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Chemfort™ Syringe Adaptor Lock - Perfect alignment with commercial luer lock syringes

Introduction

Pharmacy technical services aseptically compound chemotherapy drugs within syringes as final container systems. With the increasing use of closed system transfer devices (CSTDs) for preparation and administration of hazardous drugs (HDs) there is great interest in syringes fitted with CSTD syringe adaptor as replacement of the sterile blind hub for the closure of the syringe. The objective of this study was to conduct syringe integrity testing using Chemfort™ Syringe Adaptor Lock (SAL) as the terminal end closure device for a range of luer lock (LL) syringes in accordance with the UK NHS syringe integrity test 2nd edition 2013[1]. Testing was performed using three sizes of luer lock (LL) syringe (1mL, 20mL and 50mL) as container systems in combination with the Chemfort™ Syringe Adaptor Lock covering the most commonly used sizes of syringe. The microbiological (Method 1, partial immersion) and physical (Method 3) challenges were applied as described in the YCD with some modifications[1].

Figure 1. Chemfort™ SAL fitted to 1, 20 and 50mL BD syringes and immersed in the tank containing culture media.

Methodology

For microbiological integrity twenty syringes at each volume size (1mL, 20mL, and 50mL) were fitted with the SAL device and were aseptically filled with TSB growth media. The SAL septa was punctured during the TSB draw up from a vial fitted with Chemfort™ Vial Adaptor as would happen in clinical practice. All filled syringes were incubated for 14 days at 30-35°C and checked for growth prior to test.
The syringes were immersed in a vessel containing TSB inoculated with a culture of Brevundimonas diminuta (partial immersion test), incubated for 14 days at 30-35°C followed by visual examination for evidence of microbiological growth. Growth promotion testing (GPT) was performed to demonstrate viability of the media to support growth of the challenge organism.
Physical integrity was tested using device combinations at each syringe size (n=20), filled with MilliQ water to 75% of the maximum fill volume. The Syringe Adaptor Lock (SAL) was disconnected from the Vial Adaptor and Internal vacuum was applied to each syringe unit by drawing back the plunger to 100% of its volume. The plunger was secured in place using a mechanical fixing applied to the plunger to maintain vacuum during test. The syringes were then submerged in a vessel containing 0.4% w/v methylene blue (MB), sealed and rotated at 45rpm for 2 hours. The devices were then cleaned and inspected with absorbances measured at 660nm. A positive control syringe was included in each batch of test syringes. The puncture of the SAL septa during the draw up MilliQ water from a vial fitted with the Chemfort™ Vial Adaptor replicated actual lab practice.

Figure 2. Chemfort™ Syringe Adaptor Lock (SAL) devices subjected to the physical dye intrusion test with MB dye.

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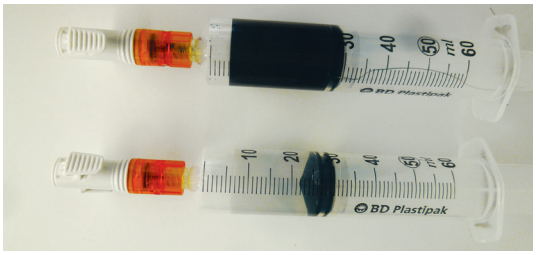
Results

1. Microbiological integrity: All combinations of Chemfort™ SAL/syringe (n=20) showed no evidence of microbiological growth demonstrating that sterility was maintained. Positive control tests (n=2) produced growth following inoculation with <100 cfu of Brevundimonas diminuta and incubation for 3 days at 30-35°C.
2. Physical integrity: All combinations of Chemfort™ SAL/syringe (n=20) were found to be free of methylene blue dye, indicating there was no ingress of methylene blue dye at the end of the test period. Positive control tests (n=3) at each size showed ingress of dye as confirmed spectrophotometrically and by visual appearance. Limit of detection (LOD) for the MB dye was determined at 1:10000 dilution of 0/4% w/v stock for both visual and instrumental readout.

Figure 3. Microbiological integrity test results for test: 1mL, 20mL and 50mL syringes.

Figure 4. 50mL physical dye intrusion test (lower) versus the 50mL positive control (upper). Presence of MB dye in the positive control syringe only.



Discussion

A stringent microbiological challenge was applied in the study using the motile bacteria Brevundimonas diminuta with an extended contact time of 14 days incubation. A long contact time with the challenge bacteria coupled with the punctured septa provides a robust test of the CSTD-syringe container system. In the physical dye intrusion testing rotation, the CSTD-syringe units for 2 hours in the dye bath provides a robust challenge of the luer lock, syringe plunger and septa against ingress. All test devices passed the test.

Conclusions

The results of this study demonstrate that the connection between the Chemfort™ SAL and commercial disposable syringes is an absolutely tight connection, effectively functions as one unit.

References

1. NHS Pharmaceutical Quality Assurance Committee 2013. Protocols for the integrity testing of syringes. Yellow cover document (YCD) 2nd edition April 2013. integrity testing of syringcument (YCD) 2nd edition April 2013: