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TECHNICAL NOTE

June 2025

Hazardous Drug Decontamination Study with PeridoxRTU® in the KIRO Oncology Automated Pharmacy Compounding Device

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Date: October 18th, 2024

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 PeridoxRTU®, an EPA-registered sporicidal, 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.** One bottle of 3.78L of PeridoxRTU® is sprayed to cover all surfaces and adaptors within the compounding area and allowed to contact the surface for at least 2 minutes.
- **Phase 2.** The PeridoxRTU® solution is rinsed with 6 liters of sterile water to remove any remaining residues.

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To understand the efficacy of the decontamination and cleaning cycle with PeridoxRTU®, 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 PeridoxRTU® (2-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	<0.006	99.98
Cyclophosphamide	<0.002	99.99
Etoposide	<0.001	99.99
Paclitaxel	<0.001	99.99
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.

The automated self-cleaning of KIRO Oncology using PeridoxRTU®, followed by the disinfection procedure recommended by Kiro Grifols before sterile compounding, are USP <800>[2] compliant cleaning procedures for hazardous drugs providing deactivation, decontamination, cleaning and disinfection.

References

1 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;27(6):1343-1353.

2 USP <800> Hazardous Drugs—Handling in Heatlhcare Settings.

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GNL-KOC-2500006