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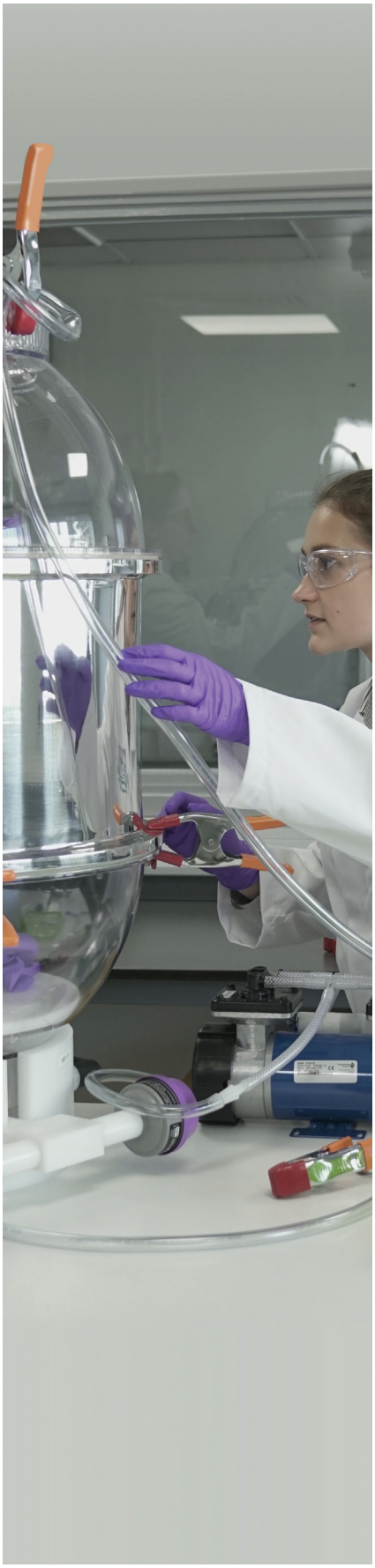
A Performance Test Protocol for Closed System Transfer Devices by NIOSH (II)



- 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). CSTD performance means preventing the release of hazardous drugs in the form of vapor, aerosol or droplets. [1]
- NIOSH issued a **draft protocol in September 2016**. The protocol listed nine proposed surrogates that are chemically and physically similar to hazardous drug molecules. [2]
- BioPharma Stability Testing Laboratory (BSTL, UK), replicated the NIOSH environmental test chamber using two of the listed surrogates, 2-phenoxyethanol (2-POE) and tetraethylurea (TEU), to evaluate CSTDs' air cleaning and mechanical barrier technologies. [3, 4, 5]
- BSTL partnered with the Health and Safety Laboratory (HSL), UK's equivalent to NIOSH, to analyze the test performance of the two tested surrogates, 2-POE and TEU.

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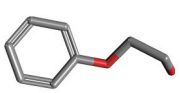
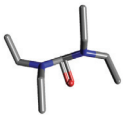
Why Use 2-Phenoxyethanol or Tetraethylurea as a Surrogate?

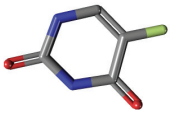
The images on the right show the molecular structure and chemically active groups for 2-POE, TEU and 5-Fluorouracil (a highly volatile chemotherapy drug).
2-POE and TEU are structurally similar to a hazardous drug such as 5-Fluorouracil.
Moreover, volatility of 2-POE and TEU is 100 fold higher than that of the most volatile chemotherapy drugs [6], such as 5-Fluorouracil, which is in line with the safety factor required by NIOSH.



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



Tetraethylurea
Molecular Weight: 172 g/mole
Formula: $C_9H_20N_2O$



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

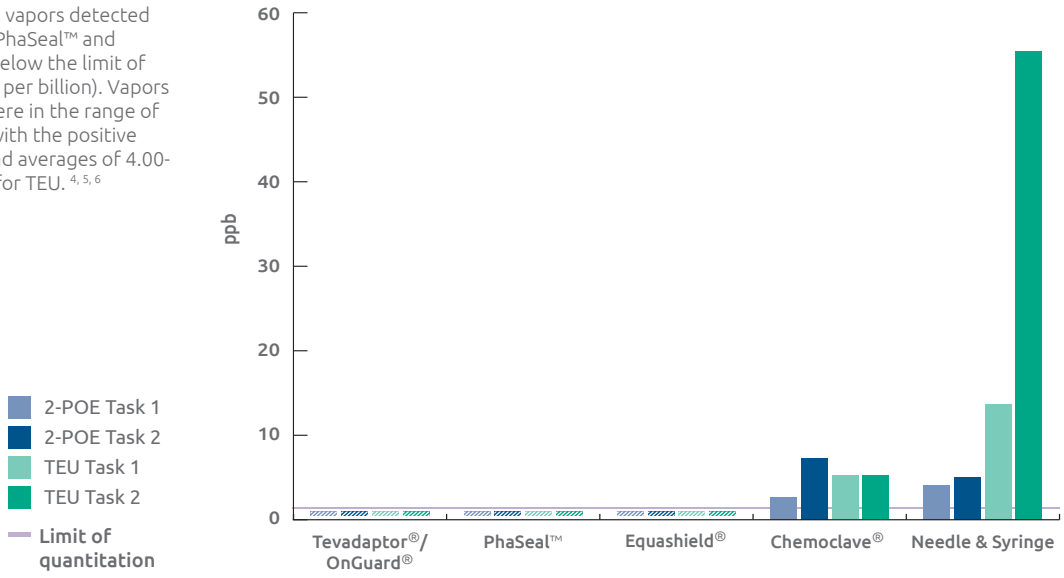
Study Outline

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. [3]

Samples Tested	
CSTDs:	Tevadaptor® (Teva)/ OnGuard® (BBraun), PhaSeal™ (BD), Equashield® (Equashield) and Chemoclave® (ICU medical)
Positive Control:	Needle and Syringe

Test Results as Analyzed by HSL

The quantity of 2-POE and TEU vapors detected with Tevadaptor®/ OnGuard®, 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 the positive control (needle and syringe) had averages of 4.00-5.00 for 2-POE and 13-55 ppb for TEU. [4, 5, 6]



Test Conclusions

- The test results for the needle and syringe show the potential risk of drug release and contamination when a CSTD is not used for drug compounding and transfer.
- Tevadaptor®/ OnGuard®, 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 detection.
- Chemoclave® results are similar (2-POE) or better (TEU) than the results of needle and syringe. Nevertheless, Chemoclave® results show a significant level of contamination.

Tevadaptor®, PhaSeal™ and Equashield® showed equal performance.
It is of great importance to have a universal test that determines the performance of all CSTDs, and includes tasks that challenge their components with chemical surrogates that are accurately chosen. 2-POE and TEU are listed as optional surrogates in the NIOSH draft protocol, and this test shows that they are suitable candidates.

The Niosh Draft Protocol was designed for both air cleaning and physical barrier CSTDs, demonstrating that both technologies can perform equally. The current test demonstrates this by showing effective prevention of vapor release with both Tevadaptor's® air-cleaning technology and Phaseal™ and Equashield's® physical barrier technologies.

1. Federal Register / Vol. 81, No. 179 / Thursday, September 15, 2016 / Notices
2. https://www.cdc.gov/niosh/docket/review/docket288a/pdfs/APerformanceTestProtocolforClosedSystemTransferDevices.pdf
3. 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), 5-6, June 2018
4. Wilkinson A.S. et al. Assessment of vapour containment performance for closed system drug transfer devices (CSTDs) that either employ a mechanically closed physical barrier or air filtration technology – a harmonised approach to NIOSH. poster session at ASHP mid year, 334-335, 2016.
5. 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.
6. Atmos. Chem. Phys., vol. 15, 4399–4981, 2015

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info@simplivia.com
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