1. **Purpose**
	1. The purpose of this SOP is to establish minimum safety standards and requirements environmental and safety controls used in non-sterile HD compounding
2. **Responsibility**
	1. It is the responsibility of the Designated Person to ensure this procedure meets local, state, and federal regulations as required
	2. It is the responsibility of the Designated Person to ensure all staff who engage in or oversee non-sterile compounding activities are trained on and adhere to this SOP
3. **Scope**
	1. This SOP applies to all personnel who engage in or oversee non-sterile compounding activities
4. **References**
	1. USP General Chapter <800> – *Hazardous Drugs – Handling in Healthcare Settings*, published in the May 31, 2019 USP Committee Revision Bulletin
5. **Acronyms & Definitions**
	1. BSC – Biological Safety Cabinet – a ventilated cabinet often used for preparation of hazardous drugs. These cabinets are divided into three general classes (Class I, Class II, and Class III)
	2. CACI – Compounding Aseptic Containment Isolator – a specific type of CAI that is designed for the compounding of sterile HDs. The CACI is designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment with unidirectional airflow for compounding sterile preparations
	3. C-PEC – Containment Primary Engineering Control - a ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants
	4. C-SEC – Containment Secondary Engineering Control - a with fixed walls in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room
	5. CVE – Containment Ventilated Enclosure – a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment
	6. HD – Hazardous Drugs - The National Institute for Occupations Safety and Health (NIOSH) considers a drug to be hazardous if it exhibits one or more of the following properties in humans or animals; carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or structure and toxicity profiles of new drugs that mimic existing hazardous drugs
	7. USP – United States Pharmacopeia
	8. Designated Person – A trained and qualified person designated by [company] to be responsible for developing and implementing appropriate HD procedures, overseeing entity compliance with local, state and federal HD regulations, ensuring personnel HD competency, and ensuring environmental control of HD storage and handling areas
6. **Frequency**
	1. This procedure must be followed for all non-sterile HD compounding activities performed at [company]
7. **General Information**
	1. In addition to the USP <800> standards for HD, all non-sterile HD compounding activities must be performed in compliance with USP <795> *Pharmaceutical Compounding – Nonsterile Preparations*
	2. Signage must be displayed outside of non-sterile HD compounding C-SEC declaring presence of HD
	3. Access to non-sterile HD compounding C-SEC must be limited to authorized, trained individuals
8. **Procedure**
	1. Non-sterile HD compounding must occur in an appropriate C-PEC within a C-SEC
		1. Note: C-PEC is not required if manipulations are limited to dispensing only activities of final dosage forms (i.e. counting and repacking) that do not result in particle, aerosol, or gas production
	2. C-PEC Requirements
		1. C-PEC used for non-sterile HD compounding must be externally vented (preferred) or have redundant HEPA filters, in series.
			1. Appropriate C-PECs for non-sterile HD compounding include CVEs, Class I or Class II BSC and CACIs
				1. Best practice: 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 daily compounding activities
			2. C-PEC must operate continuously if it is used to supply some or all of the negative pressure
			3. In the event of a power failure or other disruptions to power, non-sterile compounding activities in C-PEC must be stopped, power restored, the C-PEC must be allowed to run for the manufacturer’s stated recovery time. The C-PEC must be deactivated, decontaminated, and cleaned prior to resuming compounding activities in that C-PEC
		2. C-PECs shall be operated and maintained in accordance with manufacturer specification
	3. C-SEC Requirements
		1. A non-sterile HD compounding room must:
			1. Be physically separated (i.e. walls) from other preparation areas
			2. Be externally vented
			3. Maintain between -0.01 and -0.03 negative pressure relative to adjacent areas
			4. Maintain greater than or equal to 12 ACPH
		2. All surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the non-sterile compounding HD C-SEC must be smooth, impervious, free from cracks and crevices, and non-shedding
		3. Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs
		4. All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned
		5. Disposable equipment and devices must be single use and must be disposed of in appropriate HD waste receptacles. HD waste disposal must occur in compliance will all local, state, and federal regulations
	4. Appropriate PPE must be worn during all non-sterile HD compounding activities
		1. Refer to SOP XX.XX Hazardous Drugs; Hand Hygiene & Personal Protective Equipment
9. **Training Requirements**
	1. Personnel must be trained on this procedure:
		1. Prior to non-sterile HD compounding,
		2. Every 12 months,
		3. Each time there is a significant change to this procedure,
		4. In response to an accidental exposure of HD during non-sterile HD compounding activities that resulted in documented changes in employee health, and
		5. Any other time deemed necessary by the Designated Person
10. **Attachments**
	1. N/A
11. **History**

|  |
| --- |
| SOP: *XX.XX:* - Hazardous Drugs; Non-Sterile Compounding Revision History |
| Date Approved | Version Number | Revision Summary |
| XX/XX/XXXX | 1 | N/A – Origination  |
|  |  |  |