A comparative test for vapor containment between Corvida Halo® and BD PhaSeal® Closed System Transfer Devices

OBJECTIVE:

Evaluate the effectiveness of a novel CSTD, the Halo®, in comparison to PhaSeal® in containing vapors when using the CSTD to transfer a drug surrogate (70% Isopropyl Alcohol {IPA}) from a drug vial to syringe to IV bag.

TEST METHOD:

An IPA solution was chosen as a surrogate to detect vapor leaks for two primary reasons: (1) it volatizes rapidly and (2) is easily detected in very small amounts using readily available gas detection equipment. The IPA can be easily transferred in a liquid state from a drug vial to a syringe to an IV bag and simulate the preparation and administration of a hazardous drug. When conducted within a closed environment, any IPA vapor leaks are easily detected. The IPA is being utilized to evaluate the ability of the Halo devices to maintain vapor containment during fluid transfer across the dry to dry compression fit seal connections that are made between the CSTD components. A benchmark test was also performed using the BD PhaSeal® CSTD.

- Testing was performed by Corvida
- To evaluate containment when transferring IPA liquid from a drug vial to syringe, the Halo® Closed Syringe Adaptors and Closed Vial Adaptors were attached to syringes and drug vials respectively, following the Instruction for Use (IFU). Similarly, the PhaSeal® Injectors and Protectors were connected to syringes and drug vials respectively following the IFU.
- To evaluate containment when transferring IPA liquid from a syringe to IV bag, the Halo® Closed Syringe Adaptors and Closed Bag Adaptors were attached to syringes and IV bags respectively, following the Instruction for Use (IFU). Similarly, the PhaSeal® Injectors and Infusion Adaptors were connected to syringes and IV bags respectively following the IFU.
- Entire test was completed within a small chamber, glove box environment. Continual monitoring of air in close proximity to the test articles was performed with an RKI Eagle 2 gas monitor calibrated to detect as low as 5ppm of IPA.
- Each set of components was challenged to a total of fourteen (14) transfers between each set of components. Following each transfer, the respective components were disconnected and the dry-to-dry seal connections were held within 5cm of test probe for 10 seconds following each disconnection.
- Two different positive controls were used to verify detection ability of IPA. The first positive control involved placing one drop of IPA from a 20ml syringe on a tissue approximately 25 cm from the test probe. A decay curve was generated to show detection and dissipation of the IPA. The second positive control involved intentionally creating a tiny (under 0.25mm) pin hole in the bladder of the Halo® Closed Vial Adaptor. Leakage through this hole demonstrated the ability to detect IPA leakage from the system.
- 30 sets of Corvida Halo® components were subjected to one year accelerated aging per ASTM F1980-07 prior to testing
- 30 sets of PhaSeal® components were non-expired, commercially available components

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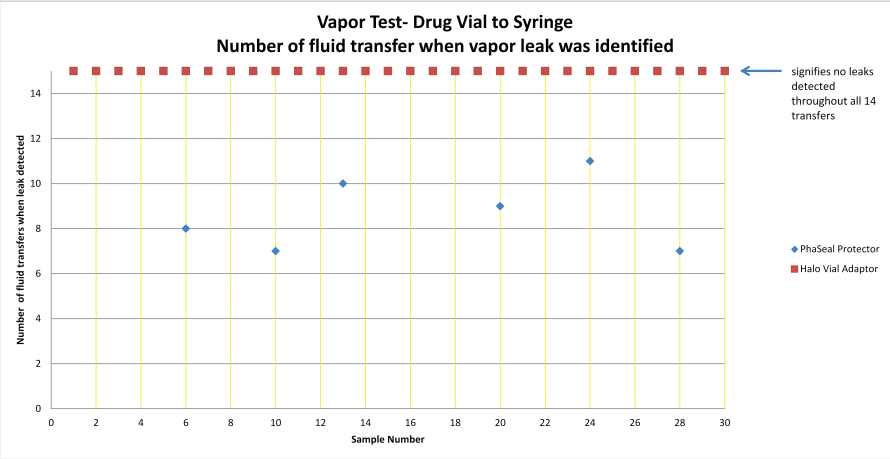
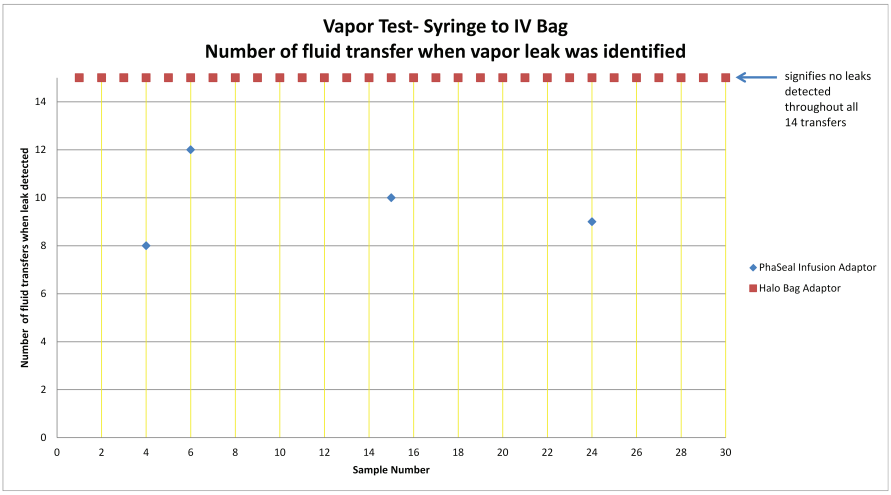
RESULTS:

There were no vapor leaks observed on any of the transfers between any of the Halo® components vs the PhaSeal® system that leaked in as little as seven (7) transfers.





CONCLUSION:

Corvida Halo® provides superior vapor containment as compared to BD PhaSeal® when subjected to multiple uses of the devices. The Halo® seal system has been designed to assure a high level of vapor containment, even when challenged to extreme conditions, such as 14 fluid transfers. This is especially important in protecting clinicians when multiple vial accesses and drug transfers are involved.

Reference:

1. TPR2005 - Halo (T=0) Vapor Leak Test Report, February 2015
2. TPR2045 - Halo CSTD System vapor Leak Test (T=1), February 2015
3. TPR2046 - BD PhaSeal System Vapor Leak Test, February 2015
4. Corvida Medical® Comparison Test Report, February 2015

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