	SOP CODE:	USA – NS – P3.5.1.1	REVISION NUMBER: 2 . 1 . 0
	ISSUE DATE:	MONTH 00, YYYY	
	IMPLEMENTATION DATE:	MONTH 00, YYYY	
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TITLE : PROCEDURE – STORING – CHEMICALS – COMPOUNDING PRACTICES (HD)

DRAFTED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**		SIGNATURE	DATE
VERIFIED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**		SIGNATURE	DATE
APPROVED BY:	**SIGNATORY:**			
	TITLE:	**DESIGNATED PERSON**	SIGNATURE	DATE
APPROVED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**	**DESIGNATED PERSON**	SIGNATURE	DATE

COMPENDIAL APPLICABILITY OF THE USP GENERAL CHAPTER <800>

"On December 1, 2019, USP's standard on the safe handling of hazardous drugs, General Chapter <800>, became official. General Chapter <800> is informational and not compendially applicable. USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings describes practice and quality standards for handling hazardous drugs. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities. (USP Publication: Compendial Applicability of USP 800).

Please see the document titled, compendial-applicability-of-usp-800.pdf in the folder titled, 10 – Supplemental Documentation\References and Standards for additional details.

To determine the regulatory applicability of the USP General Chapter <800>, you must contact your State Board of Pharmacy.

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TITLE : PROCEDURE – STORING – CHEMICALS – COMPOUNDING PRACTICES (HD)

RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION
USA - NS - L2.1.2.0	Chemical Inventory Control Log
USA - NS - F3.5.1.0	Lost or Stolen Inventory Report
USA - NS - L3.5.1.0	Pest Control Log
USA - NS - L3.6.1.0	Environmental Monitoring Log

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE
USA – NS – P0.1.1.0	Preamble – Implementing – Standard Operating Procedures – Compounding Practices
USA – NS – P0.2.1.0	Preamble – Customizing – Standard Operating Procedures – Compounding Practices
USA – NS – P0.3.1.0	Preamble – Recording – Good Documenting Practices – Compounding Practices
USA – NS – P2.1.2.0	Property – Purchasing – Chemicals – Compounding Practices
USA – NS – P3.4.1.0	Procedure – Receiving – Chemicals – Compounding Practices
USA – NS – P3.5.1.0	Procedure – Storing – Chemicals – Compounding Practices

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	ISSUE DATE:	MONTH 00, YYYY	
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TITLE : PROCEDURE – STORING – CHEMICALS – COMPOUNDING PRACTICES (HD)

RESPONSIBILITIES

1. Designated Person oversees this SOP.
2. All compounding personnel must comply with this SOP.

PURPOSE

1. To ensure proper storage of hazardous drugs.
2. To ensure proper storage of substances for hazardous non-sterile compounding practices.

SCOPE

1. Applies to hazardous non-sterile compounding practices.
2. Applies to all hazardous substances.
3. Applies to environmental monitoring of the storage area.
4. Applies to pest control in the storage area.
5. Applies to the removal of outdated chemicals from the inventory.
6. Applies to chemical inventory reconciliation.

DEFINITIONS

1. Compounded Non-Sterile Preparation (CNSP): Compounded medication.
2. Decontamination: Includes physical removal, deactivation/neutralization of contaminants and disinfection.
3. Designated Person: One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs.
4. SDS: Safety Data Sheets

FREQUENCY

1. Record the temperature of storage areas at least daily or by a continuous monitoring device with retrievable data.
2. Calibrated, or verify for accuracy, all temperature-recording devices as recommended by the manufacturer or every 12 months, whichever is stricter.
3. Verify inventory records monthly to determine products that are soon to be outdated / expired.
4. Verify the expiry date on a bottle just prior to its use.
5. Inspect pest traps monthly, or more frequently.
6. Deactivate, decontaminate, clean and disinfect hazardous storage areas:
    1. According to the following schedule:

Site	Disinfection Frequency
Floors	Daily
Counters and easily cleanable surfaces	Daily
Shelving	Every 3 months

    2. Anytime a spill occurs.
    3. Whenever contamination (e.g., splash) is known or suspected.
7. Perform physical inventory on a quarterly basis.
8. Verify temperature mapping of the chemical storage area biannually.
9. Perform mock recall on a biannual basis.

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TITLE : PROCEDURE – STORING – CHEMICALS – COMPOUNDING PRACTICES (HD)

SPECIAL CIRCUMSTANCE

1. This SOP does not apply to Narcotics and Controlled Substances.
2. This SOP does not apply to non-hazardous substances.

PROCEDURE

This SOP is divided into the following sections:

1. General Storage Area Requirements
2. Hazardous Drug Storage Requirements
3. Qualification of Operational Parameters of Storage Area or Unit
4. Routine Environmental Monitoring of Chemical Storage Area
5. Inventory Reconciliation

1. <u>General Storage Area Requirements</u>:
    1. Restrict access to chemical storage areas to authorized personnel.
    2. Don appropriate personal protective equipment prior to handling chemical inventory.
    3. Ensure storage area has suitable and sufficient space to allow orderly storage, prevent mix-ups and cross contamination.
    4. Ensure adequate lighting in the storage area.
    5. Ensure storage area is clean.
    6. Utilize approved pest control techniques at appropriate locations in the storage area or hire a vendor qualified pest control service provider.
        a. Airborne **release of pesticides is not permitted** inside the compounding practice.
        b. Wear appropriate personal protective equipment when handling pest control articles.
        c. Remove gloves immediately after handling pest control articles and wash hands.
        d. Ensure pest control articles are not stored in controlled or classified environments, other than those strategically placed and in active use in storage areas.
        e. Report promptly any pests or evidence of pest infestation.

7. Ensure segregation of chemicals according to their chemical properties and required environmental controls; different physical areas are required for the following:

Chemical Storage		
Storage Area	**Required Identified and Physically Separated Sections**	**Minimum Storage Area Requirements**
Hazardous	Current Hazardous Chemical Inventory Strong Acids Strong Bases Quarantined Rejected Inventory Quarantined Returned Inventory Quarantined Recalled Inventory	• Negative pressure • Externally vented • 12 air changes per hour
	Flammable Chemicals	• Flammable Storage Cabinet
Antineoplastic	Current Antineoplastic Agent Chemical Inventory Quarantined Rejected Inventory Quarantined Returned Inventory Quarantined Recalled Inventory	• Negative pressure • Externally vented • 12 air changes per hour

8. Store chemicals in a manner that minimizes risk of breakage and leakage.
9. Place larger/heavy chemical containers on lower shelves and smaller/lighter chemicals containers on higher shelves.
    a. Ensure no chemical containers are stored directly on the floor.
    b. Ensure no shelved containers can be hanging over the edge of storage shelves.
10. Rotate inventory using First in / First out (FIFO) stock rotation in a manner that items with the shortest expiration are used first.
11. Verify inventory for chemicals soon to be outdated / expired.
    a. Label chemicals prominently with “short expiry”, when appropriate.
    b. Remove soon to be outdated products prior to expiry.

2. Hazardous Drug Storage Requirements:

    1. Ensure hazardous drug storage areas are clearly labeled with hazardous drug storage, warning signs.
    2. Store strong acids and strong bases in their original containers.
    3. Ensure hazardous drug outer containers are labeled with appropriate hazard symbol.
    4. Store hazardous drugs on shelves with raised lips that are at or below eye level.
    5. Make sure no hazardous substances are stored on the floor.
    6. Store NIOSH Group 1 classified hazardous drugs in a controlled (unclassified) containment secondary engineering control that is a vented negative pressure room with 0.01 and 0.03 inches of water column relative to adjacent areas and with at least 12 air changes per hour (ACPH).
        a. The storage room for NIOSH Group 1 classified hazardous drugs cannot be the same room as that used for storage of the NIOSH Group 2 and 3 classified hazardous drugs.
    7. Store NIOSH Group 2 and 3 classified hazardous drugs in a controlled (unclassified) containment secondary engineering control that is a vented negative pressure room with 0.01 and 0.03 inches of water column relative to adjacent areas and with at least 12 air changes per hour (ACPH).
        a. The storage room for NIOSH Group 2 and 3 classified hazardous drugs cannot be the same room as that used for storage of the NIOSH Group 1 classified hazardous drugs.

3. Qualification of Operational Parameters of Storage Area or Unit

    1. Consider an environmental mapping of the temperature and/or humidity on an annual basis depending upon the size of the storage unit and/or trended data from the yearly record of data.
    2. Verify environmental monitoring by using an annually certified NIST traceable thermometer as a reference to compare the accuracy of the thermometer or thermostat used for temperature recording.
    3. Verify environmental monitoring by using an annually certified NIST traceable hygrometer as a reference to compare the accuracy of the hygrometer or humidity sensor used for humidity recording.
    4. Verify environmental monitoring by performing temperature and humidity mapping studies:
        a. Measure temperature and humidity in different zones of the storage area as appropriate at various points in the 3-dimensional grid of the area or unit.
    5. Perform additional temperature and humidity measurements in consideration of:
        a. Heating, ventilation, and air conditioning equipment.
        b. Airflow inside the storage location.
        c. Windows and sun-facing walls.
        d. Storage facility structural design including low ceilings or roofs.
        e. Times of the day.
        f. Times of the week (weekdays and weekends).
        g. Seasonal differences (i.e., environment outside the compounding facility).
    6. Ensure temperature and humidity measurements are within the required acceptable range.

4. Routine Environmental Monitoring of Chemical Storage Area:

    1. Record the temperature of storage areas at least daily or by a continuous monitoring device with retrievable data.
    2. Calibrated, or verify for accuracy, all temperature-recording devices as recommended by the manufacturer or every 12 months, whichever is stricter.
    3. Monitor and maintain the temperature in storage areas / units as follows:

Controlled Storage Conditions	Temperature Range
Room Temperature	20°C to 25°C
Cold/Refrigerator	2°C to 8°C
Frozen/Freezer	-25^{o}C to -10^{o}C

    4. Monitor and maintain the humidity in storage areas / units as follows:

Controlled Storage Conditions	Relative Humidity at Room Temperature
Dry Storage	≤ 40%
ISO Class Storage Area	35% to 60%

5. Inventory Reconciliation:
    1. Compare physical inventory with inventory record.
    2. Investigate all inventory discrepancies, if applicable.
    3. Verify that chemical containers are securely closed and are undamaged.
    4. Verify that labeling of chemical containers is visible and accurate.
    5. Ensure chemical is in appropriate storage environment.
    6. Ensure all chemical documentation and SDS is current and updated.
    7. Verify expiration dates.

VERIFICATION

1. In the event of the presence of pests found in traps, take the necessary corrective action and preventive action.
2. Calibrated, or verify for accuracy, all temperature-recording and humidity-recording devices as recommended by the manufacturer or every 12 months, whichever is stricter.

CORRECTIVE ACTIONS

Corrective Actions is divided into the following sections:

1. Pest Control
2. Operational Parameters

1. Pest Control:
    1. In the event of a pest sighting, infiltration or trapping:
        a. Quarantine all products suspected of being contaminated by the pest.
        b. Remove pest from trap and discard appropriately, if applicable.
        c. Take immediate steps to trap, or get rid of the pest, if applicable.
        d. Investigate possible routes of infiltration and take appropriate corrective actions.
        e. Consider hiring an external pest control provider.
        f. Verify traps at an increased weekly frequency for 6 months.
2. Operational Parameters:
    1. In the event that controlled storage conditions are out of specifications or acceptable range:
        1. Adjust the temperature or humidity as required.
        2. Assess the need to discard or reassign expiry dates of any chemicals using scientifically sound professional judgment.
            a. Consider calculating the mean kinetic temperature for the chemicals affected by the out of specification temperature recordings to determine the effect of the temperature fluctuation on the chemical.

PREVENTIVE ACTIONS

1. Pest Control:
    1. Consider the use of Pharmacy-approved pesticides by qualified service provider on the exterior of the compounding facility.
        a. Display a notice indicating where pesticides have been applied.
        b. Restricted access to zones following application of pesticides for the manufacturer's recommended duration.
2. Operational Parameters:
    1. Consider performing the Qualification of Operational Parameters procedure.

TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Medisca United States					
Thermometer					
Temperature/Humidity Meter					
Refrigerator					

EDUCATIONAL AND SERVICE RESOURCES

AVAILABLE OFFERINGS	
LP3 Network	Medisca Network
Non-Sterile Training - Home Studies	Specialized Consultation Services
Technician Training - Home Studies	Technical Support Services (TSS)
Non-Sterile Training - Live Event	
Technician Training - Live Event	
Self-Directed Learning Modules	

SPECIFICATION DOCUMENTS

DOCUMENT NUMBER	DOCUMENT NAME	SOURCE	DESCRIPTION

	SOP CODE:	USA – NS – P3.5.1.1	REVISION NUMBER: 2 . 1 . 0
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REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION

REGULATORY COMPLIANCE GUIDELINES AND STANDARDS OF PRACTICE

REFERENCE SOURCE	REFERENCE CODE	REFERENCE DATE	SECTION CODE	SECTION DESCRIPTION
USP	659	01 AUG 15		Packaging and Storage Requirements
USP	795	01 MAY 18		Pharmaceutical Compounding – Non-Sterile Preparations
USP	1079	01 AUG 15		Good Storage and Shipping Practices
USP	800	01 DEC 19		Hazardous Drugs – Handling in the Healthcare Setting
ACHC/PCAB	TCRX3-E	2018		
ACHC/PCAB	TCRX6-C	2018		
ACHC/PCAB	HDH1-A	2018		
ACHC/PCAB	HDH5-A	2018		