Aseptic Technique Sub-Section 9: USP 800

Introduction:

Like USP 797 and USP 795, the provisions of USP 800 address product transport, product storage, compounding, preparation, and administration of parenteral products. However, USP 800 builds on earlier regulations by focusing on hazardous drugs (HDs) and occupational safety.

Acronyms used in this section are listed below:

Acronym	Definition
795	USP General Chapter 795 Pharmaceutical Compounding—Nonsterile Preparations
797	USP General Chapter 797 Pharmaceutical Compounding—Sterile Preparations
800	USP General Chapter 800 Hazardous Drugs—Handling in Healthcare Settings
ACPH	Air Changes Per Hour
ASHP	American Society of Health-System Pharmacists
BUD	Beyond-Use Dating
CACI	Compounding Aseptic Containment Isolator
C-PEC	Containment Primary Engineering Control
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSP	Compounded Sterile Preparation
CSTD	Closed System Drug-Transfer Device
CVE	Containment Ventilated Enclosure
EPA	Environmental Protection Agency
HEPA	High-Efficiency Particulate Air
HD	Hazardous Drug
ISO	International Organization for Standardization
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Health and Safety Administration
PPE	Personal Protective Equipment
SDS	Safety Data Sheets
SOP	Standard Operating Procedure
USP	United States Pharmacopeial Convention

General Overview of USP 800

The USP published General Chapter 800 with a public health motivation to provide a legally enforceable standard to limit occupational exposure to HDs (Hazardous Drugs) and to protect patients, health care personnel, and the environment from the effects of handling HDs.

General Chapter 800 addresses handling HDs throughout the entire spectrum:

- receipt
- transfer
- storage
- compounding

- dispensing
- administration
- disposal of HD

USP 800 applies to any personnel who handle or come into contact with HDs, including:

- nurses
- pharmacists
- pharmacy technicians
- physicians
- physician assistants
- veterinarians
- veterinary technicians
- home health care workers

The extent of 800 includes health care settings, which includes all types of pharmacies:

- Hospital pharmacy
- Sterile compounding outpatient infusion / cancer center pharmacy
- Retail pharmacy
- Mail order pharmacy
- Non-sterile compounding pharmacy

It does not include the following non-health care settings:

- Wholesaler supplier
- Patient's home
- Manufacturing plant

USP 800 focus is to minimize the risk of and limit exposure to HDs by:

- Containment
- Risk assessment
- Work practices

Note: The HD information in 797 will be removed once 800 becomes official on July 1, 2018. 800 supplements (but does not replace) General Chapters 795 Pharmaceutical Compounding: Nonsterile Preparations, and 797 Compounding: Sterile Preparations

Requirements and Personnel

Facilities that handle HDs should include:

- Standards in occupational safety plans
- Health and safety management systems to include the following minimum items:
    - A list of HDs
    - Facility and engineering controls
    - Competent personnel (trained personnel)
    - Safe work practices
    - Proper use of appropriate personal protective equipment (PPE)
    - Policies for HD waste segregation and disposal

NIOSH Requirements

In addition to facilities and equipment changes, one of the keys to assuring compliance with USP 800 is for pharmacies to conduct an in-depth assessment of all the HDs they deliver to patients. That assessment begins with reviewing the NIOSH alert that lists the HDs found in health care settings.

The NIOSH list encompasses three groups of drugs:

- Group 1: Antineoplastic (anticancer) drugs that may also pose a reproductive risk for susceptible populations.
- Group 2: Nonantineoplastic drugs that meet one or more NIOSH criteria for an HD. Some of these may also pose a reproductive risk for susceptible populations.
- Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding

USP 800 Risk Assessments

Consider the following during an assessment of risk:

- Type of HD (e.g. antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation
- If an assessment of risk approach is taken, must document what alternative containment strategies and/or work practices are being employed to minimize occupational exposure

Risk Assessment Considerations for Final Dosage Forms

USP 800 says

- Hazardous Drugs that only require counting or repackaging of final dosage forms may be prepared for dispensing without any further requirements for containment unless
  - Required by the manufacturer (Manufacturer Safe Handling Guidance (MSHG))
  - If visual indicators of HD exposure hazard are present (i.e. dust / leakage)
- Counting / repackaging of HDs should be done carefully
- Use clean equipment dedicated for use with HDs
- Decontaminate equipment after each use
- Do not place HD tablets / capsules in automated counting machines
- Healthcare personnel should avoid crushing tablets or opening capsules of HDs
- If manipulation is required, must wear PPE and use a plastic pouch to contain any dust or particles

USP 800 Facility and Engineering Controls

HDs must be handled under conditions that promote patient and worker safety, and environmental protection. Hazard signs must be prominently displayed before the entrance to the HD handling areas. Access to HD areas must be restricted to authorized personnel to protect persons not involved in HD handling. HD handling areas should be located away from breakrooms for personnel, patients or visitors to reduce risk of exposure.

Designated areas must be available for:

- Receipt and unpacking of HDs
- Storage of HDs

- Nonsterile HD compounding (if performed by the entity)
- Sterile HD compounding (if performed by the entity)

Receipt and Unpacking of HDs

- Receipt and unpacking must occur in a neutral or negative pressure area

Storage of HDs

- HDs requiring manipulation must be stored separately from non-hazardous medications (separate refrigerator) in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH)
- Non-antineoplastic, reproductive risk only drugs and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy

Non-Sterile HD Compounding

- In a C-PEC located in a C-SEC
- C-PEC must be Externally vented (preferred) or have a redundant HEPA filter
- C-SEC must
  - Be externally vented
  - Be physically separate
  - Have 12 ACPH
  - Have a negative pressure of 0.01 – 0.03 inches of water column relative to adjacent areas

Sterile HD Compounding

- In a C-PEC located in a C-SEC
- C-PEC must
  - Be externally vented
  - Provide an ISO Class 5 or better environment
- C-SEC can be either an
  - An externally vented, negative pressure ISO Class 7 buffer room/ante room with 30 ACPH or
  - A negative pressure containment segregated compounding area that is externally vented with 12 ACPH

Closed System Transfer Devices & Environmental Sampling

- Closed system transfer devices should be used for compounding HDs when the dosage form allows
- Closed system transfer devices should be used when administering antineoplastic HDs
- Environmental wipe sampling for HD surface residue every 6 months
  - Include areas where contamination from HDs likely
  - If measurable contamination found identify, document and contain contamination then repeat wipe test

Personal Protective Equipment (PPE)

PPE is important for the health professional to protect against occupational hazards of HDs. PPE includes gloves; gowns; head, hair, shoe, and sleeve covers; eye and face protection; and respiratory protection. PPE as defined by pharmacy policy must be worn when handling HDs at all times. PPE worn when handling hazardous drugs should be disposed of as hazardous drug waste

- Chemotherapy Gloves

    - When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard
    - Chemotherapy gloves *should* be worn for handling all HDs including non-antineoplastics
    - Should be powder free
    - For sterile compounding, outer glove must be sterile
    - Change gloves every 30 minutes unless otherwise recommended by manufacturer's documentation
- Gowns
    - Must be disposable
    - Must be shown to resist permeability by HDs
    - Must close at the back, be long sleeved and have closed cuffs that are elastic or knit
    - Change per manufacturer's recommendations or every 2-3 hours and always after a spill /splash
- Head, Hair, Shoe & Sleeve Covers
    - When compounding, second pair of shoe covers must be donned before entering the CSEC and taken off when exiting
- Face and Eye Protection
    - Health professionals must use appropriate eye and face protection
    - Properly vented C-PECs provide eye (and respiratory) protection, so no additional protection is required when compounding.
    - Goggles must be used when eye protection is needed during incidents or procedures such as a spill cleanup or opening the work tray of a C-PEC.
- Respiratory Protection
    - Surgical masks are required when compounding any sterile medication (and should be considered for nonsterile compounding as well), but they do not provide respiratory protection for the compounder. Surgical masks provide protection from contamination of the compounded preparation.
    - Respiratory protection provides protection for the compounder and may be required when unpacking HDs that are not contained in plastic, when cleaning up spills, during certain decontaminating and cleaning procedures, or when vapor or gas exposure is suspected.
    - A facility's policy should describe respirators that are acceptable and available at the facility.

Deactivating, Decontaminating, Cleaning and Disinfecting

- All areas where hazardous drugs are handled and all reusable equipment must be deactivated, decontaminated, and cleaned
- Sterile compounding areas and devices must be subsequently disinfected

Cleaning process

1. Deactivation: Render compound inert /inactive
    - Agent used: EPA registered oxidizers (peroxide formulations, sodium hypochlorite (Bleach)
2. Decontamination: Remove HD residue
    - Agent used: Alcohol, water, peroxide, sodium hypochlorite
3. Cleaning: Remove organic and inorganic material
    - Agent used: Germicidal detergent
4. Disinfection: Destroy Microorganisms

- Agent used: EPA registered disinfectant, sterile alcohol

Note: Agents for deactivating, decontaminating, cleaning, and disinfecting agents must be applied through the use of wipes not by a spray bottle to avoid spreading HD residue

Personnel Training

- All personnel who handle hazardous drugs must be trained and pass competency before they handle HDs.
- Every 12 months training / competency assessment must be documented and must include:
  - An overview of the entity's HD list
  - Review of the entity's HD SOPs
  - Proper use of PPE
  - Proper use of equipment and devices (engineering controls)
  - Response to known or suspected HD exposure
  - Spill management
  - Proper disposal of HDs and trace-contaminated materials

Medical Surveillance

Healthcare workers who handle HDs should be enrolled in a medical surveillance program. The purpose of surveillance is to reduce adverse health effects in personnel possibly exposed to HDs.
Data collected in a medical surveillance program includes:

- Baseline and after HD exposure assessments
- Labs
- Medical history
- Work history (previous hazardous drug exposure)
- Estimated amount of HD handling
- Symptoms that arise post handling of HDs

Standard Operating Procedure (SOP)

The facility must maintain SOPs for the safe handling of HDs for all situations in which HDs are used in a pharmacy.
The SOPs should be reviewed every 12 months and the review must be documented.

The SOPs for handling of HDs should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt of drugs
- Storage of drugs
- Compounding
- Use and maintenance of proper engineering controls

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