

Standard Operating Procedure

	SOP CODE:	USA – NS – P3.3.1.0	REVISION NUMBER: 2 . 1 . 0
	ISSUE DATE:	MONTH 00, YYYY	
	IMPLEMENTATION DATE:	MONTH 00, YYYY	
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TITLE : PROCEDURE – SANITIZING – COMPOUNDING FACILITY – COMPOUNDING PRACTICES

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VERIFIED BY: <input type="text"/> n/a	SIGNATORY: TITLE:	_____ SIGNATURE	_____ DATE
APPROVED BY:	SIGNATORY: TITLE: DESIGNATED PERSON	_____ SIGNATURE	_____ DATE
APPROVED BY: <input type="text"/> n/a	SIGNATORY: 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.

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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RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION
USA - NS - L3.3.1.0	Technology Sanitization 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

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RESPONSIBILITIES

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

PURPOSE

1. To ensure proper cleaning and disinfecting of the compounding facility and technology used for this purpose for non-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 non-hazardous drug handling and compounding.
3. Applies to the cleaning and disinfecting of all areas where chemicals are handled and compounded.
4. Applies to the cleaning and disinfecting of all reusable technology and electromechanical equipment used for compounding.
5. Applies to all reusable devices and glassware used in non-sterile compounding.
6. Applies to cleaning and disinfecting performed using single-use disinfection 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): Compounded medication.
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. Disinfectant: A chemical or physical agent that destroys or removes vegetative forms of harmful microorganisms when applied to a surface but not necessarily highly resistant spores.
5. Sanitization: The cleaning and disinfecting requirements in non-hazardous drug handling and compounding.
6. Specified Dwell Time: The length of time required for a disinfecting agent to dwell on a surface in order to kill 99.9% of microorganisms.

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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:

Site	Disinfection Frequency
Direct compounding area (DCA), including the DCA of the primary engineering control	At the beginning and end of each shift, after spills, and when surface contamination is known or suspected or to reduce the spread of COVID-19 Clean and sanitize the work surfaces between the compounding of each CNSP
Counters and easily accessible work surfaces	Daily, after spills, and between the compounding of each CNSP
Floors	Daily, after spills, and when surface contamination (e.g., splashes) is known or suspected or to reduce the spread of COVID-19
Door knobs and handles	Frequently during a work shift
Primary Engineering Control glass panels	At least twice daily; at start and middle of shift
Scrub sink; includes faucet	Before being used for hand hygiene or before being used to clean any equipment used in non-sterile compounding
Carts; includes casters, wheels and hand bar	At least twice daily; at start and middle of shift
Storage baskets; includes handles	At least twice daily; at start and middle of shift
Waste receptacles lined with appropriately fitted garbage bag.	At least twice daily; at start and middle of shift
Ceilings	When visibly soiled and when surface contamination is known or suspected
Doors	Daily
Walls	Daily , after spills, and when surface contamination (e.g., splashes) is known or suspected or to reduce the spread of COVID-19
Shelving and storage units	Daily , after spills, and when surface contamination (e.g., splashes) is known or suspected or to reduce the spread of COVID-19
Technology (e.g., electromechanical)	Before and after each use, after spills, and when surface contamination (e.g., splashes) is known or suspected or to reduce the spread of COVID-19
Reusable devices and glassware	Prior to and after each use
Under the work tray of the Primary Engineering Control	Daily
Tables, hard-backed chairs, doorknobs, light switches, remotes, handles, desks, toilets, sinks)	Daily

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SPECIAL CIRCUMSTANCE

1. This SOP does not address deactivation procedures for hazardous drugs.
2. This SOP does not address chemical spill handling and cleaning.
3. This SOP does not address donning of personal protective equipment.

PROCEDURE

This SOP is divided into the following sections:

1. Selection of Disinfecting Agents
2. General Disinfecting Procedures
3. Surface Disinfection
4. Technology Disinfection
5. Reusable and Disposable Device Cleaning and Disinfection

1. 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 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.

2. General Disinfection Procedures:

1. Don appropriate personal protective equipment.
2. Maintain normal airflow operation of the room and/or workstation during disinfection.

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3. Apply disinfection agents to disposable mops or wipes or utilize pre-moistened wipes; do not apply directly to a surface or technology.
4. Disinfect 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.

3. Surface Disinfection:

1. When performing monthly cleaning of all sites in the environment, start disinfecting furthest away from the entrance, working your way towards the entrance to finish.
2. Remove items from containers and storage shelves before performing disinfection.
 - a. Wipe items with purified water followed by 70% isopropyl alcohol.
3. 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 following the specified dwell time.
4. Allow surfaces to dry.
5. Remove disinfectant from all surfaces after the specified dwell time.
6. Allow surfaces to dry.
7. Replace removed items.
8. **Discard cleaning and disinfection materials as biohazard waste.**

4. Technology Disinfection:

1. Unplug electrical equipment.
2. 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.
3. Allow surfaces to dry.
4. Wipe all compatible interior and exterior surfaces of the technology with the disinfectant.
5. Remove disinfectant from all surfaces of the technology after the specified dwell time.
6. **Discard wipes appropriately as biohazard waste when all surfaces have been used.**

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7. Allow surfaces of the technology to dry before use.

5. Reusable and Disposable Device Cleaning and Disinfection

1. Washing by Hand:

- a. Don regular gloves, and then don gloves used for chemical spills.
- b. Soak and brush item in hot water and appropriate detergent to remove any large quantities of chemical residue, if necessary.
- c. Properly dispose of chemical residue using proper waste management.
- d. Rinse thoroughly with purified water.
- e. Allow to dry.

2. Machine Washing:

- a. Ensure reusable devices are heat-resistant before washing in dishwasher.
- b. Soak item in hot water and appropriate detergent to remove any large quantities of chemical residue, if necessary.
- c. Properly dispose of chemical residue using proper waste management
- d. Run machine cycle with appropriate detergent.
- e. Remove items from washing machine.
- f. Rinse item thoroughly with purified water.
- g. Allow to dry.
- h. Run machine cycle with an appropriate detergent empty to sanitize the inside of the washing machine
 - i. Hot water cycles

3. Discard inner gloves, and then wash hands thoroughly for at least 20-30 seconds with soap and warm water.

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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. Ensure that microorganisms used to test the efficacy of disinfectants include *Staphylococcus aureus*, *Escherichia coli*, *Bacilli subtilis*, *Candida albicans*, *Apergillus niger*, and *Mycobacterium tuberculosis* (or similar).
2. If hand washing does not properly clean the reusable device or glassware, rewash and consider changing specific detergents or brush/sponges used.
3. If dishwasher does not properly clean the reusable device or glassware, ensure the dishwasher is working properly and effective detergent suitable for the machine is being used.

CORRECTIVE ACTIONS

1. Not applicable.

PREVENTIVE ACTIONS

1. Not applicable.

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TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Medisca United States					
Wipes					
Isopropyl Alcohol 70%					

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

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REVISION HISTORY

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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	TCRX6-E	2018		

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