRA

"A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§261.31 or 261.33(e) is empty if:

(i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed."

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered "RCRA empty," even though the pharmaceutical may be fully dispensed. If the container is not "RCRA empty," then the ***residues*** are regulated as acute hazardous waste.

From https://www.epa.gov

Exposure to Hazardous Drugs

Skin Exposure:

- Remove contaminated clothes and immediately wash skin with mild soap and cool water for at least 30 seconds
- Do NOT use alcohol containing products (ex: Purell)

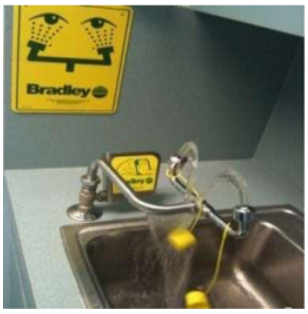
Eye Exposure:

- Immediately flush the eyes with water for at least 15 minutes.
- If Plumbed Eyewash Station not available use personal eyewash bottles – flushing for 15 minutes

Seek emergency treatment as indicated

Document ALL actual and near miss exposures

Plumbed Eyewash Station



Hazardous Drug Medical Surveillance

- Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.
- Elements:
  - Development of an organized approach to identify potential exposure
  - Protect confidentiality of employee's personal medical history in accordance with OSHA
  - Initial base line assessment
    - Records of HD handling, with quantities and dosage forms
    - Estimated number of HD per week or month
    - Estimated hours exposed handling weekly or monthly
    - Physical and laboratory studies
- Surveillance is performed annually.
- Have a follow up plan for workers who have shown health changes suggesting toxicity or have experienced acute exposure.

Some Symptoms Associated with Acute Exposure to Hazardous Drugs

- Lightheaded
- Nausea and vomiting
- Dizzy
- Local skin or mucous membrane reaction
- Abdominal pain
- Headache
- Metallic taste in mouth
- Burning/watery eyes
- Scratchy throat
- Hair loss

Spill Kit

- Have a spill kit available at all times
- Know what is in your Spill Kit
  - Have additional items/equipment needed for Spill clean-up with Spill Kit.
- If a spill happens:
  - Alert everyone in the immediate area to avoid contact with the spill
  - Use the Chemotherapy Drug Spill Kit and appropriate PPE for containment of any hazardous drug
  - Wear Double Gloves
- Document ALL spills

Quality Assurance Program

The quality assurance program for solid HD handling:

Surface sampling area(s) of exposure:

- **Receiving**
- **Storage**
- **Dispensing**
- **Sale counter**
- **Delivery area**

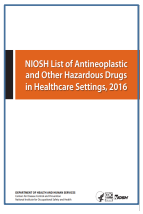
The quality assurance program for sterile compounding:

1. Verification of equipment, including the PEC;
   - Certification
   - Pressure and airflow sampling
   - Contaminate Surface sampling
   - Documentation
2. Verification of hazardous controlled areas;
   - Air sampling
   - Surface sampling
   - Monitoring environment and documenting

USP Chapter <800> and NIOSH

The NIOSH list last released 9/2016 consists of Anti-neoplastic and other Hazardous Drugs for the Healthcare Setting

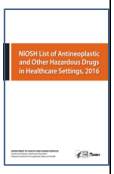
❖ Next release is this year, 2018



NIOSH Table Classification

- Antineoplastic (Table 1) (High Risk)
  - Antineoplastic drugs that may also pose a reproductive risk for susceptible populations.
- Non-antineoplastic hazardous (Table 2)
  - Non-Antineoplastic (anticancer) drugs that meet one or more of the NIOSH criteria of a hazardous drug and may also pose a reproductive risk for susceptible populations.
- Reproductive Risk Only (Table 3)
  - Non-antineoplastic drugs that primarily have adverse reproductive effects, Are a risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding.

  – ***Any other drug with similar toxicity structure as that of an HD classified product***

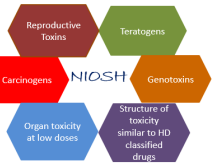


Definition of Hazardous Drug

Hazardous drugs are capable of causing harm to individual exposed.

They have at least one of the following characteristics:

- **Genotoxic** – can change DNA structure
- **Carcinogenic** – can cause cancer in animals and/or humans
- **Teratogenic** – can cause reproductive toxicity in humans
- **Fertility Impairment** – can cause birth defects or prevent reproduction for men and/or women with occupational exposure to the hazardous drug
- **Serious toxicity at low doses** – danger has been show in experimental animal models and treated patients.



Classification of Hazardous Drugs

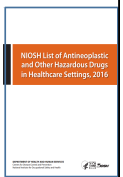
Hazardous drugs can be classified as anti-neoplastic, cytotoxic, biologic, antiviral, immunosuppressive, antibiotic and/or hormone

They are hazardous regardless of whether they are administered intravenously, orally, or topically.

USP <800>: NIOSH Requirement.

Drugs on the NIOSH list that MUST follow USP <800> requirements:
— Antineoplastic: Active Pharmaceutical Ingredient (API)
— Antineoplastic requiring manipulation

- Antineoplastic drugs on the NIOSH list **do not** have to follow all the containment requirements of USP <800> **if an *assessment of risk is performed and implemented*** include:
  - ❖ Final dosage forms of compounded preparations
  - ❖ Conventionally manufactured products, that do not require any further manipulation other than counting or repackaging (unless specified by the manufacturer)
- For NIOSH Table 2 and 3 drugs to not require following USP <800> containment requirements you **MUST *perform an assessment of risk to determine alternative containment strategies and/work practices***



2016 NIOSH Table 1 ORAL Formulations Anti-Neoplastic

- Abiraterone
- Afatinib
- Altretamine
- Anastrozole
- Axitinib
- Bexarotene
- Bicalutimide
- Bosutinib
- Busulfan
- Cabozantinib
- Capecltabine
- Chlorambucil
- Cizontinib
- **Cyclophosphamide**
- Dabrafenib
- Dasatinib
- Enzalutamide
- Dasatinib
- Enzalutamide
- Erlotinib
- Estramustine
- Etoposide
- Everolimus
- Exemestane
- Flutamide
- **Hydroxyurea**
- Imabtinib
- ixazomib
- Letrozole
- **Lomustine**
- **Megestrol**
- **Melphalan**
- **Mercaptopurine**
- **Methotrexate**
- Mitotane
- Nilotinib
- Panobinostat
- Pazopanib
- Pomalidomide
- Ponatinib
- Procarbamzine
- Regorafenib
- Sorafenib
- Suitinib
- **Tamoxifen**
- Temozolomide
- Thioguanine
- Tormifene
- Trametinib
- Trifluridine/tipiracil
- Vandetanib
- Vismodegib
- Vorinostat

2016 NIOSH Table 2 ORAL Formulations Non-Antineoplastic

- **Abacavir**
- **Azathioprine**
- **Carbamazepine**
- **Cyclosporine**
- Deferiprone
- **Divalproex**
- Entecavir
- **Estradiol**
- **Estrogen/progesterone combo**
- **Estrogen, conjugated**
- **Estrogen, estrified**
- **Estropipate**
- Fingolimod
- Fluoxymesterone
- Ganciclovir
- Leflunomide
- Lenalidomide
- **Medroxyprogesterone acetate**
- Methimazole
- **Mycolphenolate mofetil**
- **Mycophenolic acid**
- Nevirapine
- Ospemifene
- Oxcarbazepine
- Paliperidone
- Phenoxybenzamine
- **Phenytoin**
- **Progestin**
- **Progesterone**
- **Propylthouracil**
- Raloxifene
- Rasagiline
- **Risperidone**
- **Sirolimus**
- **Spironolactone**
- **Tacrolimus**
- Teriflunomide
- Thalidomide
- Tofacitinib
- Uracil mustard
- Valganciclovir
- Zidovudine

2016 NIOSH Table 3 ORAL Formulations Reproductive /non-antineoplastic

- Acitretin
- Alitretinon
- Ambrisentan
- Bosentan
- Cabergoline
- **Clomiphene**
- **Clonazepam**
- **Colchicine**
- Dronedarone
- **Dutasteride**
- **Ergonovine / methylergonovine**
- Eslicarbazepine
- **Finasteride**
- **Fluconazole**
- Lomitapide
- Macitentan
- **Methylergonovine**
- **Methyltestosterone**
- Mifepristone
- **Misoprostol**
- **Paroxetine**
- Ribavirin
- Riociguat
- **Temazepam**
- **Testosterone**
- **Topiramate**
- **Tretinoin**
- Ulipristal
- **Valproate/valproic acid**
- Vigabatrin
- **Voriconazole**
- **Warfarin**
- Ziprasidone
- Zonisamide

2018 Proposed Oral Additions

Drug	Table	Classification
ceritinib	1	antineoplastic
clobazam	3	antiepiletic
cobmetinib	1	antineoplastic
isotretinoin	3	retinoid
ivabradine	3	HCN blocker
lenvatinib	1	antineoplastic
miltefosine	3	antibiotic
olaparib	1	antineoplastic
osimertinib	1	antineoplastic
sonidegib	1	antineoplastic
triazolam	3	hypnotic

2018 Proposed Injectable Additions

Drug	Table	Classification
bevacizumab	1	antineoplastic
blinatumomab	1	antineoplastic
botulinum toxins	2	neurotoxin
darbepoetin alfa	2	erythropoiesis stimulator
dihydroergotamine	3	5HT receptor binder
exenatide	2	antidiabetic
inotuzumab	1	antineoplastic
interferon beta-1b	2	immune modulator
trabectedin	1	antineoplastic
trastuzumab	1	antineoplastic
urofollitropin	3	ovulation stimulator

Reading NIOSH List

Category

Manufacturers' Safe-handling Information

Drugs added to list are in RED

Reason made list

Additional handling information

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
pomalidomide	10:00 antineoplastic agents	yes	Females of reproductive potential must use two forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping treatment; FDA Pregnancy Category X	DailyMed; DrugBank
ponatinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
pralatrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
procarbazine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank

Risk Elements

Not all hazardous defined drugs pose a significant direct occupational exposure risk because of their dosage form:

- Medications in final dispensing form: tablets and capsules

These products may pose a risk if the dosage form requires alteration.

- Cutting
- Crushing
- Dissolving
- Piercing or opening
- Compounding

- Counting/repackaging
- Mind the "dust!"

Assessment of Risk Elements

- Drug
- Dosage form
- Risk of exposure
- Situational risk
- Packaging
- Manipulation / compounding

Documentation of alternative containment strategies & work practices
Review, at minimum, annually (document annual review)
Have a process to review and add new drugs

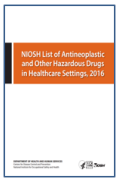
Assessing RISK

Consider containment strategies and work practices to protect from:

- Ingestion
- Inhalation
- Contact exposure
- Vapors in environment
- Residue movement

Assessment of Risk Steps

1. Determine your approach:
   - ❖ Handle all NIOSH listed drugs per USP <800>
   - ❖ Develop and implement an AoR

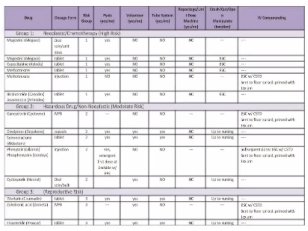


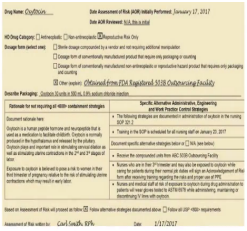
Developing AoR:

2. Obtain a copy of USP <800> www.usp.org
   - ❖ section 2 describes the Assessment of Risk
3. Download NIOSH 2016 list
   https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf
   After September 2018 download 2018 NIOSH list.
4. Compare the NIOSH list with your formulary, including non-formulary items, and even drugs purchased only as Unit Dose or Unit of Use.
5. Divide the list into the two categories:
   - Medications ineligible for an AoR (Table 1 manipulation, and others?)
   - Medications considered for AoR. (Table1 final form, Table 2 and 3)
6. Assess Risk of each eligible drug, in each dosage form.

Assessment of Risk Steps, cont.

7. Create a master spreadsheet for all NIOSH listed drugs.
8. Create a complete AoR for each eligible drug dosage form.





Assessment MUST Include

- Receiving:
  - Can you identify HDs from outside of the container?
  - What PPE will be used
- Storing:
  - Other than antineoplastic requiring manipulation and any API
    - How will you store other agents?
    - How will personnel be protected?
- Compounding:
  - Agents other than the antineoplastics and API, if compounding what controls are needed?
  - Other policy and procedures will be used for which product?
  - PPE – what will be required, what is optional

Assessment MUST Include, cont.

- Transporting:
  - How do you protect preparation?
  - How do you protect personnel?
- *Administering:*
  - *CSTD are required for antineoplastics when dosage form allows.*
    - *Will you use CSTD for other agents.*
    - *PPE for other agents?*
- Disposal:
  - EPA, State, municipal and organizational policy?
  - How are spills handled?
    - Will agents on table 2 and 3 differ from table 1?
  - Housekeeping disposal protection?
  - PPE – spills, trash removal?

Two Categories - Storage

Ineligible for AoR

Antineoplastic drugs requiring manipulation other than counting and hazardous API must:

- ❖ Follow USP <800> handling
- ❖ Storage:
- – Separately from non-HD
- – Negative pressure room, externally vented
- – 12 Air Changes per Hour (ACPH)
- – Allows for containment, preventing contamination and personnel exposure

May be Considered for an AoR

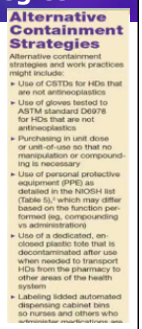
Hazardous drugs that may be stored with other inventory:

- – Non-antineoplastic
- – Reproductive risk only
- – Final dosage forms of any HD antineoplastic

Sterile and non-sterile HDs may be stored together outside of buffer area of cleanroom, but ONLY sterile HDs should be stored in a buffer room under negative pressure.

Alternative Containment Strategies

- Alternative containment strategies
  - Only purchase as UD or UU – no manipulation required
- Alternative work practices
  - Gloves meeting ASTM D6978 standard
  - **Use dedicated equipment for**
    - **Counting**
    - **Transport**
- Use PPE based on activity: Guide in NIOSH Table 5
- Labeling / identification


Alternative Containment Strategies

Alternative containment strategies and work practices might include:

- Use of CSTDs for HDs that are not antineoplastics
- Use of gloves tested to ASTM standard D6978 for HDs that are not antineoplastics
- Purchasing in unit dose or unit-of-use so that no manipulation or compounding is necessary
- Use of personal protective equipment (PPE) as detailed in the NIOSH list (Table 5),* which may differ based on the function performed (eg, compounding vs administration)
- Use of a dedicated, enclosed plastic tote that is decontaminated after use when needed to transport HDs from the pharmacy to other areas of the health system
- Labeling lidded automated dispensing cabinet bins so nurses and others who

Kienle, P and Douglass, K. Perform an Assessment of Risk to Comply with USP <800> Pharmacy, Purchasing & Products. 2017.14 (3) https://www.pppmag.com/article/2012

Master Spreadsheet Example, RISK only

Drug	Dosage Form	Risk Group	Pyxis (yes/no)	Volumetric (yes/no)	Tube System (yes/no)	Repackaging/Unit Dose Machine (yes/no)	Crush/Cut/Open in Manipulator (location)	IV Compounding
Group 1: Non-plastic/Chemotherapy (High Risk)								
Megestrol (Megace)	Oral solution/ susp	1	yes	NO	NO	NO	---	---
Megestrol (Megace)	tablet	1	yes	NO	NO	NO	BSC	---
Capecitabine (Xeloda)	tablet	1	yes	NO	NO	NO	BSC	---
Methotrexate	tablet	1	yes	NO	NO	NO	BSC	---
Methotrexate	injection	1	NO	NO	NO	NO	---	BSC w/ CSTD Sent to floor sealed, primed with line
Abiraterone [Zytiga] Anastrozole [Arimidex]	tablet	1	yes	NO	NO	NO	BSC	---
Group 2: Hazardous Drug/Non-Neoplastic (Moderate Risk)								
Ganciclovir (Cytovene)	IVPB	2	---	---	NO	NO	---	---	BSC w/ CSTD Sent to floor sealed, primed with line
Diazepam (Diastat)	capsule	2	yes	yes	yes	NO	Liq to nursing	---
Telmisartan (Micardis)	tablet	2	yes	yes	yes	NO	Liq to nursing	---
Phenytoin (Dilantin) Phosphenytoin (Cerebyx)	injection	2	yes, emergent first dose of bedside w/ PIV	NO	NO	---	---	subsequent doses BSC w/ CSTD Sent to floor sealed, primed with line
Cyclosporin (Neoral)	Oral soln/bulk	2	---	yes	NO	NO	Liq to nursing	---
Group 3: (Reproductive Risk)								
Warfarin (Coumadin)	tablet	3	yes	yes	yes	NO	Liq to nursing	---
Zoledronic acid (Zometa)	IVPB	3	---	---	yes	NO	---	---	BSC w/ CSTD Sent to floor sealed, primed with line
Finasteride (Proscar)	tablet	3	yes	yes	yes	NO	Liq to nursing	---

Master Spreadsheet Example

Master spread sheet: 2 sections, Eligibility and Risk Summary

	Determining AoR Eligibility						
Stocked	Drug Name (generic)	Dosage Form	Packaging	Type of Manipulation	AHFS Classification	HD Risk Level	eligible for alternative
NO	abiraterone				10:00 antineoplastic		
YES	methotrexate	Tablet	Unit of Use	None	10:00 antineoplastic	Type 1: antineoplastic	YES
YES	methotrexate	Tablet	Bulk	crushing/cutting	10:00 antineoplastic	Type 1: antineoplastic	NO
YES	methotrexate	injectable	Vial	compounding	10:00 antineoplastic	Type 1: antineoplastic	NO
YES	oxytocin	injectable	Unit of Use	None	76:00 oxytocics	Type 3: reproductive-only Risk	YES
YES	oxytocin	injectable	Vial	compounding	76:00 oxytocics	Type 3: reproductive-only Risk	YES

	Assessment of Risk Summary					
Receiving	Storage	Compounding	Transport	Administration	Disposal	Notes/Comments
USP 800	Ready to dispense form/ HD section of inventory	NA: ready to dispense form	USP 800	USP 800	RCRA	
USP 800	Ready to dispense form	USP 800	USP 800	USP 800	RCRA	
USP 800	Negative Pressure C-SCA	USP 800	USP 800	USP 800	RCRA	
None	regular inventory	None - ready to dispense form	none	see notes	CRA >1mL; Trace <1 mL or packaging	Women in 3rd trimester do not handle unless appropriate use of PPE, signed training and acknowledgement of risk
None	regular inventory	see notes	none	see notes	CRA >1mL; Trace <1 mL or packaging	Women in 3rd trimester do not handle unless appropriate use of PPE, signed training and acknowledgement of risk

Sample Individual Drug AoR

Drug Name: *Oxytocin* **Date Assessment of Risk (AOR) Initially Performed:** *January 17, 2017*
Date AOR Reviewed: N/A, this is initial

HD Drug Category: ☐ Antineoplastic ☐ Non-antineoplastic ☒ Reproductive Risk Only

Dosage form (select one):
☐ Sterile dosage compounded by a vendor and not requiring additional manipulation
☐ Dosage form of conventionally manufactured product that require only packaging or counting
☐ Dosage form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging and counting
☒ Other (explain): *Obtained from FDA Registered 503B Outsourcing Facility*

Describe Packaging: Oxytocin 30 units in 500 mL 0.9% sodium chloride injection

Rationale for not requiring all <800> containment strategies	Specific Alternative Administrative, Engineering and Work Practice Control Strategies
Document rationale here: Oxytocin is a human peptide hormone and neuropeptide that is used as a medication to facilitate childbirth. Oxytocin is normally produced in the hypothalamus and released by the pituitary. Oxytocin plays and important role in stimulating cervical dilation as well as stimulating uterine contractions in the 2nd and 3rd stages of labor. Exposure to oxytocin is believed to pose a risk to women in their third trimester of pregnancy relative to the risk of stimulating uterine contractions which may result in early labor.	• The following strategies are documented in administration of oxytocin in the nursing SOP 321.2 • Training in the SOP is scheduled for all nursing staff on January 23, 2017 Document specific alternative strategies below or ☐ N/A (see below) • Receive the compounded units from ABC 503B Outsourcing Facility • Nurses who are in their 3rd trimester and may also be exposed to oxytocin while caring for patients during their normal job duties will sign an Acknowledgement of Risk form after receiving training regarding the risks and proper use of PPE • Nurses and medical staff at risk of exposure to oxytocin during drug administration to patients will wear gloves tested to ASTM 6978 while administering, maintaining or discontinuing IV lines with oxytocin.

Based on Assessment of Risk will proceed as follow: ☒ Follow alternative strategies documented above ☐ Follow all USP <800> requirements

Assessment of Risk written by: *Carl Smith, RPh* Date: *1/17/2017*

- Kienle, P and Douglass, K. Perform an Assessment of Risk to Comply with USP <800> Pharmacy, Purchasing & Products. 2017.14 (3). https://www.pppmag.com/article/2012

Sample Individual Drug AoR

Sample Pharmacy
Hazardous Drug Assessment of Risk Template

Drug Name: *FLUCONAZOLE- tablet* Date Assessment of Risk (AOR) Initially Performed: March 28,2017
Date AOR Reviewed: N/A – Initial Assessment

HD Drug Category: ☐ Antineoplastic ☐ Non-antineoplastic ☒Reproductive Risk Only
Dosage form (select one):
☐ Sterile dosages compounded by a vendor and not requiring additional manipulation
☒ Dosage forms of conventionally manufactured product that require only packaging or counting
☐ Other (explain): _____

Describe Packaging: Fluconazole 200 mg Tablets: Embossed with "FLZ 200" on one side with no markings on the other side

Rationale for not requiring all <800> containment strategies	Specific Alternative Administrative, Engineering and Work Practice Control Strategies
Document rationale here: Published case reports describe a rare pattern of distinct congenital anomalies in infants exposed in utero to high dose maternal fluconazole (400–800 mg/day) during most or all of the first trimester. No MSHG listed in section 16 of the DPI SDS has no relavent Handling, Storage, or Personal Protection Recommendations. Note: In the event the tablet must be crushed or split refer the AoR dealing with fluconazole manipulation	• The following strategies are documented in handling reproductive risk hazardous drugs SOP 555.5 • Training in the following strategies was provided March 28, 2017 and documented • Specific actions have been added to the HD competency on March 1, 2017 Document specific alternative strategies below or ☐ N/A (see below): • Upon receipt product to receive appropriate alert label • Gloves will be worn by any nurse administering fluconazole and is in her first trimester • Alert to be added to EHR and ADM • • • •

Based on Assessment of Risk will proceed as follow: ☒ Follow alternative strategies documented above ☐ Follow all USP <800> requirements

Assessment of Risk written by: Joe Smith RPh Date: 3/28/2017

Reviewed by Pharmacy Manager: Jane Doe Pharm D Date: 3/28/2017

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P-700.g; Released 12/19/2016

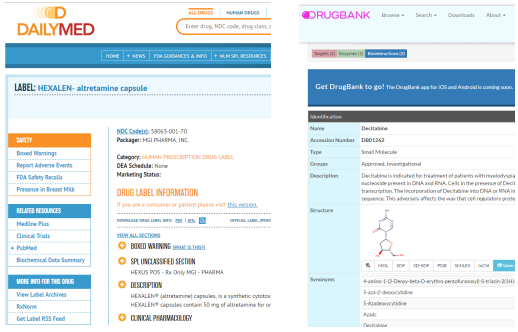
Available Drug Toxicity Information

- DailyMed http://www.dailymed.nlm.nih.gov/dailymed/
- DrugBank http://www.drugbank.ca/
- Medical Safety Data Sheets (MSDS)
- Product labeling approved by FDA (DPI)
- International Agency for Research on Cancer (IARC) http://www.iarc.fr
- Manufacturer warnings
- FDA
- Literature
- Case studies
- Healthcare professional journals
- ONS, Safe Handling for Hazardous Drugs, www.ons.org
- Recommendations from other facilities – online web search

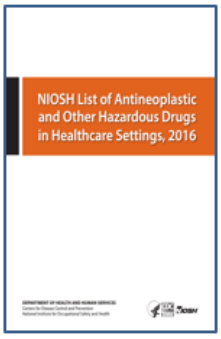
Safety Data Sheet (MSDS)

- Chemical Product and Company Info
- Ingredient information
- **Hazardous information**
- **First aid measures**
- Fire fighting measures
- **Accidental release measures**
- **Handling and storage – section 7**
- **Exposure control/ personal protection**
- Physical / chemical properties
- Stability and reactivity
- Toxicology information
- Ecological information
- **Disposal considerations**
- **Transportation information**
- Regulatory information
- Other information

DAILYMED and DRUG DATA



NIOSH Guidance on Environmental and PPE



NIOSH Guidance on Environmental and PPE

- NIOSH Table 5 is Guidance only
- Tables 2 and 3 drugs AoR to determine Environmental Controls and Personal Protective Equipment

Formulation	Activity Involved
Intact capsules	Cutting
Tablets	Crushing
Oral Liquids	Withdrawal from vial/ampule
Topical	Compounding
Vial/ampule	Administration
SC/IM/IT	Transporting
Irrigation	Storage / retrieval
Bulk Powder	"Dusty" counting/packaging
Inhalation	

NIOSH Table 5

Table 5. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used, unless spills occur)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes†
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up‡	no	N/A

NIOSH Table 5, cont.

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Oral liquid drug or feeding tube	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes[†]
	Administration	yes	yes	yes, if vomit or potential to spit up[†]	no	N/A
Topical drug	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes[†], BSC or CACI (Note: carmustine and mustargen are volatile)
	Administration	yes	yes	yes, if liquid that could splash[†]	yes, if inhalation potential	N/A
Subcutaneous/ intramuscular injection from a vial	Preparation (withdrawing from vial)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash[†]	no	N/A
Withdrawing and/or mixing intravenous or intramuscular solution from a vial or ampoule	Compounding	yes[‡]	yes	no	no	yes, BSC or CACI; use of CSTD recommended
	Administration of prepared solution	yes	yes	yes; if liquid that could splash[†]	no	N/A; CSTD required per USP 800 if the dosage form allows

NIOSH Table 5, cont.

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Solution for irrigation	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; use of CSTD recommended
	Administration (bladder, HIPEC, limb perfusion, etc.)	yes	yes	yes	yes	N/A
Powder/solution for inhalation/ aerosol treatment	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Aerosol administration	yes	yes	yes	yes	yes, when applicable
	Administration	yes	yes	yes, if liquid that could splash[†]	yes, if inhalation potential	N/A
Drugs and metabolites in body fluids	Disposal and cleaning	yes	yes	yes, if liquid that could splash	yes, if inhalation potential	N/A
Drug-contaminated waste	Disposal and cleaning	yes	yes	yes, if liquid that could splash	yes, if inhalation potential	N/A
Spills	Cleaning	yes	yes	yes	yes	N/A

Summary: Assessment of RISK

- Each entity must have a specific list of HDs (to the dosage form level) and adequate practices to protect its personnel.
- The list must be reviewed and revised regularly, at least every 12 months and that review documented.
- There must also be mechanisms to review drugs that are new to the institution and a determination made about whether or not they are hazardous.
- Additional information is available in the text of USP <800> and in resources such as those available at www.hazmedsafety.com.

Clearly defensible position on how you handle products/ practices for that product/dosage form.

Summary

- Complete an Assessment of Risk for all NIOSH listed drugs your pharmacy handles.
- Hazardous drugs can cause serious health effects in healthcare workers who do not wear appropriate PPE
- Lifetime exposure to hazardous drugs and other chemicals can cause serious health effects
- Employees can be exposed to these drugs through direct contact, ingestion, breaks in skin and through inhalation.

Summary, cont.

- Developing and following guidelines and procedures when handling HD drugs will protect you and your staff from unwanted exposure.
- The appropriate PPE required for the safe handling of hazardous drugs must be made available to all employees
  - Receiving
  - Dispensing
  - Stocking
  - Delivery
  - Cashier
  - Housekeeping
- Emergency Hazardous Spill Kit must be available and spills should be managed by employees trained to use the spill kit.

Question 1

USP <800> requires specific consideration on handling hazardous drugs in which of the following areas?

A. Receiving

B. Storage

C. Dispensing

D. Disposal

E. All of the above

Answer 1

USP <800> requires specific consideration on handling hazardous drugs in which of the following areas?

A. Receiving

B. Storage

C. Dispensing

D. Disposal

E. All of the above

Question 2

The appropriate PPE required for the safe handling of hazardous drugs must be made available to which of the job functions listed below?

A. Receiving and stocking

B. Dispensing and cashier

C. Delivery

D. Housekeeping

E. Book-keeper

Answer 2

The appropriate PPE required for the safe handling of hazardous drugs must be made available to which of the job functions listed below?

A. Receiving and stocking

B. Dispensing and cashier

C. Delivery

D. Housekeeping

E. Bookkeeper

Question 3

Which is the correct order for removal of hazardous residue?

A. Clean, decontaminate, deactivate

B. Decontaminate, deactivate, clean

C. Deactivate, decontaminate, clean

Answer 3

Which is the correct order for removal of hazardous residue?

A. Clean, decontaminate, deactivate

B. Decontaminate, deactivate, clean

C. Deactivate, decontaminate, clean

Question 4

USP <800> applies to:

A. Only Hospital Personnel involved with hazardous drugs

B. Only Pharmacy personnel involved with compounding hazardous drugs.

C. All healthcare personnel who handle hazardous preparations, store, prepare, transport or administer hazardous drugs.

D. Only to personnel involved in the administration of hazardous drugs.

E. None of the above.

Answer 4

USP <800> applies to:

A. Only Hospital Personnel involved with hazardous drugs

B. Only Pharmacy personnel involved with compounding hazardous drugs.

C. All healthcare personnel who handle hazardous preparations, store, prepare, transport or administer hazardous drugs.

D. Only to personnel involved in the administration of hazardous drugs.

E. None of the above.

Question 5

Which of the following NIOSH listings do not have to follow all of the containment requirements of USP <800>, If an *assessment of risk is performed and implemented?*

A. NIOSH table 1 antineoplastic conventionally manufactured products, that do not require any further manipulation other than counting or repackaging (unless specified by the manufacturer)

B. NIOSH table 2 drugs

C. NIOSH table 3 drugs

D. All NIOSH listed drugs must follow USP <800> containment requirements.

E. A,B and C

Question 5

Which of the following NIOSH listings do not have to follow all of the containment requirements of USP <800>, If an *assessment of risk is performed and implemented?*

A. NIOSH table 1 antineoplastic conventionally manufactured products, that do not require any further manipulation other than counting or repackaging (unless specified by the manufacturer)

B. NIOSH table 2 drugs

C. NIOSH table 3 drugs

D. All NIOSH listed drugs must follow USP <800> containment requirements.

E. A,B and C

REFERENCES

- USP <800>: http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf
- Environmental Protection Agency EPA: https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste
- DailyMed: http://www.dailymed.nlm.nih.gov/dailymed/
- DrugBank: http://www.drugbank.ca/
- Medical Safety Data Sheets (MSDS): https://www.caymanchem.com
- Product labeling approved by FDA (DPI)
- International Agency for Research on Cancer (IARC): http://www.iarc.fr
- Manufacturer warnings
- FDA website: https://www.fda.gov/
- ONS, Safe Handling for Hazardous Drugs: www.ons.org
- *The Chapter <800> Answer Book*, by Patricia C. Kienle: www.ashp.org.
- The Joint Commission: https://hazmedsafety.com.
- National Institute of Occupational Safety and Health(NIOSH);
- The *NIOSH List of Antineoplastic and Other Hazardous Drugs in Health Care Settings*, 2016, www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.
- Hazardous Substances Chapter 6, Utah Code, Part 1, Solid and Hazardous Waste Act https://le.utah.gov/xcode/Title19/Chapter6/C19-6_1800101180000101.pdf
- Healthcare Environmental Resource Center, Utah; Pharmaceuticals – Hazardous Waste http://www.hercenter.org/rmw/ut-rmw.cfm http://www.hercenter.org/hazmat/pharma.cfm#listed
- Utah State Legislation Chapter 17b Pharmacy Practice Act: https://le.utah.gov/xcode/Title58/Chapter17b/58-17b.html