5PSQ-023

LITMUS TEST METHOD FOR CSTD DRY DISCONNECTION VALIDATION

Elana A. Slutsky Smith*
Simplivia Healthcare Ltd., Kiryat Shmona, Israel

Background and Importance:

Membrane-based closed system transfer devices (CSTDs) rely on self-sealing membranes to prevent liquid release of hazardous drugs (HDs) upon connection and disconnection of adaptors.

Known methods to validate dry disconnection:

- Visual evaluation
- GC/MS detection following liquid evaporation[i]
- Litmus testing with alkaline drug 5-fluorouracil[ii]

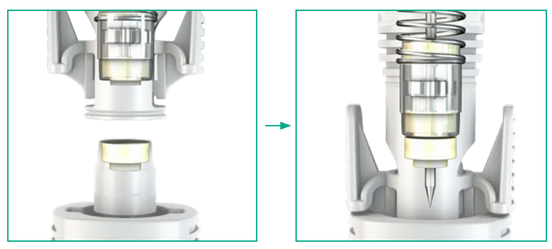

Figure 1. *Self-sealing membrane-to-membrane mechanism in Chemfort®CSTD*

Aims and Objectives:

Develop new method for dry disconnection validation using:

- litmus-based method (red paper turns blue on contact with base)
- more challenging solution than 5-fluorouracil

Validate dry disconnection of Chemfort® Vial, Syringe, and Bag Adaptors

Figure 2.

Materials and Methods:

- Prepared sodium hydroxide solution at pH 11 (basic) = worse-case representative of 5-fluorouracil (pH 9.2)
- Five transfers from vial, via syringe, to IV bag, according to Chemfort®'s instructions for use
- Device septa sampled after each disconnection with a moist litmus red paper, and color change evaluated
- Repeated for 10 sets of adaptors
- Negative control: distilled water replaced the basic solution
- Positive controls: drops of basic solution applied to litmus paper or on the septa prior to sampling

Figure 3. *Transfer and sampling method*

Results:

Litmus paper used for:

- Sampling test devices following disconnections → no color change
- Negative control → no color change
- All positive controls → blue color change

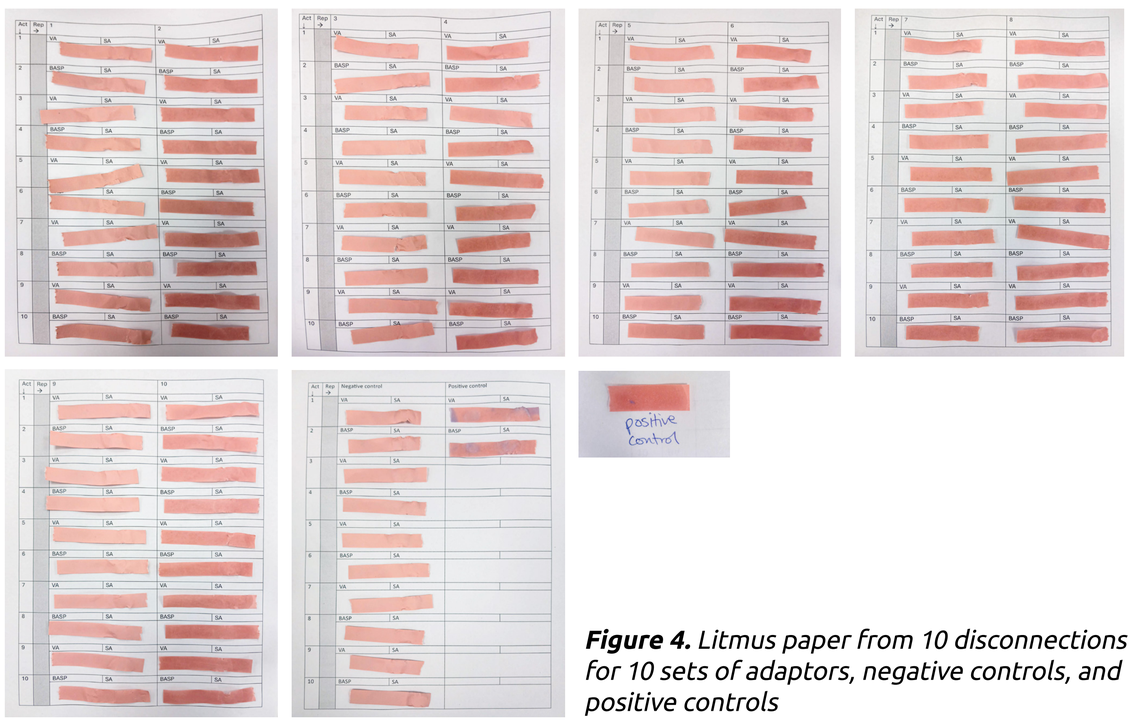

Figure 4. *Litmus paper from 10 disconnections for 10 sets of adaptors, negative controls, and positive controls*

Conclusion and Relevance:

In the CSTD tested, vapors are contained by the drug binding matrix of the ToxiGuard® (Figure 5), while liquid containment during connection and disconnection of two complementary devices is controlled by both of their septa.

Figure 5. *ToxiGuard® comprises a 0.2 µm hydrophobic membrane and a 100% activated carbon drug-binding matrix. The membrane prevents escape of liquids and aerosols, while the activated carbon locks in drug vapors.*

No liquid release was detected on septa of the tested CSTD during 5 transfers (10 disconnection cycles for syringe adaptor) using 10 sets of devices. The solution used is an even stronger base than the 5-fluorouracil used in other studies. Thus, the litmus paper is expected to be even more sensitive to releases of this solution. The study verifies the dry disconnection of the device tested, strengthening the case for CSTDs as an important layer of protection against HD exposure.

The method is inexpensive, requires no special equipment, and can readily be applied to additional CSTDs for comparison.

References:

i Wilkinson AS, et al. *PLoS One*. 2018;31;13(10):e0205263

ii ICU Medical (2024). The Role of Litmus Testing with Fluorouracil (5FU) in Analyzing a Closed System Transfer Device's Ability to Prevent External Leaks, Retrieved Sep 12, 2024 from: https://www.icumed.com/media/o3dahbxf/p24-4906_chemolock-litmus-5fu-white-paper_v5-web.pdf

Presenting Author: Elana Slutsky Smith, Ph.D. | e-mail: elana.slutskysmith@simplivia.com