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TECHNICAL NOTE

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Hazardous Drug Decontamination Study with Spor-Klenz® in the KIRO Oncology Automated Pharmacy Compounding Device

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Introduction

KIRO Oncology is an automated pharmacy compounding device (PCD) for the preparation of compounded sterile preparations (CSPs). The device integrates an automated self-cleaning system for the deactivation and decontamination of hazardous drug (HD) residues, while simultaneously cleaning and disinfecting microbial contamination on surfaces inside the device. When working with hazardous drugs, automatization of the cleaning process not only minimizes personnel exposure to cytotoxic agents but eliminates the variability associated with manual cleaning.

An extensive study was conducted to verify that the automated self-cleaning of KIRO Oncology using Spor-Klenz®, a high-level disinfectant and cleaner, effectively decontaminates hazardous drug residues that could be left on surfaces inside the device after compounding.

Methodology

The decontamination efficacy of the automated self-cleaning of KIRO Oncology is provided by the cleaning agent used and the dilution of the HD residues with at least 9 liters of cleaning solutions. There is also a mechanical removal of the HD residues by the high impact of the spraying of the cleaning solutions through the nozzles onto the surfaces of the compounding area and adaptors. The self-cleaning process of KIRO Oncology consists of 2 phases:

- **Phase 1.** Three liters of bactericidal solution are sprayed to cover all surfaces and adaptors within the compounding area and allowed to contact the surface for at least 5 minutes to disinfect bacteria and deactivate HD residues. The bactericidal solution, validated according to European standards[1,2], is a 1:25 Spor-KlenzRTU® dilution.
- **Phase 2.** The bactericidal solution is rinsed with 6 liters of sanitazing solution. The sanitizing solution is a 1:49 Spor-KlenzRTU® dilution as per instructions of the manufacturer.

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To understand the efficacy of the decontamination and cleaning cycle with Spor-Klenz®, surfaces within the KIRO Oncology device installed in the cleanroom of Kiro Grifols premises in Mondragon (Spain) were intentionally contaminated with a mixture of 8 common cytostatic drugs.

The study, carried out during November of 2023 and executed in triplicate, applied aliquots of the mixture of 8 cytostatic drugs to stainless-steel surfaces of the KIRO Oncology device, resulting in contamination levels of 15,000 ng (100 ng/cm^2) of each tested drug. After drying for 30 minutes, the automated self-cleaning cycle was conducted (**Figure 1**). Once the surfaces were dry, they were assessed for residual drug levels using commercial swab sampling kits. A pharmacist employed by Kiro Grifols performed the spiking and swabbing activities. An accredited third-party lab determined the levels of drug recovered after the self-cleaning.

Figure 1. Automated self-cleaning of KIRO Oncology PCD.

A previous study demonstrated that the self-cleaning of KIRO Oncology using a sanitizing method and an alkaline method has a minimum decontamination efficacy of 99.8% for 8 commonly used cytotoxic drugs (5-fluorouracil, cyclophosphamide, ifosfamide, gemcitabine, etoposide, methotrexate, docetaxel and carboplatin), when contamination levels were up to 100 ng/cm^2 for each tested drug.[1]

Results

Table 1. Reduction of Multiple HD Residues on 316 L Stainless Steel using Spor-Klenz® (5-minute wet contact time)

Drug Residue Applied to Surface (100 ng/cm^2)	Average Residue after Self-cleaning (ng/cm^2)	Decontamination (%)
Carboplatin	<0.066	99.80
Gemcitabine	<0.006	99.98
Methotrexate	<0.001	99.99
Ifosfamide	<0.004	99.98
Cyclophosphamide	<0.002	99.99
Etoposide	<0.001	99.99
Paclitaxel	<0.013	99.96
5-fluorouracil	<0.066	99.85

Conclusion

As shown in **Table 1**, HD residues were reduced by at least 99.80%. No measurable contamination or levels below the quantification limits were detected from surfaces contaminated with the hazardous drug mixture.

References

1 UNE-EN 13697:2015 Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2).

2 UNE-EN 13704:2002 Chemical disinfectants. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1).

3 Telleria N, García N, Grisaleña J, et al. Evaluation of the efficacy of a self-cleaning automated compounding system for the decontamination of cytotoxic drugs. *J Oncol Pharm Pract.* 2021; 2021;27(6):1343-1353.

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