WP# 23 Ultraviolet Light Disinfection Conveyor

Background

Ultraviolet light is a disinfection method that relies solely on light. The UV-C bandwidth of the ultraviolet light spectrum offers the greatest germicidal potential, with the peak kill level being 265nm. UV-C works by breaking apart the DNA of organisms through photolytic processes and prevents replication and causes cell death. There are no known resistant organisms to ultraviolet light as there are no chemicals used that could potentially allow this susceptibility. Since there are no chemicals used, there are also no residues afterwards. The various classes of organisms all require varying UV-C dosages in order to achieve particular log reductions. Falling from least to greatest durability; bacteria, viruses, followed by spores.

A particular pharmaceutical facility became interested in creating a disinfection step for items entering into their cleanroom. Critical laboratory components often arrive from an external environment and may potentially harbor harmful organisms that pose threat to the integrity of the pharmaceutical facility's lab practices. The firm has a vast array of supplies entering into the laboratory so a conveying system appeared as the best approach to transfer a large quantity of both large and small items into the cleanroom.

Case Study

The criteria for design were to establish a system condensed in size but could deliver a sporicidal kill within a brief period of time. In order to accomplish a sufficient kill on all sides there needed to be an implementation of ultraviolet lights from above, the sides, and also from below. In order to maintain a conveying line but still penetrate light through, the resulting system incorporated a grated steel belt.

The overall dimensions of the Flash Tunnel are 73.25" H x 54.25" W x 147" L and given these dimensions, ClorDiSys needed to ensure the UV-C light intensity incorporated equates to an elimination of spores. The degree of inactivation or organisms by ultraviolet light is directly related to the UV-C dose applied. UV-C intensity is typically expressed in $\mu W/cm^2$ and should be expressed at a particular distance from the light source. The UV-C dose is the product of UV intensity [I] (expressed as energy per unit surface area) and exposure time [T], therefore: Dose=I*T and is typically in mj/cm^2. Therefore, the intensity of the lights incorporated within the Flash Tunnel must be sufficient to result in an elimination of spores within the amount of time it takes an item to travel down the conveying line. The Flash Tunnel has a conveying system that can adjust to accommodate varying needs, but the time interval utilized is five minutes. For this measurement, the potentiometer is set at position 9. The pharmaceutical facility set forth the ideal of achieving at least a 3-log reduction of spores. The average dosage looking to be fulfilled was at minimum 20 mj/cm^2 which serves as a median figure in order to attain this reduction. In order to reach this target, the intensity goal ClorDiSys looked to implement at minimum 500 $\mu W/cm^2$ of UV-C intensity. To accomplish this, the design includes

a total of eighteen ultraviolet bulbs positioned to evenly distribute light throughout the enclosed chamber. The conveyor features a barrier curtain system to prohibit light leakage from entry or exit points since UV-C light is harmful to skin and eyes with direct exposure. The curtain system includes an exterior UV resistant panel positioned on either entry/exit point and an interior curtain at each side to create an antechamber void of UV-C bulbs to further reduce possible leakage.

The Flash Tunnel had the following verifications performed, an Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). The IQ is set forth to document evidence that the equipment has been supplied and installed in accordance to equipment specifications and drawings. The OQ provides evidence that the installed equipment operates within predetermined limits when used in accordance to operational procedures. The PQ follows the goals set forth by the end user which is to evaluate the ability of UV-C disinfection using the Flash Tunnel to fully eliminate microbial contamination of materials and containers entering ISO classified areas.

The scope of this PQ covers stainless steel, plastic, Tyvek, and IV bags given a five-minute exposure time.

Procedure

The performance qualification utilized both control samples and samples that would be exposed to ultraviolet light within the Flash Tunnel. Control samples for the PQ were prepared by inoculating a coupon with 0.1 mL of each specified organism in duplicate and then plating the inoculated surfaces.

For the efficacy testing of the Flash Tunnel, the samples were prepared in the same manner as the control samples. After inoculation, a 5-minute exposure time in the Flash Tunnel was applied to the organisms on each coupon.

Once the samples were collected, each was incubated for a period of 72-hours. The acceptance criteria for the PQ are 0 CFU per plate for each organism for each coupon. The criteria are established based on the intended use of the Flash Tunnel to provide a sporicidal equivalent level of disinfection of materials entering ISO classified areas.

Results

Test coupons contained the following amounts of colony forming units (CFU) of each specific organism. Both control and UV-C exposed coupons were incubated in their required media and at the appropriate temperatures. Testing for aerobic mesophilic count (TAMC) utilized Trypticase™ Soy Agar (TSA) and total yeast and molds count (TYMC) testing utilized Sabouraud Dextrose Agar (SDA).

The data set below discusses the quantity and condition of the control coupons after incubation.

Positive Control Samples						
Incubator Temp	**Organism**	**Coupon**	**Plate 1 CFU**	**Plate 2 CFU**	**Average CFU**	**Comments**
30-35°C	**S. aureus**	**Stainless Steel**	5	8	6.5	1 CFU of non-visual purity observed on Plate 2
		Plastic	7	14	10.5	1 CFU of non-visual purity observed on Plate 2
		Tyvek	12	6	9	N/A
		IV Bag	5	24	14.5	N/A
	P. aeruginosa	**Stainless Steel**	12	16	14	4 CFUs of non-visual purity observed on Plate 2
		Plastic	10	10	10	2 CFUs of non-visual purity observed on Plate 1
		Tyvek	8	11	9.5	1 CFU of non-visual purity observed on Plate 2
		IV Bag	9	11	10	1 CFU of non-visual purity observed on Plate 1
	E. coli	**Stainless Steel**	13	15	14	1 CFU of non-visual purity observed on Plate 1
		Plastic	12	15	13.5	1 CFU of non-visual purity observed on Plate 1
		Tyvek	21	16	18.5	N/A
		IV Bag	17	29	23	13 CFUs of non-visual purity observed on Plate 2

Positive Control Samples						
Incubator Temp	**Organism**	**Coupon**	**Plate 1 CFU**	**Plate 2 CFU**	**Average CFU**	**Comments**
20-25˚C	B. spizizenii	**Stainless Steel**	12	13	12.5	N/A
		Plastic	10	14	12	N/A
		Tyvek	17	6	11.5	2 CFUs of non-visual purity observed on Plate 1
		IV Bag	12	24	18	N/A
	C. albicans	**Stainless Steel**	14	13	13.5	N/A
		Plastic	11	7	9	N/A
		Tyvek	9	11	10	N/A
		IV Bag	11	10	10.5	N/A
	A. brasiliensis	**Stainless Steel**	12	12	12	N/A
		Plastic	12	13	12.5	N/A
		Tyvek	22	17	19.5	N/A
		IV Bag	13	16	14.5	N/A

The data set below discusses the quantity and condition of the inoculated coupons that received a five-minute UV-C exposure in the Flash Tunnel after incubation.

Five Minute Exposure Samples						
Incubator Temp	**Organism**	**Coupon**	**Plate 1 CFU**	**Plate 2 CFU**	**Average CFU**	**Comments**
30-35˚C	**S. aureus**	**Stainless Steel**	0	0	0	N/A
		Plastic	0	0	0	N/A
		Tyvek	0	0	0	N/A
		IV Bag	0	0	0	N/A
	P. aeruginosa	**Stainless Steel**	0	0	0	N/A
		Plastic	0	0	0	N/A
		Tyvek	0	0	0	N/A
		IV Bag	0	0	0	N/A
	E. coli	**Stainless Steel**	0	0	0	N/A
		Plastic	0	0	0	N/A
		Tyvek	0	0	0	N/A
		IV Bag	0	0	0	N/A

Five Minute Exposure Samples						
Incubator Temp	**Organism**	**Coupon**	**Plate 1 CFU**	**Plate 2 CFU**	**Average CFU**	**Comments**
20-25˚C	**B. spizizenii**	**Stainless Steel**	0	0	0	N/A
		Plastic	0	0	0	N/A
		Tyvek	0	0	0	N/A
		IV Bag	0	0	0	N/A
	C. albicans	**Stainless Steel**	0	0	0	N/A
		Plastic	0	0	0	N/A
		Tyvek	0	0	0	N/A
		IV Bag	0	0	0	N/A
	A. brasiliensis	**Stainless Steel**	0	0	0	N/A
		Plastic	0	0	0	N/A
		Tyvek	0	0	0	N/A
		IV Bag	0	0	0	N/A

Summary

The results of the control testing were used to substantiate evidence of the ability of the growth media to support the recovery of the specified organisms for each coupon tested. On all coupons; stainless steel, plastic, Tyvek, and an IV Bag, organisms were present which verified that the six organisms tested could be effectively recovered on each coupon. The outcomes of the five-minute Exposure Test performed were 0 CFU for all organisms for each coupon tested. This met the acceptance criteria stated above. Observing the results, it can be concluded that a five-minute exposure time under UV-C in the Flash Tunnel is sufficient to eliminate all microbial activity on the specified coupons used in this test.