Background and importance It is common practice for compounding facilities in Europe to retain partially used vials of physically stable drugs for future compounding needs; there are discrepancies in accepted beyond use dates (BUD). Canada NAPRA Model Standards specify a BUD of 6 hours based on the risk of microbial contamination for single use vials.

Aim and objectives To confirm that using a closed system transfer device (CSTD, Chemolock), in a class II B2 BSC installed in a class B compliant environment, would prevent microbial contamination of simulated single use vials and maintain their sterility even after repeated access for up to 9 days.

Material and methods Under standard compounding procedures, 20 vials of growth media were accessed using Chemolock vial adaptors. Aliquots (1 mL) were withdrawn and discarded from each vial at 0, 48, 96, 144, 168 and 216 hours. At the end of this 9 day period, samples were incubated in a microbiological laboratory. In order to test for growth of gram positive bacteria, gram negative bacteria, anaerobic microorganisms, yeast and mould, two types of growth media were used: 10 samples with tryptic soy broth (TSB) and 10 samples with fluid thioglycollate medium (FTM). Two temperature ranges (20–25°C and 30–35°C) were used for incubation to ensure optimum growth conditions for different microorganisms. Negative and positive controls for each growth media were also used. Concurrent with testing, each positive control FTM vial was inoculated with one of the following American Type Culture Collection Stock (ATCC) strains: Clostridium sporogenes, Pseudomonas aeruginosa and Staphylococcus aureus, and incubated with the test samples. TSB vials were inoculated with one of the following ATCC stock strains: Bacillus subtilis, Aspergillus brasiliensis and Candida albicans.

Results No growth was observed in the negative controls or study samples after 7 days at 20–25°C or after 7 days at 30–35°C. All positive controls showed growth.

Conclusion and relevance The study results suggest that single use vial sterility is maintained for up to 9 days when accessed with a ChemoLock CSTD. Prolonged sterility may support BUD extension up 9 days. BUD extension may result in improved medication supply in times of shortage, increased efficiency and decreased costs.

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