1. **Purpose** 
   1. The purpose of this SOP is to establish minimum safety standards and requirements for use of PPE during handling 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 handle HD trained on and adhere to this SOP
3. **Scope** 
   1. This SOP applies to all personnel who handle 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. Handling – includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile HD products and preparations
   2. 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
   3. PPE – Personal Protective Equipment – items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures
   4. USP – United States Pharmacopeia
   5. 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. Appropriate PPE must be worn at all times when handling HD at [company]
7. **General Information**
   1. Each entity is responsible for determining what PPE must be worn by personnel handling HD during:
      1. Receipt
      2. Storage
      3. Transport
      4. Compounding; N/A – not performed at this location
      5. Administration
      6. Deactivation, decontamination, cleaning, and disinfection (if applicable)
      7. Spill control
      8. Waste disposal
   2. Determining what PPE should be worn and during which handling activities should include a risk assessment for occupational exposure to HD handled by the entity
   3. Disposable PPE must be disposed of after each use
   4. Reusable PPE must be decontaminated after each use
   5. Types of PPE
      1. Gloves
         1. Gloves must be:
            1. Inspected for holes, rips, or tears before each use
            2. Powder free
         2. When required to be worn, chemotherapy gloves must be ASTM D6978 (or its successor) rated
      2. Gowns
         1. Gowns must:
            1. Be disposable
            2. Close in the back (i.e. no front buttons, zippers, etc.)
            3. Be long sleeved with closed, elastic or knit cuffs
            4. Shown to be resistant to HD permeability
         2. Gowns must be changed:
            1. Every 2-3 hours or in accordance with manufacturer’s information for HD permeation
            2. Immediately after splash or spill
         3. Gowns worn in HD handling areas may not be worn outside of HD handling areas
         4. Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs and cannot be used in place of gowns
      3. Head, hair (including beard and moustache), shoe, and sleeve covers
         1. All must be disposable, for single use only
         2. Items coated with polyethylene coated polypropylene or other laminate materials provide greater protection than uncoated materials
      4. Eye and face protection
         1. Goggles must be used when eye protection is required
            1. Eyeglasses alone or safety glasses with side shields do not protect the eyes adequately from splashes
            2. Face shields alone do not provide full eye and face protection
            3. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes
      5. Respiratory protection
         1. Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required.
         2. Appropriate respiratory protection may include:
            1. An elastomeric half mask with multi-gas cartridge and P100 filters
            2. A surgical N95 or better respirator

Respirators must be fit tested

* + - * 1. A Full-face piece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR)

1. **Procedure** 
   1. **PPE for Receipt of HD**
      1. Chemotherapy gloves must be worn when receiving HD
      2. If a shipping package / container appears to be damaged, respiratory protection should be worn if the shipping package / container is suspected or known to contain a HD and must be opened
   2. **PPE for Accessing HD Storage areas**
      1. Chemotherapy gloves should be worn when accessing HD storage areas/ containers
   3. **PPE for Transporting HD**
      1. Chemotherapy gloves should be worn when transporting HD
   4. **Handling (counting & repackaging) of HD**
      1. Chemotherapy gloves should be worn when handling HD
   5. **PPE for Non-Sterile Compounding with HD**
      * 1. N/A; non-sterile HD compounding not performed at this location
   6. **PPE for Administration of HD**
      1. Two pairs of chemotherapy gloves must be worn when administering HD
      2. Additional protection may be required if there is risk of splash or spill or inhalation of HD
   7. **PPE for Deactivation, Decontamination, Cleaning, and Disinfection (if applicable) of HD**
      1. PPE worn during deactivation, decontamination, cleaning, and disinfection (DDCD) (if applicable) of HD must be shown to resist permeation to HD and to agents used
      2. PPE that must be worn for DDCD:
         1. Two pairs of chemotherapy gloves
      3. Depending on the scope of the DDCD being performed, additional PPE that may be worn includes:
         1. Eye and face protection
         2. Respiratory protection
   8. **PPE for HD Spill Control** 
      1. PPE for cleaning spills may vary depending on the type and severity of the spills.
      2. For spills larger than what a spill kit can contain, additional precautions may need to be taken
      3. PPE for spill control may include:
      4. Respiratory protection
         1. N95 or better NIOSH certified respirators
         2. Elastomeric half masks with P100 cartridges
         3. Full face piece with chemical cartridge respirators
      5. Eye and face protection
      6. Two pairs of chemotherapy gloves (required)
      7. Impermeable gown with back closure and long sleeves
      8. Head, hair, shoe and sleeve covers
   9. **PPE for HD Waste Disposal** 
      1. PPE for waste disposal must include:
         1. Chemotherapy gloves
   10. **Hand Hygiene** 
       1. Hand hygiene must be performed immediately after handling HD and removing chemotherapy gloves
   11. **Disposal and Decontamination of PPE**
       1. All used PPE must be assumed to be contaminated
       2. Disposable PPE must be disposed of in HD waste after each use and cannot be reused
       3. Reusable PPE must be properly decontaminated after each use
2. **Training Requirements** 
   1. Personnel must be trained on this procedure:
      1. Prior to handling 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 related to PPE that resulted in documented changes in employee health, and
      5. Any other time deemed necessary by the Designated Person
3. **Attachments** 
   1. N/A
4. **History**

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| SOP: *XX.XX:* - RETAIL - Hazardous Drugs; Hand Hygiene & Personal Protective Equipment Revision History | | |
| Date Approved | Version Number | Revision Summary |
| XX/XX/XXXX | 1 | N/A – Origination |
|  |  |  |