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SHARING EXPERTISE

CSTD Performance Testing

BSTL Conducted CSTD Performance Testing Using One of the Proposed Surrogates in the NIOSH Universal Draft Protocol

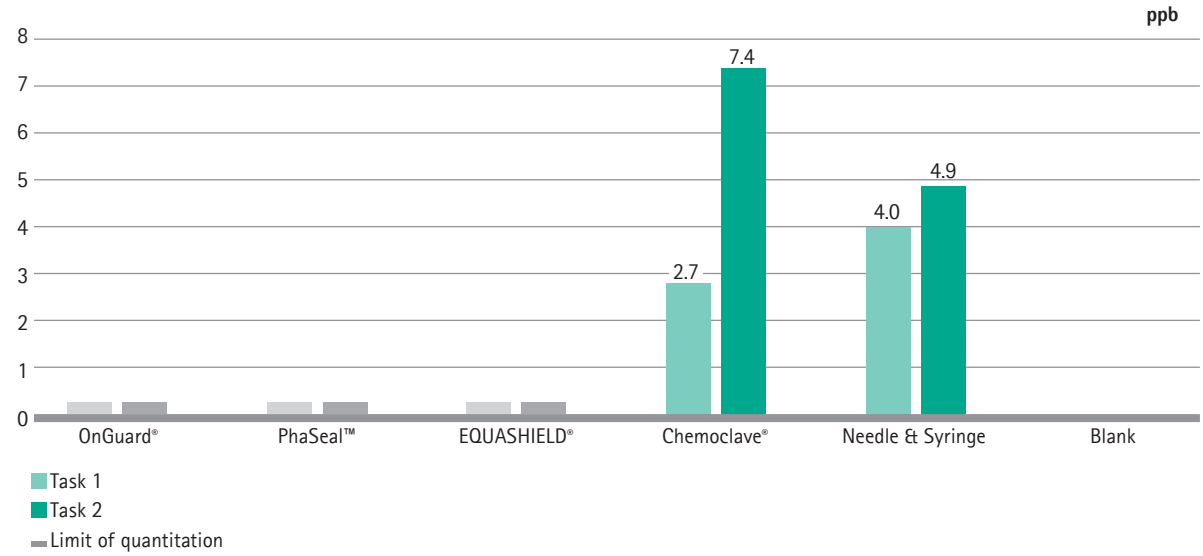
Testing with Specific Methodology and Surrogate

For Closed System Transfer Device Performance Assessment

Samples Tested	
Devices Tested:	OnGuard (B. Braun), PhaSeal (BD), EQUASHIELD (EQUASHIELD) and Chemoclave (ICU Medical)
Positive Control:	Needle and syringe
Negative Control:	Water for injection instead of 2-Phenoxyethanol
Blank:	Sampling of chamber air before the start of each test session

Vapor containment was tested during execution of Task 1 (compounding) and Task 2 (administration) as described in the draft NIOSH protocol.

QUANTITY OF 2-POE VAPORS



Test Results

The quantity of 2-POE vapors detected with OnGuard®, PhaSeal™ and EQUASHIELD® was consistently below the limit of quantitation (<0.71 ppb - parts per billion). Vapors detected with Chemoclave® ranged between 1.3-5.4 ppb, with a peak at 24 ppb and an average of 2.70 ppb for Task 1 and 7.30 ppb for Task 2. Vapors detected with a needle and syringe had an average of 4.00 ppb for Task 1 and 4.97 ppb for Task 2.

Conclusions†

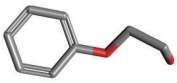
OnGuard showed similar performance to PhaSeal and EQUASHIELD, demonstrating that Onguard's air-cleaning technology is comparable to a physical barrier preventing vapor release.

NIOSH (National Institute for Occupational Safety and Health) recognized the importance of having a universal protocol for evaluating the performance of CSTDs (Closed System Transfer Devices).[1]

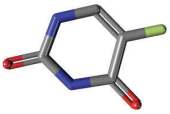
NIOSH issued a universal draft protocol for comment in September 2016 that listed nine proposed surrogates that are chemically and physically similar to hazardous drug molecules for review.[1] This protocol excluded isopropanol as a surrogate candidate due to its poor similarity to hazardous drugs.

BioPharma Stability Testing Laboratory (BSTL, an independent laboratory in the UK), replicated the NIOSH environmental test chamber using one of the listed surrogates, 2-phenoxyethanol (2-POE), to evaluate CSTDs' with mechanical barrier and air cleaning technologies.[2]

Why use 2-Phenoxyethanol and not Isopropanol as a surrogate?



2-Phenoxyethanol
Molecular Weight: 138 g/mole
Formula: $C_3H_{10}O_2$
Henry's constant: 4.72 x 10^{-8} atm x m^3/ mol



5-Fluorouracil
Molecular Weight: 130 g/mole
Formula: $C_4H_3FN_2O_2$
Henry's constant: 1.66 x 10^{-10} atm x m^3/ mol

Isopropanol
Molecular Weight: 60.1 g/mole
Formula: C3H7O
Henry's constant: 7.90 x 10^{-6} atm x m^3/mol

Left panel shows the molecular structure and chemical active groups for 2-phenoxyethanol, 5-fluorouracil, and isopropanol.

As can be seen, 2-phenoxyethanol is structurally more similar to a hazardous drug such as 5-fluorouracil, as compared to isopropanol. Moreover, Henry's constant, defining the volatility of molecules dissolved in water, is similar for 2-POE and 5-FU, the most volatile cytotoxic drug diluted in water, whereas Henry's constant for Isopropanol is 100 fold greater.[3]

B. Braun Medical Inc. | Bethlehem PA
1-800-227-2862 | BBraunUSA.com

1. Federal Register / Vol. 81, No. 179 / Thursday, September 15, 2016 / Notices
2. Data on File
3. Atmos. Chem. Phys., vol. 15, 4399–4981, 2015
† Wilkinson, A-S., Allwood, MC., Morris, CP., Wallace, A., Finnis, R., Kaminska, E., Hemingway, M. (2018). Performance testing protocol for closed-system transfer devices used during pharmacy compounding and administration of hazardous drugs. PloS ONE 13(10), 1-15.