EVALUATING THE MICROBIAL CONTAMINATION RISKS IN THE USE OF CLOSED SYSTEM DRUG TRANSFER DEVICES (CSTD)

LOCATION

HAU Tepecik Training and Research Hospital Chemotherapy Compounding Unit

DATE OF STUDY

2019.10.07 - 2019.10.11

TEST LAB

Ege University Drug Development and Pharmacokinetic Research and Application Center R&D Laboratory (ARGEFAR)

SOURCES

1 ISOPP SECTION 6 FACILITIES FOR STERILE CYTOTOXIC RECONSTITUTION AND PERSONAL PROTECTIVE EQUIPMENT, 2 ASHP GUIDELINES ON HANDLING HAZARDOUS DRUGS , 3 USP <797> PHARMACEUTICAL COMPOUNDING STERILE PREPARATIONS

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Why Is The Use of CSTD Important?

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Many national and international guidelines describe the risks of microbiological contamination during the preparation of sterile cytotoxic mixtures.

–In the sterile preparation of cytotoxic agents, both product and compounding personnel must be protected. (1)

–Many hazardous drugs are designed for parenteral administration, which requires aseptic reconstitution and dilution to obtain a sterile final product. As such, the preparation of these products is controlled by USP <797>. (2)

–Within the scope of sterile drug preparation process, there are 3 categories defined according to the potential for microbiological contamination. Low risk, medium risk and high risk sterile mixtures. Any of these carry risks of harm to patients, including death. (3)

CONCLUSION

Mold/yeast, aerobic bacteria, P. Aeruginosa , S. Aureus were not detected in any of the 80 samples collected from the vials using ONCOERA CSTD Products. It has been found that the use of CSTD eliminates many risks of microbiological contamination even with extended time period and multiple interventions.

"The use of ONCOERA CSTD products, eliminates many risks of microbial contamination even with extended time period and multiple interventions"

PURPOSE

The aim of this study is to determine whether there is any microbiological contamination in the drugs prepared using CSTD, in the samples taken immediately or after a certain period of time and after single or multiple interventions to the vial.

METHOD

Within the scope of study, 20 of preservative-free Calcium Folinate 300mg/30mL vials were used. A non-cytotoxic drug was chosen because the laboratory did not accept a cytotoxic drug for testing. ONCOERA vial adapters are attached to 20 vials. Then, 5 mL of liquid sample was collected from each vial with sterile syringes ONCOERA syringe adapter attached. Then, the vials with the vial adapter attached were placed in the refrigerator and the sample collection process was repeated at the 24th hour, 72nd hour and on the 7th day. By following this method, 20 samples per day collected during four days (80 samples in total) were sent to the test laboratory for microbiological control. Microbiological analyzes were carried out using the "Pour Plate" technique by using Biomerieux Company products. Sterile samples were studied as direct doses. The results were evaluated for the presence of both mold/yeast and aerobic bacteria.

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