

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



LOCATION

HAU TEPECİK TRAINING AND RESEARCH HOSPITAL
CHEMOTHERAPY COMPOUNDING UNIT

DATE OF STUDY

2019.07.19 - 2019.07.29

TEST LAB

EGE UNIVERSITY DRUG DEVELOPMENT AND
PHARMACOKINETIC RESEARCH AND APPLICATION
CENTER R&D LABORATORY (ARGEFAR)

TEST METHOD

QUANTITATION OF CISPLATIN (MG/KG) USING ICP-
MS DEVICE

SOURCES

1 NIOSH ALERT PREVENTING OCCUPATIONAL EXPOSURES ANTINEOPLASTIC AND
OTHER HAZARDOUS DRUGS IN HEALTHCARE SETTINGS, 2 ANTINEOPLASTİK
İLAÇLARIN GÜVENLİ KULLANIM STANDARTLARI REHBERİ, 3 ASHP GUIDELINES
ON HANDLING HAZARDOUS DRUGS, 4 USP <800> HAZARDOUS DRUGS HANDLING IN
HEALTHCARE SETTINGS

WHY IS THE USE OF CSTD IMPORTANT?

Pharm. Elvan Gökmen, Pharm. Aslı Çelebi, Pharm. Füsün Kolat, Biologist Burcu Akgül

Many national and international guidelines recommend the use of CSTD to minimize employee exposure to hazardous drugs:

- CSTDs limit aerosols and employee exposure to the drug. Evidence has shown a reduction in cytotoxic drug contamination when CSTD is used in a Class IIB biological safety cabinet. (1)
- The use of CSTD should be considered when reconstituting hazardous drugs in a Class IIB biological safety cabinet; When this type of device is used in a Class IIB biological safety cabinet there is evidence that cytotoxic drug contamination is reduced. (2)
- The use of CSTD in a Class IIB biological safety cabinet should be considered when preparing hazardous drugs. Evidence shows that it reduces cytotoxic drug contamination inside. (3)
- As a supplemental control, CSTDs should be used in a hazardous drug preparation process in a Class IIB biological safety cabinet. CSTDs will be used in the drug preparation process when drug dosage forms are appropriate. (4)

STUDY DETAIL

PURPOSE

The aim of this study; to compare the results of cytotoxic drug contamination of the drug prepared surface of the Class IIB biological safety cabinet in cytotoxic drugs prepared by the traditional method (syringe and needle) and using ONCOERA CSTD products.

METHOD

During the study, cisplatin drug preparation process was carried out in the manual cabinet and samples were collected from the surface, where the drug was prepared in 4 stages, into test tubes. (1) The cabinet was cleaned in accordance with the relevant standards and samples were taken from the working surface by swab method. (2) In the cabinet, ten bags containing 50 mL of cisplatin (from 10 commercial forms of cisplatin) were prepared using ONCOERA CSTD products and samples were taken from the working surface by swab method. (3) The cabinet was cleaned in accordance with the relevant standards and samples were taken from the working surface by swab method. (4) In the cabinet, ten bags containing 50 mL of cisplatin (from 10 commercial forms of cisplatin) were prepared using syringe & needle (traditional method) and samples were taken from the working surface by swab method. Cisplatin quantification was performed on the collected samples using the ICP-MS device.



"The use of CSTDs in chemo compounding process significantly reduces the cytotoxic drug contamination of surface compared to the traditional method."

FINDING-1: There is drug residue on the surface after cleaning process

It was determined that there was a trace amount of cisplatin on the surface of the biological safety cabinet for which manual drugs were prepared, even after the cleaning process in accordance with the cytotoxic cleaning regulations.

FINDING-2: A significant increase in the amount of drug on the surface has been detected in the drug preparation process with the traditional method

636.75% increase in cisplatin amount was observed on the drug prepared surface of the biological safety cabinet in the cytotoxic drug preparation process made with the traditional method (syringe and needle tip).

FINDING-3: The use of CSTD significantly reduced the drug residue on the surface

In the traditional method, compared to the method using CSTD, 478 times more cisplatin drug contamination was detected on the drug-prepared surface of the biological safety cabinet.

CONCLUSION

The use of ONCOERA CSTD products in chemotherapy drug preparations significantly reduces cytotoxic drug contamination of surface compared to the traditional method, and thus, it is important in ensuring personnel and environmental safety. However, considering the presence of cisplatin drug residues on the surface even after cleaning in accordance with the regulations, it is important to use personal protective equipment to protect the environment and personnel from this possible contamination.