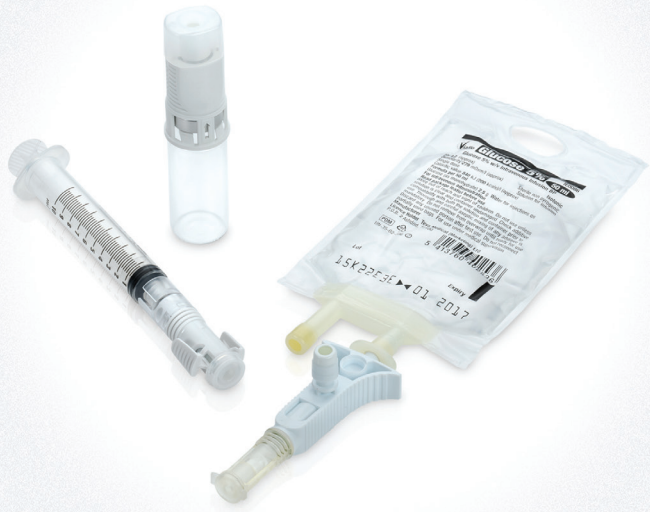
Chemfort™

Keeps you safe. Simply click

CSTD GUIDELINES

NIOSH Test being replicated at BSTL.
Environmental chamber described in the NIOSH protocol.



Chemfort™ demonstrates high performance, efficacy and safety, compared to other available CSTDs in the market and to traditional needle and syringe, when tested with the NIOSH draft protocol for evaluation of Closed System Transfer Devices (CSTDs)

- NIOSH (The National Institute for Occupational Safety and Health, US) recognized the importance of having a universal protocol for evaluating the performance of CSTDs (Closed System Transfer Devices). [1]
  CSTD performance means preventing the release of hazardous drugs in the form of vapor, aerosol or droplets.

- NIOSH issued a **draft protocol in September 2016**. The protocol listed nine proposed surrogates that are chemically and physically similar to hazardous drug molecules. [1]

- BioPharma Stability Testing Laboratory (BSTL, UK) in collaboration with the Health and Safety Laboratories (HSL), the UK's equivalent to NIOSH, replicated the NIOSH environmental test chamber using 2-Phenoxyethanol (2-POE) to evaluate CSTDs' mechanical barrier and air cleaning technologies. [2, 3, 4]

- Chemfort™, launched in 2020, was tested for its performance according to the NIOSH protocol, and was compared to Tevadaptor® and other CSTDs and devices in the market. [4]
  Chemfort™ performed equally as Tevadaptor® and other CSTDs.

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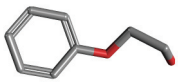
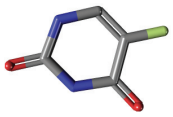
Why Use 2-Phenoxyethanol as a Surrogate?

The panel on the right shows the molecular structure and chemically active groups for 2-POE and 5-Fluorouracil (a highly volatile chemotherapy drug).
As can be seen, 2-POE is structurally similar to a hazardous drug such as 5-fluorouracil. Moreover, volatility of 2-POE is 100 fold higher than those of the most volatile chemotherapy drugs, such as 5-Fluorouracil, which is in line with the safety factor required by NIOSH. [5]



2-Phenoxyethanol
Molecular Weight: 138 g/mole
Formula: $C_3H_{10}O_2$



5-Fluorouracil
Molecular Weight: 130 g/mole
Formula: $C_4H_3FN_2O_2$

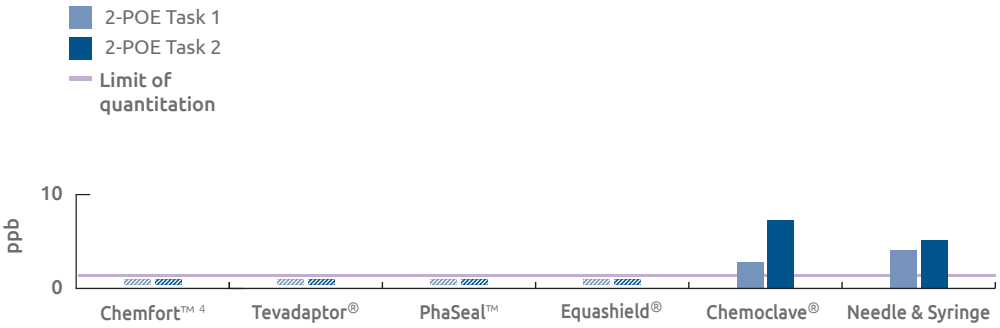
Study Outline

Hazardous drug contamination was tested during execution of Task 1 (reconstitution and transfer to an IV bag) and Task 2 (reconstitution followed by an IV push), as described in the NIOSH protocol.

Samples Tested	
CSTDs:	Chemfort™ (Simplivia) Tevadaptor® (Simplivia) PhaSeal™ (BD) Equashield® (Equashield) Chemoclave® (ICU medical)
Positive Control:	Needle and Syringe

Test Results as Analyzed by HSL

The quantity of 2-POE vapors detected with Chemfort™, Tevadaptor®, PhaSeal™ and Equashield® was consistently below the limit of quantitation (<0.71 ppb - parts per billion). Vapors detected with Chemoclave® were in the range of 2.7-7.3 ppb. Vapors detected with needle and syringe had averages of 4.00-5.00 for 2-POE.



Test Conclusions

- Chemfort™, Tevadaptor®, PhaSeal™ and Equashield® reduced the quantity of contamination between 5 to 60 fold, relative to the needle and syringe, and results were below limit of quantitation.
- The test results for the needle and syringe show the potential risk of drug release and contaminiation when a CSTD is not used for drug compounding and transfer.
- Chemoclave® results are similar to those of needle and syringe, thus, showing a significant level of contamination.

Chemfort™ showed equal performance to previously tested Tevadaptor®, PhaSeal™ and Equashield® when tested with the NIOSH draft protocol. This test validates that Chemfort™'s air-cleaning technology preserves performance of Tevadaptor®'s previous device and is as effective as physical barrier technology in preventing vapor release.

It is of great importance to have a universal test that compares the safety and efficacy of all CSTDs and includes tasks that challenge different CSTD components in relevant clinical procedures.
When using 2-POE as a surrogate, the NIOSH test protocol effectively tests the designs of CSTDs and their components, and the capacity of each component to prevent drug vapor, aerosol or droplet release.

1. Federal Register / Vol. 81, No. 179 / Thursday, September 15, 2016 / Notices
2. Wilkinson A.S. et al., Containment performance assessment of closed system drug transfer devices (CSTDs) using the NIOSH draft protocol and TEU as surrogate, J. Onc. Pharm. Practice, Vol. 24: 4(S), June 2018
3. Wilkinson A.S., Allwood MC, et al. Performance testing protocol for closed-system transfer devices used during pharmacy compounding and administration of hazardous drugs. PLoS ONE 13(10), 2018: e0205263.
4. Chemfort data on file, Study 189, March 2018
5. Atmos. Chem. Phys., vol. 15, 4399 -4981, 2015

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