USP ‹800›* CSTD
Compliance Reference

Your quick reference for the United States Pharmacopeial Convention (USP) Chapter ‹800› Closed System Transfer Device (CSTD) language and overview of compliant ICU Medical CSTD systems.

*Enforceable by the State Boards of Pharmacy on July 1, 2018.

Quick Facts:

1. What is the difference between USP ‹797› and ‹800› as it relates to use of CSTDs?

- USP Chapter ‹797› only pertains to pharmacy preparation, not nursing administration, and does not include specific requirements.
- USP Chapter ‹800› applies new controls for nursing administration, requiring that a CSTD be used during administration of Hazardous Drugs (HDs).
  - This CSTD language is outlined in the Containment Supplemental Engineering Control (C-SECs) section of Chapter ‹800›. An SEC is an adjunct control (e.g., CSTD) that may be used concurrently with primary and secondary engineering controls. SECs offer additional levels of protection and may facilitate enhanced protection, especially when handling HDs outside of primary and secondary engineering controls (e.g., during administration).

2. What is the specific USP ‹800› language regarding CSTDs?

- Compounding: "CSTDs should be used when compounding HDs when the dosage form allows."[1]
- Administering: "CSTDs must be used when administering antineoplastic HDs when the dosage form allows."[1]

3. What is the USP ‹800› definition of a CSTD?

- USP ‹800› relies on the NIOSH definition of a CSTD, which is a drug-transfer device that "mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system."[2]

4. How do ICU Medical CSTD systems meet the NIOSH definition of a CSTD?

› ICU Medical's CSTD systems have been shown in microbial ingress testing to prohibit the transfer of environmental contaminants into the system over a seven-day period.[3,4]

› HD surface contamination testing has shown that ICU Medical CSTDs prohibit the escape of hazardous drug vapor concentration outside the system.[5]

5. Which ICU Medical CSTD systems meet the USP ‹800› requirement for CSTDs?

› Both ICU Medical ChemoClave® and ChemoLock™ CSTD systems meet the USP ‹800› requirement for CSTDs. Each system is comprised of a selection of vial adapters that mechanically prohibit the transfer of environmental contaminants into the system and the escape of vapor concentrations outside the system, as well as needlefree bag spikes and primary add-on and administration sets.

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[1] U.S. Pharmacopeial Convention (USP) General Chapter ‹800›: Hazardous Drugs—Handling in Healthcare Settings
[2] National Institute for Occupational Safety and Health (NIOSH). NIOSH alert 2004-165. Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. Cincinnati, OH. ‹http:// www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf›. [3] Microbial Ingress Study for ChemoLock™ Devices. AAIPHarma Services Corp. 2014. [4] Microbial Ingress Study for ChemoClave® Devices. AAIPHarma Services Corp. 2013. [5] Evaluation of ICU Medical's ChemoLock™ and ChemoClave® Systems Using Methotrexate (MTX) as a Marker. RJ Lee Group, Inc.

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