1. **Purpose** 
   1. The purpose of this SOP is to establish minimum safety and quality standards for safe handling of hazardous drugs (HD) at [company]
   2. The purpose of this SOP is also to document that compounding with HD is not permitted at this location
2. **Responsibility** 
   1. It is the responsibility of the Designated Person to ensure that all HD handling meets local, state, and federal regulations as required
   2. It is the responsibility of the Designated Person to ensure that all staff are trained on this SOP and that all staff are aware that we do not engage HD compounding
3. **Scope** 
   1. This SOP applies to all personnel dispensing HD at [company]
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. 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
   2. 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
   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 [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 handled for dispensing purposes
   2. This procedure must be followed for each request for a HD compound received by [company]
7. **General Information**
   1. According to USP <800>, HD compounding requires engineering controls, such as C-PECs and C-SECs, not available at [company]. Therefore, HD compounding is not permitted at this location.
8. **Procedure** 
   1. Dispensing
      1. Handling of HD for the purpose of dispensation is limited to activities, such as counting and repackaging of commercially manufactured products that do not require addition manipulation (such as crushing, mixing, or opening capsules) prior to dispensing
      2. Appropriate PPE must be worn during all dispensing activities
         1. Refer to SOP XX.XX Hazardous Drugs; Hand Hygiene & Personal Protective Equipment
      3. Automated counting/ dispensing devices (such as Kirby Lester, Rx Count, Pixus Machines, etc.) are prohibited for HD counting/ dispensing
      4. Disposable or clean equipment for HD dispensing (such as counting trays and spatulas) should be dedicated for use with HDs.
         1. Non-HD counting / repackaging may not occur on equipment designated for HD use unless they are labeled and treated as HD
      5. All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned
      6. Disposable equipment and devices must be single use and must be disposed of in appropriate HD waste receptacles.
      7. All HD waste must be disposed of in accordance with local, state, and federal laws
   2. HD compounding
      1. If a request for a HD compound is received, we will politely inform the patient/ patient care representative that we are unable to prepare the medication for them
      2. We may help the patient find an alternative pharmacy to use for their HD compounding needs
      3. Check PCAB website for list of local and national PCAB accredited non-sterile and/ or sterile compounding pharmacies
9. **Training Requirements** 
   1. Personnel must be trained on this procedure:
      1. Prior to dispensing 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 during dispensing 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**

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| SOP: *XX.XX:* - RETAIL – Hazardous Drug Dispensing Revision History | | |
| Date Approved | Version Number | Revision Summary |
| XX/XX/XXXX | 1 | N/A – Origination |
|  |  |  |