

Background

Closed system transfer devices (CSTD) allow the reconstitution of hazardous drugs into infusion bags, while preserving the sterility of the product and preventing the escape of liquids and aerosols into the environment. Air-cleaning technology CSTD is based on an activated carbon filter and a membrane which enable maintaining the drug sterile by filtration of air entering the vial during pressure equalization.

Objective

We examined if an air-cleaning CSTD (Chemfort, Simplivia Healthcare) can prevent liquid viral contamination by human coronavirus OC43 (HCoV-OC43).

Methods

Methods: an IV bag and an empty vial inside a sealed glove box contaminated by HCoV-OC43 aerosols. This was repeated 5 times for a total of 12 devices (60 liquid transfers) divided to 4 different groups of 3 samples each (1) with Toxi-Guard system (intact) and with disinfecting the septa before every connection; (2) without Toxi-Guard system (control) with disinfection; (3) intact devices used without initial disinfection and (4) control devices without initial disinfection. In addition, vial adaptors were challenged by direct spray of HCoV-OC43 solution on the septum and filter areas. Air inside the glove box was sampled using an air sampler before and after the procedure. HCoV-OC43 RNA was extracted from samples of the transferred liquid and compared between all groups.

Results

Analysis of air filters qPCR demonstrated that when the box was aerosolized with sterile medium, no viral RNA was detected in the air. However, when the box was aerosolized with the HCoV-OC43 stock solution, air samples displayed presence of viral RNA, both before and after the Chemfort were tested. Use of Chemfort CSTD with the Toxi-Guard system resulted in non-detectable cycle threshold (CT) values, indicative of no detectable HCoV-OC43 RNA in the transferred liquid, even when the septa and filter areas were directly sprayed with the virus. In contrast, use of the CSTD with no Toxi-Guard system resulted in a detectable CT value of the transferred liquid.

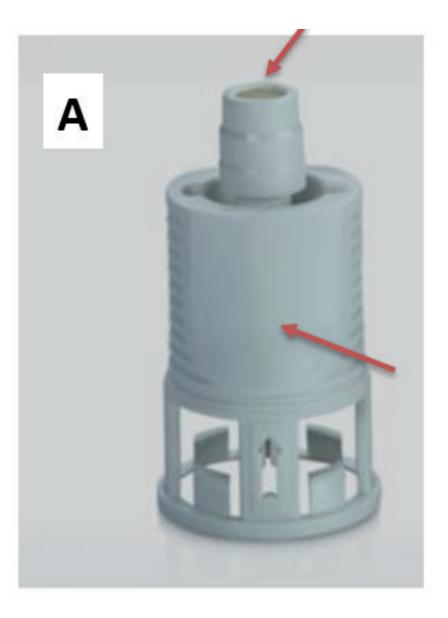
Conclusions

Using Chemfort CSTD with an integral Toxi-Guard technology can prevent the introduction of microbial and airborne contaminants into the fluid path, thus potentially protecting patients from infection.



Figure 1. Chemfort CSTD with Toxi-Guard System

Vial adaptor, which firmly connects to any standard vial (left), equipped with the Toxi-Guard system with a 100% activated carbon drug adsorbing matrix (middle) and a 0.2 micron hydrophobic and oleophobic membrane (right), serving together as an effective sterile, particulate, and toxic drug vapor barrier



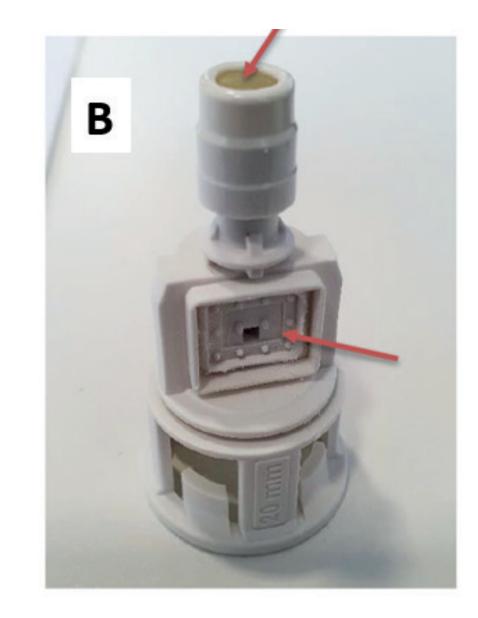


Figure 2. Tested CSTDs with challenged areas

CSTD were either intact vial adaptor (A) or vial adaptor lacking both the sterilizing membrane and activated carbon system (B). The challenged areas sprayed directly with HCoV-OC43 stock solution are indicated by red arrows.

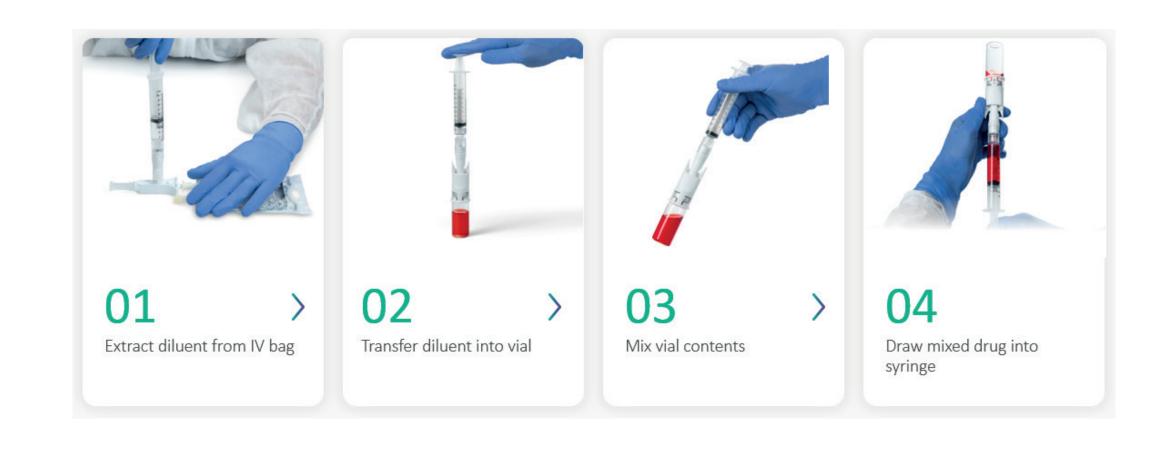


Figure 3. Using Chemfort CSTD inside glove box

This procedure mimics actual drug reconstitution and preparation done by pharmacists for IV administration in clinics and hospitals.

