A CLEANROOM SURFACE TREATMENT THAT PROVIDES ON-DEMAND HYDROGEN PEROXIDE AT THE NANOSCALE FOR MICROBE CONTAMINATION CONTROL

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BACKGROUND

Contamination in pharmaceutical cleanrooms is a critical concern due to the potential impact on product quality, efficacy, and patient safety. Bacteria, viruses, and fungi can enter cleanrooms through human contact, airborne transmission, or inadequate cleaning practices. This can lead to product spoilage and safety risks. Routine cleaning and disinfection of surfaces, equipment, and air handling systems are crucial. Using effective disinfectants and proper cleaning protocols can significantly reduce microbial load

OBJECTIVE

This study investigated the ability of a continuous disinfectant (NanoRAD) to provide better microbe control in an ISO 7 cleanroom compared to normal disinfection practices of daily IPA and weekly rotation of Vesphene, LpH III and SporKlenz.

METHODOLOGY

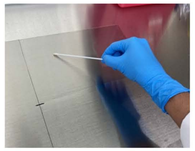
Environmental sampling of surface bacteria were evaluated with Millipore Sigma MC-Media Pads. Sterile media (PBS) was used with aseptic techniques for sampling. Media Pads were incubated for 48 hours at 35 ± 2 °C and colony forming units (CFU) were counted. An initial baseline was taken prior to surface treatment with NanoRAD. Treated and untreated surfaces were evaluated viable bacteria for 8 weeks. Environmental sampling was performed prior to the weekly deep clean of the facility to allow for build up of microbes to assess the ability of NanoRAD to maintain low bacterial load over the disinfection protocol used in the facility.

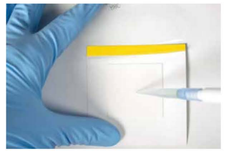
1 ISO 7 CLEANROOM BASELINE

2 NANORAD APPLIED

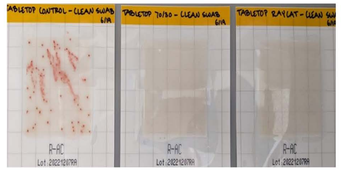
nanoRAD

3 TREATED AND UNTREATED SURFACES SWABBED





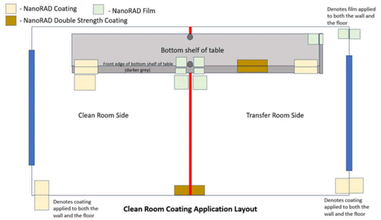
4 BACTERIA ANALYSIS



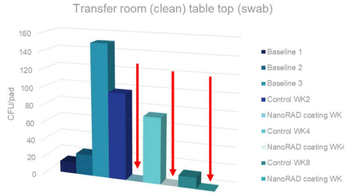
RESULTS

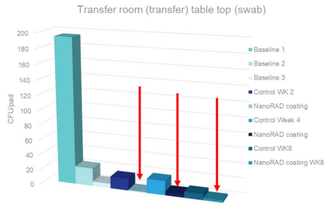
LAYOUT

Study was conducted in the transfer room of the ISO 7 cleanroom, focusing on the stainless steel table and floor. Treatment and control (untreated) surfaces were monitored on the "Clean Room" and "Transfer Room" side of the demarcation line within the transfer room. NanoRAD Coatings were used as the surface treatment for the study



TABLE

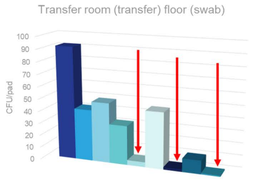


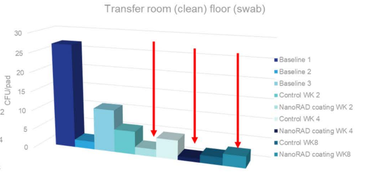


A stainless steel table that was treated with NanoRAD coating showed sustained suppression of microbes for the 8 weeks of the study. On the cleanroom side, no microbes (0 CFU) were cultured while untreated saw an average of 72 CFU. On the transfer room side of the table, On the transfer room side, the NanoRAD coating saw an average of 4 CFU compared to untreated at 64 CFU.

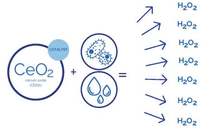
FLOORS

The floor in the transfer room showed that NanoRAD treatement significantly reduced viable bacteria cultured from the floor. On the transfer room side, NanoRAD treatment showed and average of 2 CFU compared to 45 CFU over the course of the study. On the cleanroom side of the floor, NanoRAD treated floor showed and average CFU of 2 compared to 9 CFU on the untreated side.





DISCUSSION



NanoRAD coatings provide on demand hydrogen peroxide at the nanoscale by converting water into hydrogen peroxide when "turned on" by a bacteria, virus or fungus. Hydrogen peroxide is a broad spectrum disinfectant, giving NanoRAD potent antimicrobial activity.

NanoRAD coatings showed significantly enhanced contamination reduction (from bacteria) compared to daily use if IPA and rotating weekly use of Vesphene, LpH III and SporKlenz. This demonstrates that even with wear and presence of other chemicals, NanoRAD is able to still effectively produce hydrogen peroxide for 2 months in cleanrooms to protect against contamination.

- 100% reduction Cleanroom Side Table
- 94% reduction Transfer Side Table
- 96% reduction Transfer Side Floor
- 78% reduction Cleanroom Side Floor

CONCLUSIONS

NanoRAD coatings provide continuous protection on surfaces from bacteria, viruses and fungus. In regulated settings where contamination can spoil products or lead to human illness or death, a continuous disinfecting surface treatment provides extra protection against potential non-compliance with protocols or SOPs. NanoRAD coatings showed superior performance in control of viable bacteria when compared to normal disinfection alone. Use of NanoRAD on floors and tables in critical areas (like transfer rooms and other buffer areas) can drastically reduce the likelihood of contamination in classified areas that can lead to issues like product contamination or the need to shut down production in these areas due to the spread of microbes in the facility.

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