

Foundation of Pharmacy Compounding and the USP ‹795› and ‹800›

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Disclosure

Jorge Reyes RPh., faculty for this CE, individuals in control of the content, and the planners for this activity have no relevant financial relationship(s) with ineligible companies to disclose.



Objectives

In this conference we will discuss:

- Nonsterile compounding; definition, evolution and how it differs from pharmaceutical manufactures.
- Main markets, dosage forms, distributors and professional organization related to this area.
- Existing regulation to prepare CNSP including reviewed USP chapter 795 and USP chapter 800 that will be implemented on November 1st, 2023



Pharmacy History Timeline



Galen – Experimenter in Drug Compounding

- “Galen (130-200 A.D.) practiced and taught both Pharmacy and Medicine in Rome
- He was the originator of the formula for a cold cream, essentially similar to that known today.
- “Many procedures Galen originated have their counterparts in today's modern compounding laboratories”



130-200 A.D.



Pharmacy History Timeline



The First Apothecary Shops

- The Arabs separated the arts of apothecary and physician, establishing in Bagdad late in the eighth century the first privately owned drug stores.
- They preserved much of the Greco-Roman wisdom, added to it, developing with the aid of their natural resources syrups, confections, conserves, distilled waters and alcoholic liquids.



Late 18th century



Pharmacy History Timeline



Separation of Pharmacy and Medicine

- “1240 A.D. : Sicily and southern Italy, Pharmacy was separated from Medicine.
- Frederick II of Hohenstaufen presented subject Pharmacists with the first European edict completely separating their responsibilities from those of Medicine, and prescribing regulations for their professional practice”.



1240 A.D.



Pharmacy History Timeline



The Marshall Apothecary

- “Christopher Marshall, an Irish immigrant, established his apothecary shop in Philadelphia in 1729.
- During 96 years, this pioneer pharmaceutical enterprise became a leading retail store, nucleus of large-scale chemical manufacturing; a "practical" training school for pharmacists; an important supply depot during the Revolution



1729



Pharmacy History Timeline

- It was managed by granddaughter Elizabeth, America's first woman pharmacist”.



The Marshall Apothecary



1729



Pharmacy History Timeline



First Hospital in Colonial America

- Colonial America's first hospital (Pennsylvania) was established in Philadelphia in 1751; the first Hospital Pharmacy began operations there in 1752.
- First Hospital Pharmacist was Jonathan Roberts; but it was his successor, John Morgan, whose practice as a hospital pharmacist (1755-56), and whose impact upon Pharmacy and Medicine influenced important changes.



1751



Pharmacy History Timeline



First Hospital in Colonial America

- First as pharmacist, later as physician, he advocated prescription writing and championed independent practice of two professions.



1751



Pharmacy History Timeline



**Scheele – Greatest of the
Pharmacists-Chemist**

- Carl Wilhelm Scheele: With rare genius, he made thousands of experiments, discovered oxygen, chlorine, prussic acid, tartaric acid, tungsten, molybdenum, glycerin, nitroglycerin, and countless other organic compounds that enter into today's daily life, industry, health, and comfort.



Pharmacy History Timeline



The Pharmacopeia Comes of Age

- The first "United States Pharmacopoeia" (1820) was the work of the medical profession.
- It was the first book of drug standards from a professional source to have achieved a nation's acceptance.



1820



Pharmacy History Timeline



The Pharmacopeia Comes of Age

- In 1877, the "U.S.P." was in danger of dissolution due to the lack of interest of the medical profession.
- "Committee on Revision" The "U.S. Pharmacopoeia" surged to new importance.



1820



Pharmaceutical compounding vs drug manufacturing

Pharmaceutical Compounding

Traditional compounding is the preparation of a medication to meet the prescriber's exact specifications directly to the patient, pursuant to a valid prescription for the patient.

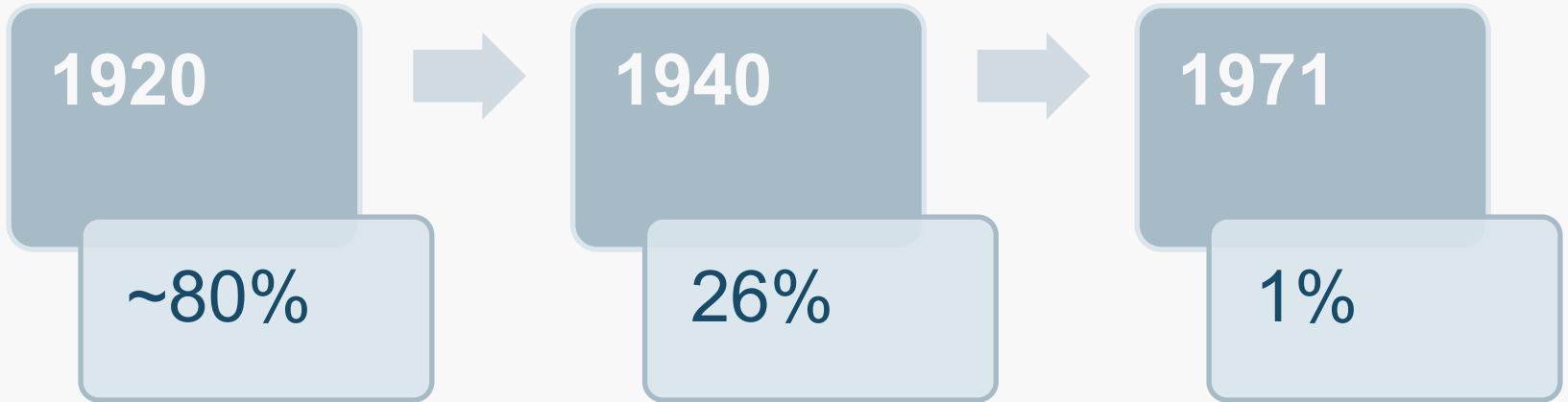
Pharmaceutical compounding is performed or supervised by a pharmacist licensed by a state board of pharmacy.

Drug Manufacturing

Manufacturing is the mass production of drug products that have been approved by the Food and Drug Administration (FDA). These products are sold to pharmacies, health care practitioners, or others who are authorized under state and federal law to resell them.



Disappearance Of compounding medicines in U.S.



Timeline

Year	Drug
1820	Colchicine
1869	Chloral hydrate
1879	Nitroglycerin
1899	Aspirin
1909	Oxytocin
1912	Phenobarbital
1914	Estrone estrogen
1933	Progesterone
1935	Testosterone
1942	Belladonna
1942	Nitrogen mustard
1948	Tetracyclines

Year	Drug
1949	Chloramphenicol
1949	Cortisone
1958	Griseofulvin
1958	Diuril
1964	Propranolol
1973	Tamoxifen
1974	Tagamet
1981	Captopril
1982	Acyclovir
1987	Cipro
1987	Ivermectin
1997	Synthroid



**Proposed Revisions to
USP General Chapter <795>
Pharmaceutical Compounding
– Nonsterile Preparations
Nov 1, 2023**

Jorge Reyes, RPh
August 26, 2023




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01

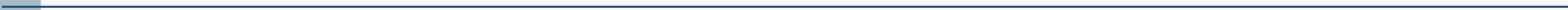
Introduction and Scope

This chapter describes the minimum standards to be followed when preparing compounded nonsterile preparations (CNSPs) for human and animals.



Compounding

The combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer package insert, or otherwise altering of a drug or bulk drug substance to create a nonsterile medication. Reconstituting a conventionally manufactured nonsterile product in accordance with the directions contained in approved labeling provided by the product's manufacturer is not considered compounding as long as the product is prepared for an individual patient and not stored for future use.



Compounded Nonsterile Preparations Affected

CNSPs that may be affected by this chapter include but are not limited to the following dosage forms:

- **Solid oral** preparations
 - **Liquid oral** preparations
 - **Rectal** preparations
 - **Vaginal** preparations
 - **Topical** preparations (i.e., creams, gels, irrigations for non-internal and non-surgical body cavities)
 - **Nasal and sinus** preparations intended for local application
 - **Otic** preparations
-

Handling of Hazardous Drugs

Compounding of nonsterile hazardous drugs must also comply with **Hazardous Drugs – Handling in Healthcare Settings <800>**.



Affected Personnel and Settings

This chapter applies to all persons who prepare CNSPs and all places where CNSPs are prepared. This includes but is not limited to:

- **pharmacist**
- **technicians**
- **physicians**
- **veterinarians**
- **dentists**
- **naturopaths**
- **chiropractors**
- **nurses**



Affected Personnel and Settings

In all places including but not limited to:

- **Pharmacies**
- **Hospitals**
- **Other healthcare institutions**
- **Patient treatment sites**
- **Physicians' or veterinarians' practice sites.**



Affected Personnel and Settings

The compounding facility must designate one or more individuals (i.e., the designated person) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs.

If the compounding facility has only one person responsible for all the compounding in the facility, the that person will become the designate.

Affected Personnel and Settings

The **responsibilities** of the designated person include but are not limited to:

- Developing and implementing a training program
- Routinely monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed
- Demonstrating the procedures for personnel and observing and guiding personnel throughout the training process.



Affected Personnel and Settings

The **responsibilities** of the designated person include but are not limited to:

- Evaluating whether individuals with certain conditions, such as rashes or respiratory illnesses, will be allowed to work in compounding areas before their conditions are resolved because these conditions carry the risk of contaminating the environment of CNSPs.
- Ensuring that standard operating procedures (SOPs) are fully implemented. The designated person must ensure that follow-up is carried out if problems, deviations, or errors are identified
- Establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/ or components of CNSPs.





02

Personal Qualifications

Training, Evaluation, and Requalification



Personal Qualifications – Training, Evaluation, and Requalification

All personnel involved in the preparation and handling of CNSPs must be trained, must demonstrate competency, and must undergo annual refresher training. Training and competency of personnel must be documented as described in *14. Documentation*.

Personnel engaged in the compounding of CNSPs must also comply with the applicable laws and regulations of the regulatory jurisdiction.



Personal Qualifications – Training, Evaluation, and Requalification

The designated person must develop:

- A written training program that describes the required training
- The frequency of training
- The process for evaluating the competency of personnel involved in nonsterile compounding and handling of CNSPs.

This program must equip personnel with knowledge and training in the required skills necessary to perform their assigned tasks.



Personal Qualifications – Training, Evaluation, and Requalification

Before independently beginning to prepare CNSPs, personnel must complete training and be able to demonstrate proficiency in the theoretical principles and hand—on skills of nonsterile manipulations for the type of compounding they will be performing.



Personal Qualifications – Training, Evaluation, and Requalification

Proficiency must be demonstrated in at least the following core competencies:

- Hand hygiene
 - Garbing
 - Cleaning and sanitizing
 - Component selection, handling, and transport
 - Performing calculations
 - Measuring and mixing
 - Use of equipment
 - Documentation of the compounding process (e.g., Master Formulation Records and Compounding Records)
-

Personal Qualifications – Training, Evaluation, and Requalification


Steps in the training procedure must include the following:

- Read and understand this chapter
 - Have access to *USP* compounding monographs, others applicable general chapters, and other relevant literature.
 - Understand and interpret Certificated of Analysis (COAs) and Safety Data Sheets (SDS)
 - Read and understand procedures related to their compounding duties, including those regarding the facility, equipment, personnel, garbing, actual compounding processes, evaluation, packaging, storage, transport, and dispensing.
-

Personal Qualifications – Training, Evaluation, and Requalification

An employee will be permitted to perform the procedure without direct supervision only after independently demonstrating understanding and competency to the designated person. Upon completion of the training program, the designated person must document that the employee has been trained and successfully completed competency assessments.

If the facility has only one person in the compounding operation, that person must document that they have obtained appropriate training outside of the facility and demonstrated competency, and the must comply with the other requirements of this chapter.





03

Personal Hygiene and Garbing



Personnel Hygiene and Garbing

Compounding personnel must maintain personal hygiene. Individual that may have higher risk of contaminating CNSPs and the environment (e.g., due to rashes, sunburn, recent tattoos or oozing sores, conjunctivitis, active respiratory infections) must report these conditions to the designated person. The designated person must evaluate whether these individuals will be allowed to work in compounding areas before their conditions are resolved because of the risk of contaminating the environment and CNSPs.

Personnel Preparation

- Remove personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests)
- Remove all hand, wrist, and other exposed jewelry or piercing that can interfere with the effectiveness of the garb or hand hygiene (e.g., watches, rings that may tear gloves)
- Remove headphones and earphones
- Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures



Hand Hygiene

Hand hygiene is required when initially entering the compounding area and when re-entering the compounding area after a break. Hand hygiene is also required before initiating any compounding activity related to a new CNSP. Perform hand hygiene as described in Box 3-1. If gloves are already donned, wash hands with donned gloves. Gloves must be changed if they have been compromised (i.e., if they are torn or contain holes).



Hand Hygiene

Box 3-1. Hand Hygiene Procedures

- Wash hands and forearms up to the elbows with soap and water for at least 30 s. Alcohol hand sanitizers alone are not sufficient.
- Dry hand and forearms to the elbows completely with disposable towels or wipes.
- Allow hand and forearms to dry thoroughly before donning gloves.



Garb and Glove Requirement

Gloves are required to be worn for all compounding activities.

Other garb (e.g., shoe covers, head and facial hair covers, face masks, gowns) must be appropriate for the type of compounding performed as needed for the protection of personnel from chemical exposures and for the prevention of preparation contamination.

Garb must be stored to prevent contamination (e. g., away from sinks to avoid splashing onto garb). Visibly soiled garb or garb with tears or punctures must be changed immediately.



Exiting and Reentering Compounding Area

When compounding personnel exit the compounding area during a work shift, if the gown is used but not soiled, it can be removed and retained in the compounding area a re-donned during the same work shift only.

Gloves, shoe covers, hair covers, facial hair covers, face masks, or head coverings, if used, may not be reused and must be replaced with new ones.

Non-disposable garb, such as goggles or respirators, if used, should be cleaned and sanitized with 70% isopropyl alcohol before re-use.





04

Buildings and Facilities




Buildings and Facilities

Compounding facilities must have space that is specifically designated for compounding. Areas related to non-sterile compounding must be separated from areas not directly related to compounding.

Compounding areas used to compound hazardous CNSPs must not be used for compounding nonhazardous CNSPs (see <800>).

Compounding facilities must be designed and controlled to provide a well-lighted working environment, with temperatures and humidity controls. Also, the space must be designed, arranged, and used in a way that prevents cross-contamination from non-compounding areas.



Buildings and Facilities

Carpet is not allowed in the compounding area, and surfaces should be resistant to damage by cleaning and sanitizing agents.

A source of hot and cold water and an easily accessible sink must be available for compounding.

The areas used for compounding must be maintained in a clean, orderly, and sanitary condition.



Buildings and Facilities

Table 1. Minimum Frequency for Cleaning and Sanitizing Surfaces in Nonsterile Compounding Areas

Site	Minimum Frequency
Floors	Daily, after spills, and when surface contamination (e.g., splashes) is known or suspected.
Walls	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected.
Ceilings	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected.
Storage shelving	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected.




06

Equipment and Components

Equipment

The equipment and supplies used for compounding a CNSP must be suitable for the specific compounding process. Equipment surfaces that contact components must not be reactive, additive, or sorptive, and must not alter the quality of the CNSPs.

Automated, mechanical, electronic, and other types of equipment used in the compounding or testing of compounded preparations must be inspected prior to use and verified for accuracy at the frequency recommended by the manufacturer, and at least annually. Immediately after compounding, the equipment must be cleaned to prevent cross-contamination of the next preparation.



Equipment

Any weighing, measuring, or other manipulation of an active pharmaceutical ingredient (API) or added substance in powder form that could generate airborne contamination from drug particle must occur inside a containment device such as a containment ventilated enclosure (CVE) (i.e., powder containment hood).

The CVE must be cleaned as described next and must be certified annually.



Equipment

Table 2. Minimum Frequency for Cleaning and Sanitizing Equipment in Nonsterile Compounding Areas

Site	Minimum Frequency
CVE and work surfaces outside the CVE	At the beginning and end of each shift, after spills, and when surface contamination is known or suspected. Clean and sanitize the horizontal work surface of the CVE between compounding of different drugs.
Equipment used in compounding operations	Before first use and thereafter in accordance with the manufacturer's recommendations. If no recommendations is available, after each use.




Components

Compounding personnel must establish, maintain, and follow written SOPs for the selection and inventory control of all components, including all ingredients (i.e., APIs, inactive ingredients), containers, and closures, from receipt to use in a CNSP.

SDSs must be readily accessible to all personnel working with drug substances or bulk chemicals located in the compounding facility.

Personnel must be instructed on how to retrieve and interpret needed information.



Components

The designated person is responsible for component selection. Compounders must use qualified vendors.

A vendor is qualified when there is evidence to support its ability to supply a material that consistently meets all quality specifications.

In the U.S.A., APIs and all ingredients other than APIs used in compounding must be manufactured by an FDA registered facility.



Components

Each API must be accompanied by a valid COA that includes the specifications and test results and shows that the API meets an official *USP-NF* monograph, if one exists, and any additional specifications required to appropriately use the API in preparing the CNSP.

Purified water, or an equivalent quality of water, must be used to reconstitute conventionally manufactured nonsterile products when water quality is not stated in the manufacturer's labeling.



Component Receipt

Upon receipt, each lot of the component must be visually inspected to ensure that the labeling correctly identifies the component, and that the components meets the expected appearance.

The lot must be examined for evidence of deterioration and other aspects of unacceptable quality (e.g., foreign objects, whether the outer packaging is damaged and whether temperature-sensing indicators show that the component has been exposed to excessive temperature excursions).



Component Receipt

The containers and closures used to package CNSPs must be stored off the floor, handled and stored in a manner that prevents contamination, and rotated so that the oldest stock is used first. The containers and container closures must be stored in a manner that permits inspections and cleaning of the storage area.

Any ingredient found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to ensure that they are not inadvertently used. Any other lots of that ingredient from that vendor must be examined to determine whether the other lots demonstrate the same unacceptable quality.



Component Evaluation Before Use

Before use, compounding personnel must visually re-inspect all components. Ingredients packages must be inspected to detect container breaks, looseness of the cap or closure, or deviation from expected appearance, aroma, or texture of the contents that might have occurred during storage.



Component Handling and Storage

All ingredients used to prepare CNSPs must be handled and stored in accordance with the manufacturer's instructions or per applicable laws and regulations of the regulatory jurisdiction.

Package of ingredients that lack a vendor's expiration date must not be used after 1 year from the date of receipt by the compounding facility.

Once removed from the original container for compounding (e.g., weighing or mixing), components not used in compounding (e.g., excess after weighing) must be discarded and not returned to the original container.



Component Spill and Disposal

The facility must maintain chemical hazard and disposal information (e.g., SDSs) and must review and update its chemical hazard and disposal information annually.

The facility must have a spill kit in the designated compounding area.

The condition and expiration date of the chemical spill kit should be verified annually and replaced, as necessary.



Component Spill and Disposal

The capacity of the spill kit should be affixed to the packaging of the spill kit if not readily visible on the manufacturer's label.

In the case of spills, immediate remediation is necessary.

The facility must have an SOP for the management of nonhazardous component spills and disposal.

These activities must be documented, and corrective action taken, if necessary.



Component Spill and Disposal

All personnel who may be required to remediate a spill must receive training in spill management of chemicals used and stored at the compounding facility.

Refresher training must be conducted annually and documented for all personnel who may be required to clean up a spill.

The disposal of components must comply with the applicable laws and regulations of the regulatory jurisdiction.





07

SOPs and Master Formulation and Compounding Records



SOPs and Master Formulation and Compounding Records

The compounding facility must establish and follow written SOPs for compounding CNSPs. A Master Formulation Record and Compounding Record is required for each CNSP.

Creating and Following SOPs

Facilities preparing CNSPs must develop SOPs on all aspects of the compounding operation.

All personnel who conduct or oversee compounding activities must be trained in the SOPs and are responsible for ensuring that they are followed.

The designated person must ensure that SOPs are fully implemented, and follow-up occurs if problems, deviations or errors are identified.



Creating and Following SOPs

All compounding personnel must be able to:

- Immediately recognize potential problems, deviations, or errors associated with preparing a CNSP (e.g., related to equipment, facilities, materials, personnel, compounding process, or testing) that could potentially result in contamination or other adverse impacts on CNSP quality associated with their work duties.
- Document and report any problems, deviations, or errors to the designated person, who must take corrective action.



Creating Master Formulation Records

A Master Formulation is a detailed record of procedures that describes how the CNSP is to be prepared.

Box 7-1. Master Formulation Record

A Master Formulation Record must include at least the following information:

- Name, strength, and dosage form of the CNSP
- Physical description of the final CNSP
- Ingredients identities and amounts, and container-closure systems, including necessary characteristics of components (e.g., particle size, salt form, purity grade, solubility)



Creating Master Formulation Records

Box 7-1. Master Formulation Record Continuation

A Master Formulation Record must include at least the following information:

- Complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps.
- Beyond-use date (BUD) assignment and storage requirements
- Reference source of the BUD assignment and storage requirements
- Quality control procedures (e.g., pH, visual inspection)
- Any other information needed to describe the operation and ensure its repeatability (e.g., adjusting pH, temperature)

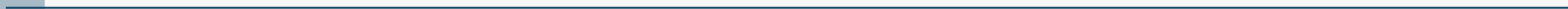


Creating Compounding Records

A Compounding Record documents the compounding of each CNSP. It must be created for each CNSP.

The Master Formulation Record can be used as the basis for preparing the Compounding Record.

For example, a copy of the Master Formulation Record can be made that contains spaces for recording the information needed to complete the Compounding Record.



Creating Compounding Records

Box 7-2. Compounding Record

Compounding Records must include at least the following information:

- Name, strength, and dosage form of the CNSP
 - Physical description of the final CNSP
 - Master Formulation Record reference for the CNSP
 - Date and time of preparation of the CNSP
 - Assigned internal identification number (e.g., prescription or lot number)
 - Signature or initials of individuals involved in each step
 - Name, vendor or manufacturer, lot number, and expiration date of each ingredient and container- closure system
 - Weight or measurement of each ingredient
-

Creating Compounding Records

Box 7-2. Compounding Record Continuation

Compounding Records must include at least the following information:

- Documentation of the calculations made to determine and verify quantities and/or concentrations of components, if appropriate
 - Documentation of quality control procedures in accordance with the SOP (e.g., pH, visual inspection)
 - Any deviations from the Master Formulation Record, and any problems or errors experienced during the compounding of the CNSP
 - Total quantity compounded
 - Beyond-use date (BUD) assignment and storage requirements
 - Reference source of the BUD assignment and storage requirements
-



08

Release Testing



Release Testing

At the completion of compounding and before release and dispensing, the CNSP must be visually inspected to determine whether the physical appearance is as expected. The inspection must also confirm that the CNSP and its labeling match the Compounding Record and the prescription or the medication order.

Pre-release inspection also must include a visual inspection of container-closure integrity (e.g., checking for leakage, cracks in the container, or improper seals). CNSPs with observed defects must be immediately discarded, or marked and segregate from acceptable units in a manner that prevents them from being released or dispensed.





09

Labeling

The term “labeling” designates all labels and other written, printed, or graphic matter on an article’s immediate container or on, or in, any package or wrapper in which the article is enclosed

Labeling

Every dispensed CNSP must be labeled with adequate, legible identifying information to prevent errors during storage, dispensing, and use.

All labeling must be in compliance with applicable laws and regulations of the regulatory jurisdiction.



THIS MEDICINE WAS SPECIALLY
COMPOUNDED IN OUR PHARMACY FOR YOU
AT THE DIRECTION OF YOUR PRESCRIBER

Labeling

The label on the CNSP must, at minimum, display the following information:

- Assigned internal identification number (e.g., prescription or lot number)
- Chemical and/or generic name(s), or active ingredient(s), and amounts or concentrations
- Dosage form
- Total amount or volume
- Storage conditions
- BUD
- Indication that the preparation is compounded



Labeling

The labeling on the CNSP must, at minimum, display the following information:

- Route of administration
- Any special handling instructions
- Any warning statements that are applicable
- Name, address, and contact information of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded





10

Establishing Beyond-Use Dates



Establishing Beyond-Use Dates

Each CNSP label must state the date beyond which the preparation cannot be used and must be discarded (i.e., the BUD). The parameters described in this section must be considered before establishing these dates.

A BUD is the time period after which a CNSP must not be used. BUDs for CNSPs are calculated in terms of hours, days, or months.

The BUD indicates the days after the CNSP is prepared and beyond which the CNSPs cannot be used. The day that the preparation is compounded is considered Day 1.



Establishing Beyond-Use Dates

The term “expiration date” is not appropriate for CNSPs because the types of fully stability studies conducted by manufactures to establish expiration dates for conventionally manufactured products are not typically performed for CNSPs.

A BUD cannot be extended past the expiration date of any component in the CNSP.

The assigned BUD must not exceed 180 days regardless of stability information or antimicrobial activity.



Establishing Beyond-Use Dates

Table 3. Minimum BUD by Type of Preparation in the Absence of CNSP-Specific Stability Information

Type of Preparation	BUD (days)	Storage Temperature
Solid dosage forms	180	Controlled room temperature
Preserved aqueous dosage forms	30	Controlled room temperature
Non-preserved aqueous dosage forms	14	Refrigerator
Nonaqueous dosage forms	90	Controlled room temperature

Establishing Beyond-Use Dates

Table 4. Current Minimum BUD by Type of Preparation in the Absence of CNSP-Specific Stability Information

Type of Preparation	BUD
Nonaqueous Formulations	The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations	The BUD is not later than 14 days when stored at controlled cold temperatures.
Water-Containing Topical/ Dermal and Mucosal Liquid and Semisolid Formulations	The BUD is not later than 30 days.



11

Quality Assurance and Quality Control




Quality Assurance and Quality Control

A **quality assurance (QA)** and **quality control (QC)** program is necessary to ensure that consistently high-quality CNSPs are prepared.

QA is a set of **written processes** that, at a minimum, verifies, monitors, and reviews the adequacy of compounding process.

QC is the **observation** of techniques and activities that demonstrate that requirements are met.

For further guidance on recommended quality control procedures, see *Quality Assurance in Pharmaceutical Compounding* <1163>.




Quality Assurance and Quality Control

The roles and duties of personnel responsible for each aspect of the QA program must be described in the SOPs.

Designated personnel responsible for the QA program must have the training, experience, responsibility, and authority to perform these duties.

An annual assessment of the quality assurance and quality control programs must be documented.

Noted deficiencies must be addressed through corrective action, which must be describe in the facility's SOPs.





12

CNSP: Handling, Packaging, Storage, and Transport



CNSP Handling, Packaging, Storage, and Transport

SOPs must describe processes or techniques for storing, handling, packaging, and transporting CNSPs. Personnel who will be storing, handling, packaging, and transporting CNSPs within the facility must be trained in accordance with the facility's SOPs.



Handling and Storage of CNSPs

The designated person has the responsibility to establish, monitor, and document a program that will provide both the information and protections needed for safe handling and storage of CNSPs and/or any of the components of the CNSPs. Garb, spill kits, and SDSs must be readily accessible.

Hazard labels (if applicable) should be on all chemical containers.

The **humidity** of the storage room temperature area should be maintained **at or below 60%**.



Shipping and Transporting CNSPs


The facility must have written SOPs that describe appropriate shipping containers, insulating materials, and packaging materials based on the chemical and physical characteristics of the CNSP.





13

Complaint Handling and Adverse Event Reporting



Complaint Handling and Adverse Event Reporting

Compounding facilities must develop and implement SOPs for complaint receipt, acknowledgment, and handling. Complaints may include concerns or reports on the quality and labeling of, or possible adverse reactions to, a specific CNSP.

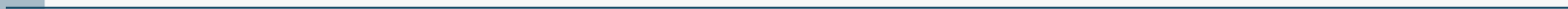


Complaint Handling

The designated person must review all complaints to determine whether the complaint indicates a potential quality problem with the CNSP.

If it does, a thorough investigation into the cause of the problem must be initiated and completed.

The investigation must consider whether the quality problem extends to other CNSPs.



Complaint Handling

Corrective action, if necessary, must be implemented for all potentially affected CNSPs.

Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected.



Complaint Handling

A readily retrievable written or electronic record of each complaint must be kept by the facility regardless of the source of the complaint (e.g., e-mail, telephone, mail). The record must contain:

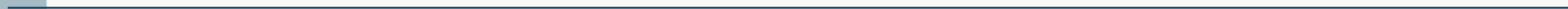
- The name of complainant
- The date the complaint was received
- The nature of the complaint
- The response to the complaint
- The name and strength of the CNSP



Complaint Handling

A readily retrievable written or electronic record of each complaint must be kept by the facility regardless of the source of the complaint (e.g., e-mail, telephone, mail). The record must contain:

- The prescription or medication order
- The lot number if one is assigned
- The findings of any investigation
- Any follow-up



Complaint Handling

Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record-keeping requirements in *14. Documentation*.

A CNSP that is returned in connection with the complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with applicable laws and regulations of the regulatory jurisdiction.



Adverse Event Reporting

Reports of potential adverse events involving a CNSP must be reviewed by the designated person. If the investigation into an adverse event reveals a quality problem with a CNSP that is likely to affect other patients, those patients and prescribers potentially affected must be informed.

In addition, adverse events associated with a CNSP should be reported to the FDA through the **MedWatch program** for human drugs and through **Form FDA 1932a** for animal drugs.





14

Documentation



Documentation

All facilities where CNSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with this chapter. **This documentation must include**, but is not limited to, the following:

- Personnel training, competency assessment, and qualification records including corrective actions for any failures
- Equipment records (e.g., calibration, verification, and maintenance reports)
- Receipt of components



Documentation

All facilities where CNSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with this chapter. **This documentation must include,** but is not limited to, the following:

- SOPs, Master Formulation Records, and Compounding Records
- Release testing, including corrective actions for any failures
- Information related to complaints and adverse events including corrective actions taken




Documentation

Documentation must comply with all applicable laws and regulations of the regulatory jurisdiction.

Records must be legible and stored in a manner that prevents their deterioration and/or loss.

All required compounding records for a particular CNSP (e.g., Master Formulation Record, Compounding Record, and testing results) must be readily **retrievable for at least 3 years after the preparation or as required by the applicable laws and regulations of the regulatory jurisdiction, whichever is longer.**

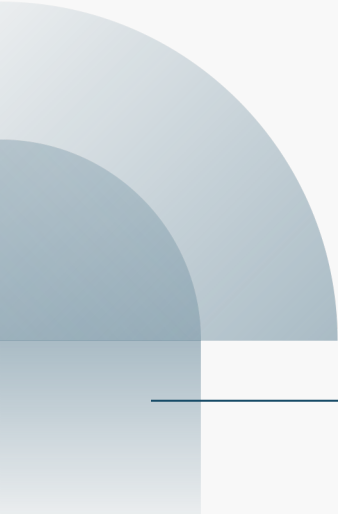




Thanks!

Any questions?

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USP General Chapter <800>

Hazardous Drugs – Handling in Healthcare
Settings

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1

Introduction and Scope

Introduction and Scope

- Describes practice and quality standards for handling hazardous drugs (HDs) to promote:
 - Patient safety
 - Worker safety
 - Environmental protection
- Handling HDs includes, but is not limited to:
 - The receipt
 - Storage
 - Compounding
 - Dispensing
 - Administration
 - Disposal of sterile and nonsterile products.

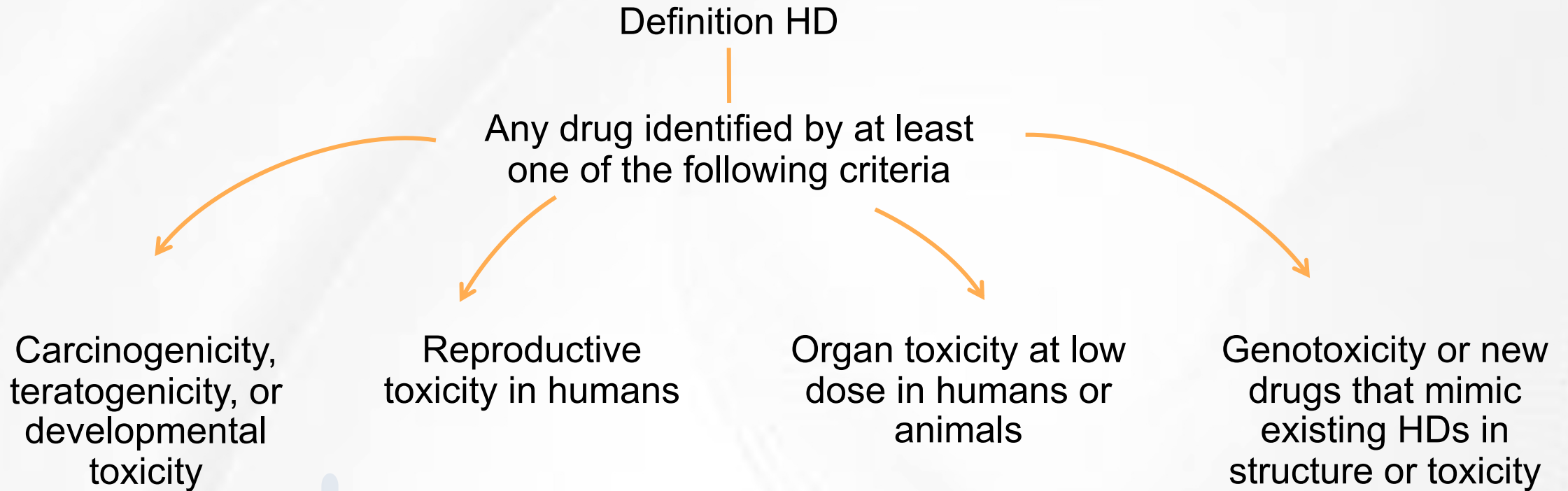
Introduction and Scope

- The chapter applies to all healthcare personnel who:
 - Handle HD preparations
 - And all entities that:
 - Store, prepare, transport or administer HD
 - (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' office).
- Personnel who may potentially be exposed to HDs include, but are not limited to:
 - Pharmacists
 - Pharmacy technicians
 - Nurses
 - Physicians
 - Physician assistants
 - Home healthcare workers
 - Veterinarians
 - Veterinary technicians

Introduction and Scope

- Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan.
- The entity's health and safety management system must, at a minimum, include:
 - A list of HDs
 - Facility and engineering controls
 - Competent personnel
 - Safe work practices
 - Proper use of appropriate Personal Protective Equipment (PPE)
 - Policies for HD waste segregation and disposal

Introduction and Scope





Exposure

Exposure

- Some dosage forms of drugs defined as HD may not pose a significant risk of direct occupational exposure because of their dosage formulation (e.g., tablets or capsules-solid, intact medications that are administered to patients without modifying the formulation).
- However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation.
- Routes of unintentional entry of HDs into the body include:
 - Dermal and mucosal absorption,
 - Inhalation
 - Injection
 - Ingestion (e.g., contaminated foodstuffs, spills, or mouth contact with contaminated hands)

Example of Potential Opportunities of Exposure Based on Activity

Activity	Potential Opportunity of Exposure
Receipt	Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors
Dispensing	Counting or repackaging tablets and capsules
Compounding and other manipulations	<ul style="list-style-type: none">• Crushing or splitting tablets or opening capsules• Pouring oral or topical liquids from one container to another• Weighing or mixing components• Constituting or reconstituting powdered or lyophilized HDs• Withdrawing or diluting injectable HDs from parenteral containers• Expelling air or HDs from syringes• Contacting HD residue present on PPE or other garments• Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs• Maintenance activities for potentially contaminated equipment and devices

Example of Potential Opportunities of Exposure Based on Activity

Administration	<ul style="list-style-type: none">• Generating aerosols during the administration of HDs by various routes (e.g., injection, irrigation, oral, inhalation, or topical application)• Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation)• Priming an IV administration set
Patient-care activities	Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
Spills	Spill generation, management, and disposal
Transport	Moving HDs within a healthcare setting
Waste	Collection and disposal of hazardous waste and trace contaminated waste




4

Responsibilities of Personnel Handling Hazardous Drugs



Responsibilities of Personnel Handling Hazardous Drugs

- Entities must have a designed person who is qualified and trained to be responsible for:
 - Developing and implementing appropriate procedures;
 - Overseeing entity compliance with this chapter and other applicable laws, regulations
 - Ensuring competency of personnel
 - Ensuring environmental control of the storage and compounding areas.
- 
-



Facilities and Engineering Controls



Facilities and Engineering Controls

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






Facilities and Engineering Controls

- Designated areas must be available for:
 - Receipt and unpacking
 - Storage of HDs
 - Nonsterile HD compounding (if performed by the entity)
 - Sterile HD compounding (if performed by the entity)
 - Certain areas required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure. Consideration should be given to **uninterrupted power sources** (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.
-



Receipt


- Antineoplastic HDs and all HD APIs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/ normal or negative pressure relative to the surrounding areas.
 - HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.
- 

Storage

- HDs must be stored in a manner that prevents spillage or breakage if the container falls.
- Do not store HDs on the floor.
- In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.
- Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure.
- These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH)



Storage


- Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.
 - Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)].
- 

Compounding

- Engineering controls are required to protect the preparation from cross-contamination and microbial contamination (if preparation is intended to be sterile) during all phases of the compounding process.
- Engineering controls for containment are divided into three categories representing primary, secondary, and supplementary levels of control.
- A containment **primary engineering control** (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs. The containment **secondary engineering control** (C-SEC) is the room in which the C-PEC is placed.
- A sink must be available for hand washing.
- An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available.



Nonsterile Compounding

- In addition to this chapter, nonsterile compounding must follow standards in *Pharmaceutical Compounding—Nonsterile Preparations* <797>.
 - A C-PEC is not required if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses.
- 

Nonsterile Compounding

Engineering Controls for Nonsterile HD Compounding	
C-PEC	C-SEC Requirements
Externally vented (preferred) or redundant- HEPA filtered in series	Externally vented
Examples: CVE, Class I or II BSC, CACI	12 ACPH
	Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas

Nonsterile Compounding

- Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as:
 - Class I Biological Safety Cabinet (BSC)
 - Containment Ventilated Enclosure (CVE)
 - A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used.
- Due to the difficulty of cleaning HD contamination, surfaces of:
 - Ceilings
 - Walls
 - Floors
 - Fixtures
 - Shelving
 - Counters and cabinets


In the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding



Personal Protective Equipment




Personal Protective Equipment

- Appropriate PPE must be worn when handling HDs including during:
 - Receipt
 - Storage
 - Transport
 - Compounding (sterile and nonsterile)
 - Administration
 - Deactivation/decontamination, cleaning, and disinfecting
 - Spill control
 - Waste disposal
- 




Gloves

- When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor).
 - 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.
- 




Gloves

- When used for sterile compounding, the outer chemotherapy gloves must be sterile.
 - Chemotherapy gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated.
 - Hands must be washed with soap and water after removing gloves.
- 



Gowns

- When gowns are required, they must be disposable and shown to resist permeability by HDs.
 - Gowns must be selected based on the HDs handled.
 - Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.
 - Gowns must close in the back (i.e., no open front), be long-sleeved, and have closed cuffs that are elastic or knit.
 - Gowns must not have seams or closures that could allow HDs to pass through.
- 




Gowns

- Gowns must be changed per the manufacturer's information for permeation of the gown.
 - If no permeation information is available for the gowns used, change them every 2-3 hours or immediately after spill or splash.
- Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.






Head, Hair, and Shoe Covers

- Head and hair covers (including beard and mustache, if applicable), shoe covers, and sleeve covers provide protection from contact with HD residue.
 - When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC.
 - Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.
- 




Eye and Face Protection

- Many HDs are irritating to the eyes and mucous membranes.
 - Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suit, working at or above eye level, or cleaning a spill).
- 



Eye and Face Protection

- A full-facepiece respirator provides eye and face protection.
 - Goggles must be used when eye protection is needed.
 - Eyeglasses alone or safety glasses with side shields do not protect the eyes adequately from splashes.
 - Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes.
 - Face shields alone do not provide full eye and face protection.
- 



Hazard Communication Program

Hazard Communication Program

- Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling.
- The entity must develop SOPs to ensure effective training regarding:
 - Proper labeling
 - Transport
 - Storage
 - Disposal of the HDs and use of Safety Data Sheets (SDS)


Based on the Globally Harmonized System of Classification and Labeling of Chemical (GHS)



Personnel Training




Personnel Training

- All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administering, and disposing of HDs).
 - Training must occur before the employee independently handles HDs.
 - The effectiveness of training for HD handling competencies must be demonstrated by each employee.
 - Personnel competency must be reassessed at least every 12 months.
 - Personnel must be trained prior to the introduction of new HD or new equipment and prior to a new or significant change in process or SOP.
 - All training and competency assessment must be documented.
- 



Personnel Training.

- The training must include at least the following:
 - Overview of entity's list of HDs and their risks
 - Review of the entity's SOPs related to handling of HDs
 - Proper use of PPE
 - Proper use of equipment and devices (e.g., engineering controls)
 - Response to known or suspected HD exposure
 - Spill management
 - Proper disposal of HDs and trace-contaminated materials
- 



10

Receiving



Receiving

- The entity must establish SOPs for receiving HDs.
 - HDs should be received from the supplier in impervious plastic to segregate them from other drugs and allow for safety in the receiving and internal transfer process.
 - HDs must be delivered to the HD storage area immediately after unpacking.
- PPE, including chemotherapy gloves, must be worn when unpacking HDs.
- A spill kit must be accessible in the receiving area.

Receiving

Summary of Requirements for Receiving and Handling Damaged HD shipping Containers

If the shipping container appears damaged

Seal container without opening
and contact the supplier

If the unopened package is to be
returned to the supplier, enclose
the package in an impervious
container and label the outer
container "Hazardous"

If the supplier declines return,
dispose of as hazardous waste.



11

Labeling, Packaging, Transport, and Disposal



Labeling, Packaging, Transport, and Disposal

- The entity must establish SOPs for the:
 - Labeling
 - Packaging
 - Transport
 - Disposal of HDs
 - The SOPs must address prevention of accidental exposure or spills, personnel training on response to exposure, and use of a spill kit.
-




Labeling

- HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport.
- Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.





Packaging


- Personnel must select and use packaging containers and materials that will 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.
 - The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.
- 

Transport

- HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.
- HDs must be transported in containers that minimize the risk of breakage and contamination.
- When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS. The entity must ensure that labels and accessory labeling for the HDs include:
 - Storage instructions
 - Disposal instructions
 - HD category information in a format that is consistent with the carrier's policies.



Disposal

- 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, including, but not limited to:
 - Unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.
- 



12

Dispensing Final Dosage forms

Dispensing Final Dosage forms

- Counting or repackaging of HDs must be done carefully.
- Clean equipment should be dedicated for use with HDs and should be decontaminated after every use.
- Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.



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Compounding

Compounding

- Entities and personnel involved in compounding HDs must be compliant with the appropriate USP Standards for compounding including <795> and <797>.
- Compounding must be done in proper engineering controls as described in *Compounding*.
- When compounding HD preparation in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC.
 - The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity.
- Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs.



Compounding

- Bulk containers of liquid and API HD must be handled carefully to avoid spills.
 - If used, APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).
- 



15


**Deactivating,
Decontaminating,
Cleaning and
Disinfecting**

Deactivating, Decontaminating, Cleaning and Disinfecting

- All areas where HDs are handled, and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected.
 - The entity must establish written procedures for decontamination, deactivation, and cleaning
 - For sterile compounding areas: disinfection
 - Cleaning of nonsterile compounding areas must comply with <795> and cleaning of sterile compounding areas must comply with <797>.
 - Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.
-



Deactivating, Decontaminating, Cleaning and Disinfecting

- All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination.
 - All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns.
 - Eye protection and face shields must be used if splashing is likely.
 - If warranted by the activity, respiratory protection must be used.
- 



Cleaning steps

Cleaning step	Purpose	Example agents
Deactivation	Render compound inert or inactive	As listed in the HD labeling or other agents which may incorporate Environmental Protection Agency (EPA)-registered oxidizers (e.g., peroxide formulations, sodium hypochlorite, etc.)
Decontamination	Remove HD residue	Materials that have been validated to be effective for HD decontamination, or through other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent
Disinfection (for sterile manipulations)	Destroy microorganisms	EPA-registered disinfectant and/or sterile alcohol as appropriate for use




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Spill Control




Spill Control

- All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators.
 - Spills must be contained and cleaned immediately only by qualified personnel with appropriate PPE.
 - Qualified personnel must be available at all times while HDs are being handled.
 - Signs must be available for restricting access to the spill area.
- 




Spill Control

- Spill kit containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled.
 - If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator must be available.
 - All spill materials must be disposed of as hazardous waste
- 



Spill Control

- The circumstances and management of spills must be documented.
 - Personnel who are potentially exposed during the spill or spill clean-up or who have direct skin or eye contact with HDs require immediate evaluation.
 - Non-employees exposed to an HD spill should follow entity policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.
- 



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Documentation and Standard Operating Procedures





Documentation and Standard Operating Procedures

- The entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility.
 - The SOP must be reviewed at least every 12 months by the designated person, and the review must be documented.
 - Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.
- 
-

Documentation and Standard Operating Procedures

The SOPs for handling of HDs should include:

- Hazard communication program
 - Occupational safety program
 - Designation of HD areas
 - Receipt
 - Storage
 - Compounding
 - Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs)
 - Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)
 - Deactivation, decontamination, cleaning, and disinfection
 - Dispensing
 - Transport
 - Administering
 - Environmental monitoring (e.g., wipe sampling)
 - Disposal
 - Spill control
 - Medical surveillance
-



Documentation and Standard Operating Procedures

Personnel who transport, compound, or administer HDs must document their training according to OSHA standards (see OSHA standard 1910. 120 Hazardous Waste Operations and Emergency Response) and other applicable laws and regulations





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Medical Surveillance



Medical Surveillance

- Medical surveillance is part of a comprehensive exposure control program complementing engineering control, safe work processes, and use of PPE.
 - Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.
 - The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs.
 - Medical surveillance programs involve assessment and documentation of symptoms complaints, physical findings, and laboratory values (such as blood counts) to determine whether there is a deviation from the expected norms.
- 