Application of Medium-Pressure UV for Disinfection in an Air Handling System

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INTRODUCTION

Pharmaceutical manufacturing often takes place in a Clean Room Facility (CRF). CRFs are "sterile" areas where personnel wear protective clothing, the room's interior surfaces are designed and installed to minimize collection of dust particles, and the ventilation system is engineered to continuously remove particles generated by the room's activities in an efficient manner. A CRF comprises of rooms, corridors, etc., any of which may be designated anywhere from a Class 1 to a Class 100,000. For US standards (US 1992), the CRF "class" is related to the maximum number of particles (> 0.5 microns and larger) permitted per cubic foot of room space (US, September 1992). Particles may be either non-viable, or inert (e.g. dust), or viable (e.g. bacterial cells), where the latter is typically bacteria and to a lesser extent, spores. Table 1 lists the design standards for bioburden, or the level of viable particles in the various classes of clean rooms.

Table 1: Airborne Bioburden Standards

Clean Room Class	**USP Standard (US 1987)** (CFU*/10 ft^3) (US, June 1987)	**EU Standard (EU 1997)** (CFU /10 ft^3, CFU/m^3) (EU, 1997)
100 EU Class A	1	3.5, < 1
10,000 EU Class B	5	18, < 10
100,000 EU Class C	25	88, < 100

* Colony Forming Units.

The operators of a pharmaceutical CRF were interested in testing UV as a supplemental feature in the air handling system to reduce airborne levels of *Bacillus subtilis*. If the UV lamps can be located between the air handler unit and the terminal HEPA filter modules, then the amount of plate-out onto the ducts, filters, and diffusers should be minimized.

EXPERIMENT

A pilot unit was designed and tested in an isolated portion of an air handling system. A medium-pressure UV system was initially selected for the study because of the high airflow rates involved. The first two air sampling sequences involved air samplers located upstream and immediately downstream of the UV lamp installation. Subsequent testing used a single air sampler located at the end of an isolated portion of the duct, downstream of the UV installation. Air samples were taken at the isolated downstream diffuser with the light "off", and then "on".

Samples were taken with an Aerotech 6 Microbial Sampler, which is a single stage microbial bioaerosol impaction sampler designed to test for viable bacteria and fungi. An AeroLite vacuum pump connected to the sampler was set at a rate of 28.3 L/min. Figure 1 depicts the sampling equipment. Samples were taken over a 5 min span, resulting in sample volumes of 141 L. The culture media plates consisted of both tryptic soy agar (TSA) and TSA with 5% sheep blood.

Figure 1: Air sampling equipment.

The UV lamp was installed in the middle of an 8" wide by 12" high duct constructed of galvanized steel. Figure 2 illustrates the UV lamp installation onto a panel for placement into the duct. With the lamp installed in the parallel position, there was limited UV irradiation up and downstream of the lamp. The testing used both standard quartz and ozone-free quartz lamps. Standard quartz UV lamps emit UV wavelengths from about 200 nm up to 400 nm. The ozone-free quartz lamp emitted UV wavelengths from about 245 nm to 400 nm. When tested, each lamp was positioned parallel to airflow. UV sensors were positioned both on the bottom and on the side walls of the duct, each located at the middle of the lamp's arc length.

Figure 2: UV lamp installation.

Since the duct supplied air to an isolated room, ozone testing was carried out to determine whether the lamps had emitted ozone. A Draeger Chip Management System (CMS) hand-held instrument was used to detect ozone. The standard quartz lamps did emit sufficient ozone to accumulate to a detectable level (> 25 ppb) of ozone in the confined testing room. When operating the ozone-free quartz lamps in the ventilation duct, there was no detectable emission of ozone in the room.

An electronic ballast was matched with the medium-pressure UV lamps. A power supply equipped with a potentiometer was used to allow variation of the UV output.

Table 2 lists the average operating parameters of the study that was performed over several days.

Table 2: Average Operating Parameters of UV Disinfection Study

Parameter	Average Value
Air Flow	500 cfm
Air Temperature	70 °F (21 °C)
Air Relative Humidity	60% RH

RESULTS

The first two sampling events were performed where two samplers were used for an "in-line" effect. The subsequent sampling events involved taking a set of "pre-UV" samples to determine the biological population. All "pre-UV" samples had viable bacteria counts. Generically, *Bacillus* and undetermined gram-negative and gram-positive micro-organisms were identified in the air stream. Twelve samples were taken after UV irradiation. Six tests involved the standard quartz lamp and the remaining six tests used the ozone-free quartz lamp. Two of the ozone-free lamp studies reflected a 60% UV output reduction, which was accomplished by turning down the potentiometer. All "post-UV" results had zero growth on the sample plates, suggesting that the airborne concentration had been reduced to zero colony forming units/cubic meter (CFUs/m^3).

Tables 3 and 4 contain the performance data of the single lamp installation at 100% and 60% power, respectively.

DISCUSSION

The biological species contained in the airflow were inactivated within a small fraction of a second. The bacteria found in the pre-UV samples was not speciated, but only generalized as *Bacillus*, gram-negative and gram-positive. The ozone-free lamp powered at 60% of full output generated sufficient germicidal UV irradiance to inactivate the biological species. The lowest UV Fluence measured in the air duct was calculated to be only 1.8 mJ/cm^2.

CONCLUSIONS

1. In a single-pass demonstration, medium-pressure UV irradiation was successful in completely inactivating a few types of airborne bacteria, including a *Bacillus* species that was not further speciated.
2. Use of ozone-free medium-pressure lamps did not emit any detectable amount of ozone in the confined space for testing.

Table 3: Summary of Performance Data for the Single-Lamp, Ozone-Free Medium-Pressure Lamp Installation at 100% Power.

Parameter	Value
Residence Time along Arc Length	0.07 seconds
Combined UV Fluence* at Closest Edge of Duct	6.0 mJ/cm^2
Combined UV Fluence* at Furthest Edge of Duct	3.0 mJ/cm^2

*Combined UV Irradiation is a sum of the measured UV-A/B and UV-C values.

Table 4: Summary of Performance Data for the Single-Lamp, Ozone-Free Medium-Pressure Lamp Installation at 60% Power.

Parameter	Value
Residence Time along Arc Length	0.07 seconds
Combined UV Fluence* at Closest Edge of Duct	3.0 mJ/cm^2
Combined UV Fluence* at Furthest Edge of Duct	1.8 mJ/cm^2

*Combined UV Irradiation is a sum of the measured UV-A/B and UV-C values.

REFERENCES

US (1992) US Federal Standard 209E (this has been superseded by ISO Standards 14644-1 and 14644-2).

US (1987) US Federal Guideline on Sterile Drug Products Produced by Aseptic Processing, June 1987.

EU (1997) European Commission 1997 GMP Guide, Annex 1, Manufacture of Sterile Medicinal Products