November 2019
Longueuil, CANADA

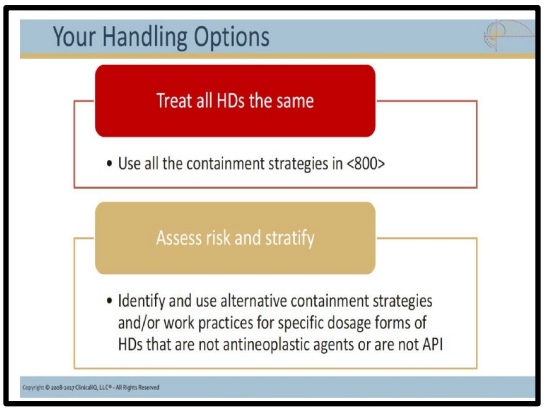
Memo re: SynMed® and USP<800>

There has been much concern as to the impact of USP General Chapter <800> (USP <800>) on the use of pharmacy automation, such as SynMed®. Specifically, Section 12 states that "*Tablet and capsule forms of antineoplastic hazardous drugs (HD) must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.*"

The need to help ensure a quality environment and to protect healthcare personnel from hazardous drugs has been a topic of concern for decades. While NIOSH defines criteria and identifies hazardous drugs, USP developed standards for handling these HD to minimize the risk to public health. The goals of these standards are to help increase awareness, provide uniform guidance to reduce the risk of managing HD, and help reduce the risk posed to patients and the healthcare workforce.

USP<800> officially goes into effect December 1, 2019, and while the standard articulated in <800> *is only required in the context of compounding*, it is a science-based standard that can be utilized in healthcare settings beyond compounding at the discretion of regulatory authorities and other oversight organizations with jurisdiction over these settings. Accordingly, state agencies (e.g. State Boards of Pharmacy), other regulators (e.g. Occupational Safety and Health Administration), and oversight organizations (e.g. The Joint Commission) may make their own determinations regarding the applicability and enforceability of <800> for entities within their jurisdiction.

For all NIOSH classified HDs, each Pharmacy is expected to perform a risk assessment on each medication, to categorize them, and to establish their handling strategy for hazardous drugs.



For assistance with the risk assessment process, please see the sample Assessment of Risk Template in ***Appendix I***, as provided by the National Community Pharmacists Association (NCPA).

SynMed® technical support team: **1 866 764 7966, ext. 1** / support@synmedrx.com

NIOSH has categorized hazardous drugs into three (3) categories.

It is clear, and consistent with current practice, that **all antineoplastic HDs (Group 1) be kept external to any automation**.

With respect to the SynMed® system, all Group 1 medications should be positioned in the patient-specific blister card by hand. This can be done securely and efficiently using the SynMed® Assist module.

TABLE 1. NIOSH HAZARDOUS DRUG CATEGORIES

GROUP 1	GROUP 2	GROUP 3
Antineoplastic drugs—many may also pose reproductive risk in susceptible populations[1] (AHFS classification 10:00)	Nonantineoplastic drugs that meet 1 or more of NIOSH criteria for a hazardous drug—some may also pose reproductive risk in susceptible populations[1]	Drugs that primarily pose reproductive risk to men and women trying to conceive and women who are pregnant or breast-feeding—some may be present in breast milk[1]

AHFS indicates American Hospital Formulary Service; NIOSH, National Institute for Occupational Safety and Health.

SynMed® technology is unique among automated compliance packaging machines. We provide below all the relevant facts to allow you to complete a thorough risk assessment with respect to the nonantineoplastic (Group 2 & Group 3) HDs within the SynMed® system.

SynMed® uses a patented Pick & Place technology, i.e. gentle suction removes the oral solid from the medication container and allows it to be gently dropped into the blister pack cavity.

If the Pharmacist has any concern as to the safety of including a specific molecule inside the automated SynMed® system, said medication should be positioned in the patient-specific blister card by hand. This can be done securely with the help of the SynMed® Assist guidance system. Manually positioning the medication in the blisters of a specific patient ensures that there is no contact with other patients' medications throughout the preparation process.

SynMed® is the only automation system with which all HD classified medications can be securely positioned in the same compliance pack.

Key features of SynMed® technology for consideration:

- SynMed® uses gentle suction, apt for handling fragile medications and not breaking tablets
- SynMed® containers do not have a motor and crown, nothing to create stress on the medications
- The FDA-grade stainless steel pipettes are the only touch point in the system
- Not being a gravity-fed system, there is no common chute down which all the medications travel
- The vacuum system contains a series of filters for any pill dust, including a HEPA filter
- All external medications are securely positioned **directly** in the patient-specific blisters, with no cross-contamination, using SynMed® Assist

Additionally, Synergy Medical has ensured software enhancements that will alert the operator to use *special handling* when positioning HDs by hand.

Similarly, an alert will advise the operator to use *special handling* during the container replenishment of a nonantineoplastic HD (Group 2 & Group 3).

We trust that the above information is useful as you navigate any required handling changes for NIOSH classified hazardous drugs.

As always, should you require any further information or clarification, our team is available to assist you.

Dave Joyal, Pharm.D., MBA
Director of Professional Affairs
Synergy Medical
dave.joyal@synmedrx.com
450.501.2859

APPENDIX I

Assessment of Risk for USP <800> Compliant Alternative Containment Strategy

Drug Name: Testosterone	**Assessment of Risk Completed on (Date):** 6/26/19

Type of HD

☐Antineoplastic
☒Non-antineoplastic (may pose a reproductive risk)
☐Reproductive risk primarily

Dosage Form

☐Tablet of conventionally manufactured product that requires only packaging or counting
☐Capsule of conventionally manufactured product that requires only packaging or counting
☐Oral liquids of conventionally manufactured product that requires only packaging or counting
☐Injectables of conventionally manufactured product that requires only packaging or counting
☒Other (explain): Bulk Powder API

Packaging - *Include drug name, strength, and dosage form.*

Testosterone 50 mg/ml cream

Risk of Exposure

- **NIOSH Table 1:** The drug meets one or more of the NIOSH criteria for a hazardous drug. Many of these drugs are cytotoxic and may also be hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

  Supplemental Information:

  Route of exposure: Contact with skin (injectables, repackaged oral liquids)

  Ingestion of HD materials (capsules)
  Inhalation (powder)

- **NIOSH Table 2:** The drug meets one or more of the NIOSH criteria for a hazardous drug. Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

  Supplemental Information:

  Route of exposure: Contact with skin (injectables, repackaged oral liquids)

  Ingestion of HD materials (capsules)
  Inhalation (powder)

☒**NIOSH Table 3:** Potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk.

Supplemental Information: Children should avoid contact with unwashed or unclothed application sites on skin; FDA pregnancy category X

Route of exposure: Contact with skin (injectables, repackaged oral liquids)

Ingestion of HD materials (Capsules)
Inhalation (Powder)

Alternative Containment Strategies

- The receipt of any HD, except for an antineoplastic or API, will be handled and stored per the manufacturer.
- HD tablets and capsules will be cut, crushed, or otherwise manipulated ONLY in a C-PEC work station (double HEPA or vented to the outside) with a powder shield to protect the worker's face and eyes from exposure.
- Protection of face (with face shields), eyes (with goggles), and skin (with gloves) when manipulating HD liquids.
- The final compounded HD product will be placed in a sealed impervious plastic bag and labeled as per protocol.
- Non-disposable materials used to compound the HD will be cleaned in an empty sink with a specified lab grade detergent and suitable cleaning process as determined by protocol.

- The materials, sink, and designated compounding area will be decontaminated per protocol or material data sheet.
- Plastic wrap, PPE, and cleaning materials will be placed in hazardous waste disposal located near the compounding area, if necessary per HD disposal protocol.

Based on Assessment of Risk our pharmacy will proceed as follows:

☒Follow alternative containment strategies documented above

☐Follow all USP <800> requirements

Assessment of Risk written by: _____ Date: 6/26/2019

Reviewed by Pharmacy Manager: _____ Date: 6/26/2019

*Disclaimer: This assessment of risk is a baseline template and may need to be individualized for different drug products per USP <800> standards as required by your State. The information contained in this template is not intended to constitute legal advice, nor serve as a substitute for the engagement of qualified professionals.

APPENDIX II - REFERENCES

- General Chapter 800

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf

- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

https://www.cdc.gov/niosh/docs/2016-161/default.html

- USP800 Risk Assessment Templates

https://www.ncpanet.org/innovation-center/diversified-revenue-opportunities/compounding