inclusIV compounding portfolio

TECHNICAL NOTE

June 2025

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

Author: Jaione Grisaleña. KIRO Grifols S.L. Email: jaione.grisalena@grifols.com
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 the surfaces inside the device. Automatization of the cleaning process not only minimizes personnel exposure to cytotoxic agents but eliminates the interindividual variability associated with manual cleaning ensuring biological decontamination efficacy results during routine use of the device.

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 disinfects bioburden on exposed surfaces inside the device.

Methodology

The biological decontamination efficacy of the automated self-cleaning of KIRO Oncology (**Figure 1**) is provided by the cleaning agent used. The self-cleaning process of KIRO Oncology consists of 2 phases:

- **Phase 1.** One bottle of 3.78 L 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 to disinfect bacteria and fungi and deactivate HD residues as per instructions of the manufacturer.
- **Phase 2.** The PeridoxRTU® solution is rinsed with 6 L of sterile water to remove any remaining residues.

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

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To assess the biological decontamination efficacy of the self-cleaning process with PeridoxRTU®, a high workload production was carried out in the KIRO Oncology PCD installed in Onkologikoa hospital in San Sebastián (Spain). Eighty (80) preparations were compounded per day for 3 days of the study during July of 2024. At the end of each compounding day, the automated self-cleaning cycle was conducted. On the following day, once the surfaces of the compounding area of KIRO Oncology and the adaptors had dried, surface sampling was performed to determine the microbial bioburden of the adaptors and surfaces within the compounding area of the KIRO Oncology device (**Figures 2** and **3**).

Figure 2. Contact plates for measuring surface bioburden.

Figure 3. Swab sampling of irregular surfaces for measuring surface bioburden. Swabs were subsequently transferred to contact plates to recover bioburden.

Each day of the study, eight (8) contact plate samples (including a negative control) and four (4) swab samples were collected (**Figure 4**). All surfaces sampled were within the Grade A/ISO Class 5 compounding area of KIRO Oncology, where the sterile compounding occurs and, therefore, where disinfectant efficacy is required.

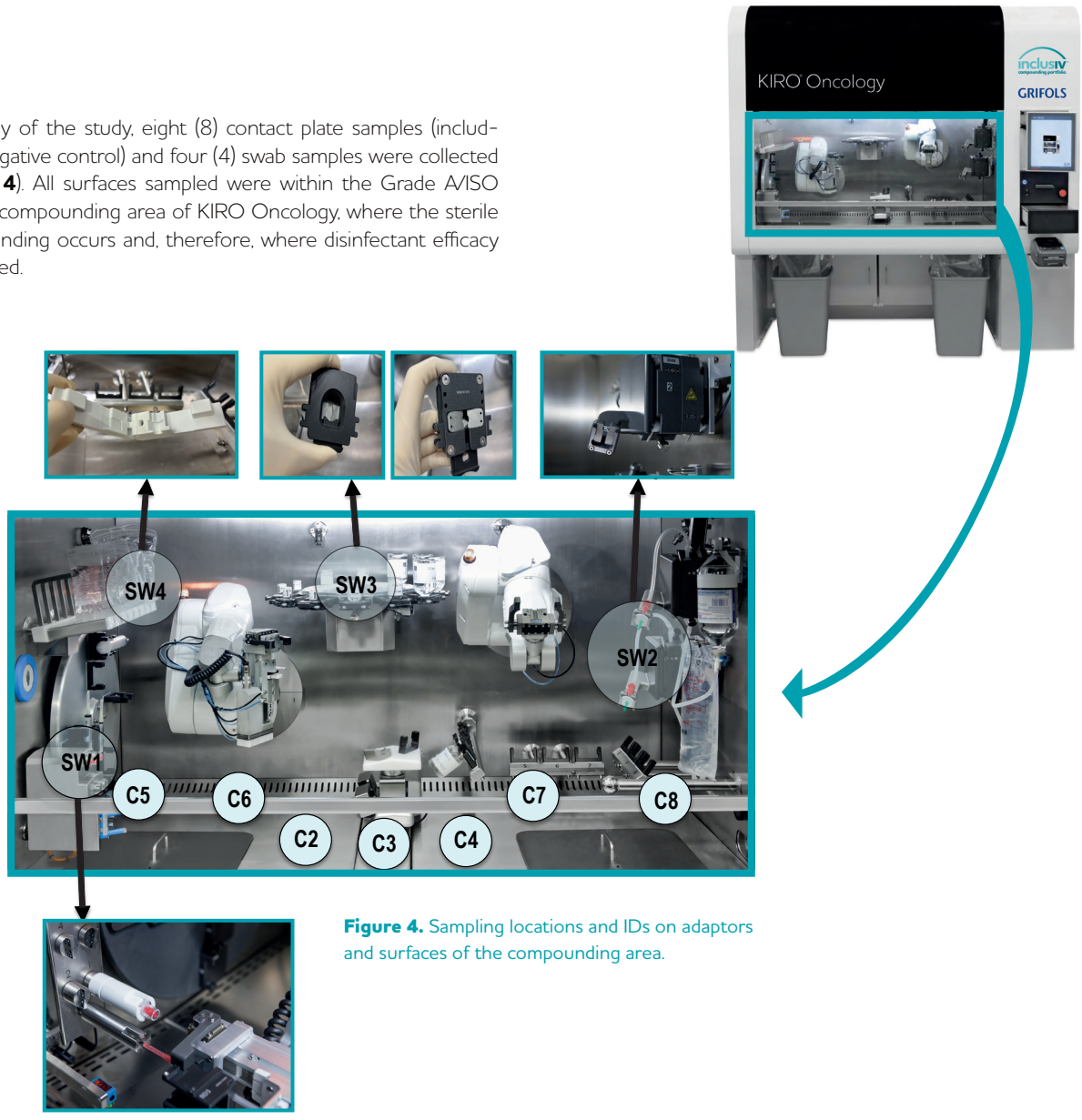

Figure 4. Sampling locations and IDs on adaptors and surfaces of the compounding area.

Results

An accredited third-party lab collected and processed the surface samples. Each sample was incubated at different temperatures: *Tryptic Soy Agar* from 30 °C to 35 °C for 5 days, and *Sabouraud Dextrose Chloramphenicol Agar* from 20 °C to 25 °C for 5 to 7 days. Results of the surface samples over the 3 days of the study are shown in **Table 1** (Contact Plates) and **Table 2** (Swabs).

Table 1. Contact plate bioburden results.

DESCRIPTION OF THE SAMPLE	SAMPLE ID	MEDIA	DAY 1	DAY 2	DAY 3
Negative control	C1	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Front left surface of the compounding area	C2	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Front central surface of the compounding area	C3	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Front right surface of the compounding area	C4	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Surface underneath the final container storage	C5	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Surface underneath the dosing robotic arm	C6	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Surface underneath the reconstitution arm	C7	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Surface underneath the peristaltic pumps	C8	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)

Table 2. Swab sample bioburden results.

DESCRIPTION OF THE SAMPLE	SAMPLE ID	MEDIA	DAY 1	DAY 2	DAY 3
Loading surface of four (4) cap/CSTD adaptors	SW1	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Loading surface of two (2) spike holders	SW2	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Loading surface of six (6) vial adaptors	SW3	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
Loading surface of eight (8) bag adaptors	SW4	Bacteria	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)
		Fungi	0 CFU (No growth)	0 CFU (No growth)	0 CFU (No growth)

CFU: colony-forming unit.

Conclusions

The automated self-cleaning of KIRO Oncology standardizes the cleaning process and provides the wet-contact time required for the disinfection of bacteria and fungi for PeridoxRTU®. The PeridoxRTU® based self-cleaning method meets the surface cleanliness requirement established by Annex 1 of GMPs,[1] NAPRA[2] and USP <797>[3] for sterile compounding. Disinfection of bacterial spores was not studied but is expected to occur if the wet contact time is extended to 3 minutes as per instructions of the manufacturer.

References

1. EudraLex Vol 4. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use. Annex 1. Manufacture of Sterile Medicinal Products. August 2022.
2. NAPRA, National Association of Pharmacy Regulatory Authorities. 2016.
3. USP Compounding Compendium, Chapter <797> Pharmaceutical Compounding - Sterile Preparations. November 2022.

ABOUT THE PORTFOLIO

inclusiv is a comprehensive IV compounding portfolio of integrated technology, software, and service solutions designed to support your needs for sterile compounding from the design and building of your sterile compounding environment, to the preparation and verification of your products, through the ongoing management and optimization of your pharmacy operation.

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Grifols International, S.A.
Parc empresarial Can Sant Joan, Av. de la Generalitat, 152-158
08174 Sant Cugat del Vallès, Barcelona - SPAIN
Tel. +34 935 710 500
hospital.division@grifols.com
www.grifols.com

GNL-KOC-2500010