Evaluation of a Closed System Transfer Device Based on NIOSH Performance Test Protocol,
NIOSH Docket Number 288-A, CDC-2016-0090

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Background

No peer accepted performance standard currently exists for closed system transfer devices (CSTDs). As such, NIOSH researchers along with healthcare industry representatives and individual researchers are developing a performance test protocol for CSTD. While the original protocol was only applicable to barrier-type CSTD, the second iteration of the protocol is applicable to both barrier and air-cleaning types of CSTD. Changes to the original protocol include the use of a new surrogate whose vapor pressure is more representative of current hazardous drugs as well as the use of desorption tubes to be analyzed by TD-gas chromatography-mass spectrometry (TD-GC-MS).

Objective

The objective was to evaluate the ICU Medical ChemoLock CSTD with two different vial adaptor technologies based on the NIOSH draft test protocol, NIOSH Docket Number 288-A, CDC-2016-0090, which is intended to challenge a CSTD’s ability to function as a closed system that restricts drug mass (vapor or liquid) from crossing the system boundary and escaping into the surrounding environment.

The two vial adaptor technologies tested included:

1. A barrier technology that utilizes an external balloon designed to equalize pressure in the vial and limit the escape of hazardous drug particles and air.

2. An air-cleaning technology that utilizes a 0.22 micron filter designed to equalize pressure in the vial and limit the escape of hazardous drug particles while allowing air to escape.

Methods

The protocol as outlined by NIOSH Docket Number 288-A, CDC 2016-0090 was used for the evaluation of the CSTD. Propylene glycol diluted in a 10:1 ratio in water and a stainless steel thermal desorption tube was used to collect vapor or liquid. The air pump flow rate was set to 50ml/min with a task time of 5 minutes.

Task 1 - Reconstitution: Simulate reconstitution using a vial adapter, CSTD syringe adapter and bag spike.

Task 2 - Administration: Simulate administration by reconstituting drug followed by an IV push using a vial adapter, CSTD syringe adapter and administration set with a Y-site and CSTD port.

Task 3 - Liquid Compounding: Simulate compounding medication with liquid drug using a vial adapter, CSTD syringes adapter and bag spike. This task is not outlined in the NIOSH protocol, however, was added to simulate a commonly performed task in the pharmacy.

These tasks were performed multiple times utilizing different vial adaptor technologies and an 18G needle and syringes. The desorption tubes were then sent to an independent laboratory for analysis. All results of propylene glycol detected will be averaged and reported.

As Task 1 represents the most comprehensive compounding task, only task 1 was utilized with a 18G needle and syringe. The positive control was established by placing a 1ml drop of propylene glycol in the chamber and running the air flow for 5 minutes.

Results

Detection of Propylene Glycol outside of a Closed System Transfer Device

<table>
<thead>
<tr>
<th>Task</th>
<th>Positive Control</th>
<th>Negative Control</th>
<th>ChemoLock with Barrier</th>
<th>ChemoLock with Air-Cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task 1 - Reconstitution</td>
<td>0.00</td>
<td>Non-detectible</td>
<td>Non-detectible</td>
<td>Non-detectible</td>
</tr>
<tr>
<td>Task 2 - Administration</td>
<td>47000</td>
<td>4817</td>
<td>Non-detectible</td>
<td>Non-detectible</td>
</tr>
<tr>
<td>Task 3 - Liquid Compounding</td>
<td>2</td>
<td>Non-detectible</td>
<td>Non-detectible</td>
<td>Non-detectible</td>
</tr>
</tbody>
</table>

The test shows that all tasks using both the barrier and air-cleaning vial adaptor CSTD technologies pass the current NIOSH test protocol including the additional liquid drug compounding task. Therefore, pharmacies can standardize on a preferred vial adaptor technology that best fits their facilities needs when taking into account cost, workflow and ease of use.

This performance test protocol reinforced the efficacy of using a CSTD to reduce potential hazardous drug exposure, especially when compared to using a traditional needle and syringe. While the purpose of the draft NIOSH performance test protocol is to test the capability of a CSTD to perform as such, it is important to remember that all current CSTDs on the market are FDA cleared and USP <800> compliant.

Conclusions

The test shows that all tasks using both the barrier and air-cleaning vial adaptor CSTD technologies pass the current NIOSH test protocol including the additional liquid drug compounding task. Therefore, pharmacies can standardize on a preferred vial adaptor technology that best fits their facilities needs when taking into account cost, workflow and ease of use.

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REFERENCES


ASHP Guidelines on Handling Hazardous Drugs.


AIR FROM VIAL 0.22 MICRON FILTER