1. **Purpose** 
   1. The purpose of this SOP is to establish minimum safety standards and requirements for storage 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 adhere to this SOP
3. **Scope** 
   1. This SOP applies to all personnel who access 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 where HDs are stored
   2. Access to HD storage area must be limited to authorized, trained individuals
8. **Procedure** 
   1. Each bottle/ box/ container of HD must be clearly labeled as hazardous
   2. Final dosage forms of antineoplastic HD, non-antineoplastic and reproductive only HD that do not require handing outside of counting, repackaging and labeling may be stored with other non-HD inventory for dispensing, if permitted and documented by entity policy
      1. Perform and document risk assessment
   3. Surfaces of fixtures, shelving, counters, and cabinets of areas where HD are stored should be smooth, impervious, free from cracks and crevices, and non-shedding
   4. 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
   5. HD cannot be stored on the floor
   6. 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:* - RETAIL - Hazardous Drugs; Storage Revision History | | |
| Date Approved | Version Number | Revision Summary |
| XX/XX/XXXX | 1 | N/A – Origination |
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