2SPD-005

NEW CLOSED SYSTEM TRANSFER DEVICE CONTAINS REAL DRUG VAPOURS FOR UP TO 28 DAYS

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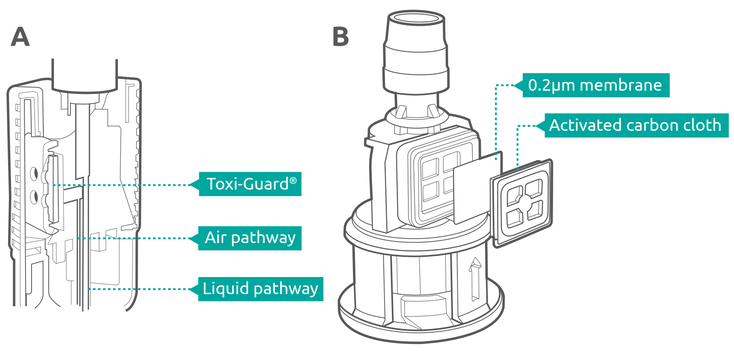
Background and Importance:

Chemfort® is a Closed System Drug Transfer Device (CSTD) that prevents the escape of hazardous drug vapors during reconstitution and administration. Chemfort® incorporates the patented Toxi-Guard® air-cleaning technology for pressure equalization. The Toxi-Guard® comprises a 0.2 µm hydrophobic/oleophobic membrane and a 100% activated carbon matrix. The membrane prevents microorganisms and particles from entering into the vial and aerosols and liquids from being released into the environment. The carbon matrix is highly efficient in the adsorption of drug vapors, thus preventing their release into the environment.

Chemfort® is currently approved for 7-day usage and is proven to contain drug vapors for up to 7 days.[1] However, some reconstituted drugs are approved for use for more than 7 days. In such cases, the CSTD usage period could be a limiting factor, leading to waste of costly drugs. The increasing need to reduce drug costs has created a demand for CSTDs that contain hazardous drug vapors for 28 days.



Aim and Objectives:

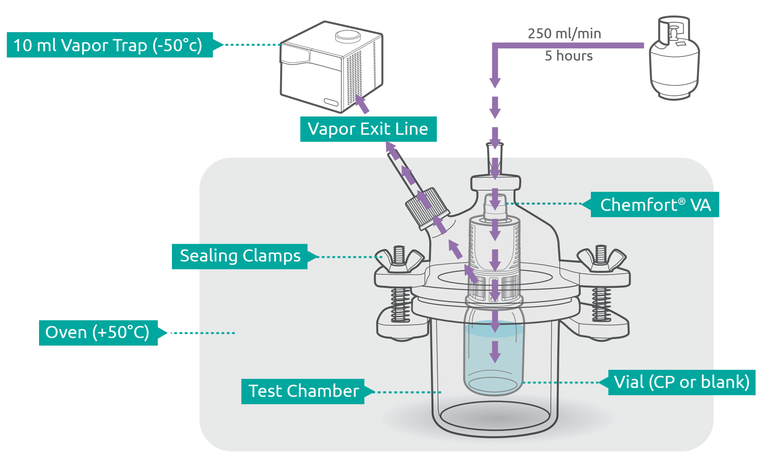
The aim was to test drug vapor containment of the Chemfort® Vial Adaptor (VA) under extreme conditions for 28 days.

Materials and Methods:

Cyclophosphamide (CP), one of the antineoplastic drugs in the list of hazardous compounds published by NIOSH,[2] was chosen as the representative drug, since, among these compounds, it has one of the highest vapor pressures and Henry's constants.[3] Thus, compared to other commonly used antineoplastic drugs, it is either as or more likely to generate vapors.

VAs at the end of their shelf life, representing extreme conditions, were tested either immediately following reconstitution or 28 days later, with and without (positive control) intact Toxi-Guard® air-cleaning systems. A VA connected to a vial containing distilled water represented a negative control for CP escape.

Each vial was transferred to a closed test chamber connected to a vapor trap. To increase drug vaporization, the chamber was heated to 50°C and nitrogen gas was constantly introduced into the vials (250 ml/min for 5 hours). Any vapors potentially released from the Chemfort® VA were trapped and then extracted with solvent.



Results:

Vial Number	Vial Content	Toxi-Guard®	Incubation 28 days (30°C)	CP detected (ng)
1	CP	Intact	+	ND
2				ND
3				ND
4				ND
5				ND
6	CP	Intact	-	ND
7				ND
8 (positive control)	CP	Lacking activated carbon layer	-	110.3
9 (negative control)	H_2O	Intact	+	ND

No CP was detected for any of the VAs with intact Toxi-Guard® components, whether tested immediately or 28 days after reconstitution, even when heat and gas flow were employed to encourage the production of vapors and when the VA was at the end of its shelf life. The limit of detection of the method was estimated at 0.2 ng. Without an intact Toxi-Guard®, 110.3 ng of CP were released into the environment.

Conclusion and Relevance:

The Toxi-Guard® air-cleaning technology of the Chemfort® VA contained drug vapors after a 28-day usage period, even under extreme conditions. A recent study proved 28-day prevention of microbial ingress by the Chemfort® CSTD.[4] Taken together, the two studies support pharmacists' decision to use drugs for their full shelf life or to extend the beyond-use-date up to 28 days when using an appropriate CSTD, such as Chemfort®, thus reducing cost and waste.

References:

[1] Levin, G., Sessink, P. J. (2021). Validation of chemotherapy drug vapor containment of an air cleaning closed-system drug transfer device. *Journal of Oncology Pharmacy Practice,* 10781552211030682.

[2] NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. https://www.cdc.gov/niosh/docs/2016-161/default.html

[3] Wilkinson, A. S., Allwood, M. C., Morris, C. P., 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), e0205263.

[4] R. Terkola, C.N.A Pietrzak, A.S. Nebel; Poster 3PC-005 at 27th EAHP Congress, March 22-24, 2023: Closed System Transfer Device (CSTD) Extends Practical In-Use Shelf Life to 28 Days After First Puncture of Non-Preserved Single-Use-Vials in Both Controlled and Uncontrolled Environments.

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