1. **Purpose**
	1. The purpose of this SOP is to establish minimum safety standards and requirements for the receipt of Hazardous Drugs (HD)
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 that receive HD are trained on and compliant with this SOP
3. **Scope**
	1. This SOP applies to all personnel who receive HD
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. API – Active Pharmaceutical Ingredient - Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body
	2. C-PEC - A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants
	3. 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
	4. USP – United States Pharmacopeia
	5. Designated Person – A trained and qualified person designated by NAME OF 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 each time a HD is received
7. **General Information**
	1. HD must be unpacked (i.e. removed from external shipping containers) in an area that is neutral or negative pressure relative to the surrounding areas
	2. HD must not be unpacked from shipping package/ containers in sterile compounding areas or positive pressure areas
	3. At least 1 pair of ASTM D6978 (or its predecessor) chemotherapy gloves must be worn when unpacking HD from their shipping package/ containers
	4. A HD spill kit must be accessible to the HD receiving area
8. **Procedure**
	1. [company name] utilizes a tiered approach to receiving antineoplastic HD or HD API
		1. Don at least 1 pair of ASTM D6978 (or its predecessor) chemotherapy gloves.
		2. Perform visual inspection of exterior of shipping package/ containers.
		3. *Tier 1:*
			1. If no damage evident, unpack HD in a designated receiving area of neutral or negative pressure
			2. Immediately transfer unpacked HD into negative pressure storage area
		4. *Tier 2:*
			1. If the shipping package/ container appears damaged, attempt to contact and return the damaged package/ container to the supplier **without** opening it
				1. Seal damaged package/ container in an impervious container and contact supplier; label container as “hazardous”
				2. Establish return process with supplier
				3. Store sealed, damaged package/ container in a designated negative pressure area until time of return to supplier

If supplier will not accept return of damaged package, dispose of damaged package/ container in HD waste

* + 1. *Tier 3:*
			1. If the shipping package/ container appears damaged, but must be opened
				1. Seal damaged package/ container in a plastic or impervious container and transfer into negative pressure storage area or C-PEC

Best practice – C-PEC

* + - * 1. Open the package/ container and remove undamaged contents
				2. Wipe surfaces of undamaged contents with disposable wipe
				3. Reseal damaged package/ container in an impervious container and contact supplier; label container as “hazardous”
				4. Establish return process with supplier for return

Store sealed, damaged package/ container in a designated negative pressure area until time of return to supplier

If supplier will not accept return of damaged package/ container, dispose of damaged package/ container in HD waste

* + 1. Damaged shipping package/ containers must be considered spills. Report receipt of a damaged package/ container to the Designated Person.
		2. Deactivate, decontaminate, and clean negative pressure area where damaged packaged/ containers were opened in accordance with company policy and procedure
1. **Training Requirements**
	1. Personnel must be trained on this procedure:
		1. prior to receiving HD,
		2. every 12 months,
		3. each time there is a significant change to this procedure,
		4. in response to an accidental exposure of HD leading to changes in employee health, and
		5. any other time deemed necessary by the designated person
2. **Attachments**
	1. N/A
3. **History**

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