	SOP CODE:	USA – NS – P3.3.1.1	REVISION NUMBER: 2 . 2 . 0
	ISSUE DATE:	MONTH 00, YYYY	
	IMPLEMENTATION DATE:	MONTH 00, YYYY	
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TITLE : PROCEDURE – SANITIZING – COMPOUNDING FACILITY – 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

This SOP contains modified procedural steps for use against SARS-CoV-2, the novel coronavirus that causes the disease COVID-19.

RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION
USA - NS - L3.3.1.0	Technology Sanitization Log
USA - NS - F3.3.1.1	Hazardous Drug Sampling
USA - NS - L3.3.1.1	Hazardous Drug Sampling

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

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RESPONSIBILITIES

1. Designated person oversees this SOP.
2. All compounding personnel can perform this SOP.

PURPOSE

1. To ensure proper deactivating, decontaminating, cleaning and disinfecting of the compounding facility and technology used for hazardous drug handling and compounding.
2. To ensure appropriate preventive steps are taken to reduce the spread of COVID-19.

SCOPE

1. Applies to non-sterile compounding.
2. Applies to hazardous drug handling and compounding.
3. Applies to the cleaning and disinfecting of all areas where chemicals are handled and compounded.
4. Applies to deactivating, decontaminating, cleaning and disinfecting of all reusable technology and electromechanical equipment used for compounding.
5. Applies to deactivating, decontaminating, cleaning and disinfecting performed using single-use decontamination supplies.

DEFINITIONS

1. Compounding Facility: The compounding area, receiving area, unpacking area and anywhere else chemicals may reside for any length of time.
2. Compounded Non-Sterile Preparation (CNSP): A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk substance.
3. Deactivation: Treatment of a hazardous substance with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent.
4. Decontamination: Includes physical removal, deactivation/neutralization of contaminants and disinfection.
5. 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.
6. Disinfection: A chemical or physical procedure that destroys or removes vegetative forms of harmful microorganisms when applied to a surface but not necessarily highly resistant spores.

7. Sanitization: The deactivating, decontaminating, cleaning and disinfecting requirements in hazardous drug handling and compounding.

FREQUENCY

1. Anytime a spill occurs.
2. Whenever contamination is known, suspected or as a preventive step to reduce the spread of COVID-19.
3. When work surfaces are visibly soiled.
4. According to the following schedule or to reduce the spread of COVID-19.

Site	Disinfection Frequency
Direct compounding area (DCA), including the DCA of the primary engineering control	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination is known or suspected Clean and sanitize the work surfaces between compounding CNSPs with different components
Counters and work surfaces	Daily on days when compounding occurs, after spills, and when surface contamination is known or suspected
Floors	Daily on days when compounding occurs, after spills, and when surface contamination is known or suspected
Door knobs	Daily on days when compounding occurs
Containment Ventilated Enclosure	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination is known or suspected Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components
Biological Safety Cabinets	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination is known or suspected Clean and sanitize the horizontal work surface of the BSC between compounding CNSPs with different components Clean and sanitize under the work surface at least monthly
Scrub sink	Before being used for hand hygiene or before being used to clean any equipment used in non-sterile compounding
Carts, storage baskets and waste receptacles	Weekly
Ceilings	When visibly soiled and when surface contamination is known or suspected
Doors	Monthly
Walls	Every 3 months, after spills, and when surface contamination is known or suspected
Shelving and storage units	Every 3 months, after spills, and when surface contamination is known or suspected
Technology	Before and after each use, after spills, and when surface contamination (e.g., splashes) is known or suspected
Reusable devices and glassware	Prior to and after use

5. Perform surface sample hazardous drug contamination assays:
    1. Initially as a benchmark.
    2. After a hazardous spill.
    3. Every six (6) months, or more frequently.

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SPECIAL CIRCUMSTANCE

1. This SOP does not address chemical spill handling and cleaning.
2. This SOP does not address donning of personal protective equipment.

PROCEDURE

This SOP is divided into the following sections:

1. Selection of Deactivating Agents
2. Selection of Disinfecting Agents
3. General Decontaminating and Disinfecting Procedures
4. Surface Decontamination and Disinfection
5. Technology Decontamination and Disinfection
6. Reusable and Disposable Device Deactivation, Decontamination, Cleaning and Disinfection

1. Selection of Deactivating Agents:
    1. Ensure the deactivation agent is compatible with applicable technologies and surfaces.
    2. Ensure the deactivation agents are not corrosive to applicable surfaces at the working concentration.
    3. Ensure that the deactivation agent is a registered oxidizer with the Environmental Protection Agency (EPA) or equivalent.
    4. Ensure the deactivation agent will effectively inactivate the specific hazardous substances through evaluation of manufacturer data, literature or safety data sheets.
        a. Select commercially available multi-component chemical deactivation systems that provide more than one chemical degradation mechanism, whenever possible or; consider using a minimum 2% sodium hypochlorite (bleach) solution with purified water.
2. Selection of Disinfecting Agents:
    1. Refer to the Environmental Protection Agency (EPA) for updated information on disinfecting agents.

        https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2
    2. Ensure that the disinfectant is registered with the Environmental Protection Agency (EPA) or equivalent.
    3. Select disinfectants registered as a one-step process, whenever possible.
        a. Obtain appropriate cleaning solution with detergent if the disinfectant is not registered as a one-step solution.

4. Ensure the disinfectant is compatible with applicable surfaces and technologies.
5. Ensure that the disinfectant is not corrosive to applicable surfaces at the working concentration.
6. Select a broad-spectrum disinfectant that is known to result in a comprehensive lethality against various classes of bacteria and microorganisms, particularly for use against SARS-CoV-2, the novel coronavirus that causes the disease COVID-19.
7. Select disinfectants based on microbicidal activity, inactivation by organic matter and shelf life.
8. Select and rotate disinfectants with a different mechanism of action.

3. General Decontaminating and Disinfecting Procedures:
    1. Don appropriate personal protective equipment.
    2. Maintain normal airflow operation of the room and/or airflow workstation during decontamination or disinfection procedures.
    3. Apply required agent type to disposable mops or wipes or utilize pre-moistened wipes; do not apply directly to a surface or technology.
    4. Apply to surfaces in order of cleanest to dirtiest.
    5. Wipe in direction away from personnel, whenever possible.
    6. Wipe in one direction with overlapping strokes; never clean in circular motions.
    7. Use a clean surface of the wipe for every stroke.
4. Surface Decontamination and Disinfection:
    1. Start decontaminating from the side of the room furthest away from the entrance, working your way towards the entrance to finish.
    2. Remove items from surfaces (e.g., shelving units) before performing decontamination.
        a. If there is an incompatibility between the deactivating agent and the surface, then wipe items with 70% isopropyl alcohol prior to application.
    3. Wipe surfaces with the deactivating agent.
    4. Remove the deactivating agent and the inactivated drug residue from all surfaces with purified water after the specified dwell time.
    5. Wipe all surfaces with isopropyl alcohol.
    6. Allow surfaces to dry.
    7. Discard deactivation materials appropriately.

8. Return to the side of the room furthest from the entrance and finish with the entrance when performing cleaning and disinfecting of all sites in the environment.
9. Clean surfaces with detergent, if the disinfectant is not registered as a one-step disinfectant.
    a. Ensure the disinfectant is appropriate for use against SARS-CoV-2, the novel coronavirus that causes the disease COVID-19.
    b. Remove detergent with purified water after the specified dwell time.
10. Allow surfaces to dry.
11. Wipe surfaces with the disinfectant.
12. Remove the disinfectant from all surfaces after the specified dwell time.
13. Allow surfaces to dry.
14. Replace removed items.
15. Discard cleaning and disinfection materials as biohazard waste.

5. Technology Decontamination and Disinfection:
    1. Unplug electrical equipment.
    2. Wipe all compatible interior and exterior surfaces of the technology with the deactivation agent.
    3. Remove the deactivation agent and the inactivated drug residue from all surfaces of the technology with purified water after the specified dwell time.
    4. Wipe all surfaces of the technology with isopropyl alcohol.
    5. Allow surfaces to dry.
    6. Discard wipes appropriately when all surfaces have been used.
    7. Clean the technology with detergent, if disinfectant is not registered as a one-step disinfectant.
        a. Remove detergent from all surfaces of the technology with purified water after the specified dwell time.
    8. Allow surfaces to dry.
    9. Wipe all compatible interior and exterior surfaces of the technology with the disinfectant.
    10. Remove disinfectant from all surfaces of the technology after the specified dwell time with isopropyl alcohol.
    11. Discard wipes appropriately as biohazard waste when all surfaces have been used.
    12. Allow surfaces of the technology to dry before use.

5. Reusable and Disposable Device Deactivation, Decontamination, Cleaning and Disinfection

    1. Don regular gloves, and then don gloves used for chemical spills.
    2. Remove noticeable chemical debris from the glass using disposable wipes.
    3. Discard the wipes in the appropriate waste receptacle (i.e., non-hazardous versus hazardous waste receptacle).
    4. Deactivate and decontaminate glassware used during hazardous drug compounding using appropriate chemical agents.
    5. Rinse glassware containing water-soluble residue in hot water.
    6. Wipe glassware containing water-insoluble residue with disposable wipes.
    7. Wash with low-residue detergents if glassware is exposed to non-water soluble substances.
    8. Wipe glassware with alcohol and a disposable wipe.
    9. Wash thoroughly with detergent and hot water.
    10. Wash thoroughly with hot water.
    11. Rinse with purified water, USP.
    12. Discard inner gloves, and then wash hands thoroughly for at least 20-30 seconds with soap and warm water.
    13. Dry in a drain rack.
    14. Inspect for broken or chipped glass.
    15. Label/Identify as ready for non-sterile use.
    16. Return items to their appropriate storage areas.

VERIFICATION

1. Ensure through manufacturer data or literature that disinfectants have been validated to kill 99.9% of microorganisms within the specified disinfectant dwell time and at the working concentration.
    1. Ensure selection of the disinfectant appropriate for use against SARS-CoV-2, the novel coronavirus that causes the disease COVID-19.
2. Perform surface sample hazardous drug contamination assays to verify hazardous drug decontamination procedures.
    1. Select commercially available drug specific assay kits based on the hazardous drugs used in the compounding practice.
    2. Select surface sampling locations and their testing frequency using a risk-based approach.
    3. Swab or wipe selected sites as per kit instructions.
    4. Assess results as per kit instructions.

CORRECTIVE ACTIONS

1. In the event that the surface contamination assay is out of specification:
    1. Decontaminate immediately.
    2. Determine the root cause and consider the following corrective measures:
        a. Increase the frequency of decontamination.
        b. Assess the effectiveness of the deactivation agents used.
        c. Evaluate the effectiveness of hazardous drug handling techniques.
        d. Evaluate the effectiveness of closed system transfer devices.
        e. Assess the effectiveness of primary and secondary engineering controls.
        f. Perform additional personnel training on decontamination procedures.

PREVENTIVE ACTIONS

1. Not applicable.

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TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Medisca Equipment & Devices					

EDUCATIONAL AND SERVICE RESOURCES

AVAILABLE OFFERINGS	
LP3 Network	Medisca Compounding Services
Non-Sterile Training - Home Studies	Medisca Formulation Support
Technician Training - Home Studies	Medisca Specialized Consultations
Non-Sterile Training - Live Event	
Technician Training - Live Event	
Non-Sterile Training - Practical Lab	
Hazardous Drug Compounding - Live Event	
Self-Directed Learning Modules	

SPECIFICATION DOCUMENTS

DOCUMENT NUMBER	DOCUMENT NAME	SOURCE	DESCRIPTION

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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	795	01 MAY 18		Pharmaceutical Compounding – Nonsterile Preparations
USP	1072	01 AUG 15		Disinfectants and Antiseptics
USP	800	01 DEC 19		Hazardous Drugs – Handling in Healthcare Settings
OTM	VI	20 JAN 99	2	Controlling Occupational Exposure to Hazardous Drugs
EPA[1]				List N: Disinfectants for Use Against SARS-CoV-2
ACHC/PCAB	TCRX3-E	2018		
ACHC/PCAB	TCRX6-A	2018		
ACHC/PCAB	TCRX6-E	2018		
ACHC/PCAB	HDH11-A	2018		
ACHC/PCAB	HDH12-A	2018		

[1] https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2