1. **Purpose** 
   1. The purpose of this SOP is to establish minimum safety standards and requirements for storage of Hazardous Drugs (HD) used in non-sterile 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 that receive HD are trained on and adhere to this SOP
3. **Scope** 
   1. This SOP applies to all personnel who access non-sterile compounding HD storage areas
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. 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
   2. USP – United States Pharmacopeia
   3. 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
   4. ACPH – air changes per hour – frequency at which air volume in a designated space or room is cycled per hour
6. **Frequency** 
   1. This procedure must be followed for all HD stored at [company]
7. **General Information**
   1. Signage must be displayed declaring HD present in all storage areas
   2. Non-sterile and sterile HD may be stored together, but non-sterile HD cannot be stored in a sterile compounding environment.
   3. Access to HD storage area must be limited to authorized, trained individuals
8. **Procedure** 
   1. Antineoplastic HD requiring manipulation outside of counting and repacking and all HD API used in non-sterile compounding must be stored separate from non-HD.
   2. Once unpacked from shipping package/ containers, these HDs must be immediately transferred to and stored into a designated, externally vented room with at least 12 ACPH -0.01 to -0.03 negative pressure relative to the surrounding areas
      * 1. Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory for dispensing, if permitted and documented by entity policy
   3. Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the HD storage area must be smooth, impervious, free from cracks and crevices, and non-shedding
   4. HD cannot be stored on the floor
   5. Storage shelving units and cabinet shelves/ bays should be equipped with safety features such as raised front/ side edges to prevent falling and breakage of HD containers
   6. If a refrigerator is required for HD storage, it must be designated for HD and stored within the negative pressure HD storage room
   7. Appropriate PPE, including but not limited to chemotherapy gloves must be worn when handing HD in storage areas
9. **Training Requirements** 
   1. Personnel must be trained on this procedure:
      1. Prior to accessing HD storage area,
      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 access to storage 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**

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