ATS實驗室最終報告-諾羅病毒

ATS LABS

STUDY REPORT

STUDY TITLE

Evaluation of Antiviral Activity of Odorox Device

Virus: Murine Norovirus

PRODUCT IDENTITY

Mobile Disinfection Unit M.D.U

AUTHOR

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STUDY COMPLETION DATE

July 16, 2014

PERFORMING LABORATORY

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SPONSOR

HGI Industries
2055 High Ridge Rd
Boynton Beach, FL 33426

PROJECT NUMBER

A16907

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antiviral Activity of Odorox Device

Project Number: A16907

TRF Number: HGI01061614.MNV

TEST SUBSTANCE IDENTITY

Test Substance Name: Mobile Disinfection Unit M.D.U

STUDY DATES

Date Sample Received: August 21, 2013
Study Initiation Date: June 19, 2014
Experimental Start Date: July 8, 2014
Experimental End Date: July 10, 2014
Study Completion Date: July 16, 2014

TEST PARAMETERS

Dilution:	Ready to use (RTU)
Virus:	Murine Norovirus, Strain MNV-1.CW1 Obtained from Washington University, St. Louis, MO
Exposure Times:	3 hours and 6 hours
Exposure Temperature:	Room temperature (21.0°C)
Organic Soil Load:	No organic soil load required
Test and Neutralization Medium:	Complete 2X MEM
Indicator Cell Cultures:	RAW 264.7 cells
Carriers:	1" x 1" stainless steel and 1" x 1" cotton fabric Duplicate carriers per exposure time, utilizing each of the two carrier types.

EXPERIMENTAL DESIGN

Prior to use of the test device, a room was divided in half using poly (plastic) sheeting resulting in a space approximately 6' wide x 8'9" long x 10' high. The Mobile Disinfection Unit M.D.U. was placed into the room and plugged in. The power dial was turned on and was turned fully clockwise to initiate the slowest fan speed. The processor knob was turned to "high" and the unit was allowed to run for 2.75 hours prior to placing the carriers in the room.

For each exposure time, duplicate 1" x 1" carriers (stainless steel and cotton fabric) were inoculated with a 100 µL aliquot of virus suspension. The virus was spread to within 1/8" of the edge of the stainless steel carriers and was dotted about the fabric carriers. The virus was allowed to air dry. Following drying, the carriers were placed on a cart in the prepared room. The fabric carriers were allowed to hang freely, while stainless steel carriers were exposed within Petri dishes with the dish lids completely removed. The carriers were exposed to the test device for the Sponsor requested 3 hour and 6 hour exposure times. Following each exposure time, a 2.00 mL aliquot of test medium was inoculated onto each stainless steel carrier and each carrier was individually scraped with a cell scraper to resuspend the contents. The contents were transferred to individual conical tubes, mixed using a vortex type mixer, serial 10-fold dilutions were performed and each dilution was assayed for infectivity and/or cytotoxicity. The cotton fabric carriers were transferred to individual conical tubes containing a 2.00 mL aliquot of test medium with sterile glass beads and mixed using a vortex type mixer. Serial 10-fold dilutions were performed and each dilution was assayed for infectivity and/or cytotoxicity.

Additional duplicate 1" x 1" carriers (stainless steel and cotton fabric) were inoculated with virus suspension and allowed to air dry. The additional carriers were used for the zero time virus control and the dried virus control held for each exposure time. The zero time virus control carriers were neutralized immediately after drying, using the same methods as in the test. The dried virus control carriers were exposed for each exposure time, under simulated temperature and humidity conditions as in the test. Following each exposure time, the dried virus control carriers were neutralized as in the test. The dilutions prepared from the zero time virus control and the dried virus control carriers held for each exposure time were assayed for viral infectivity.

The average titer of the dried virus control replicates, for each carrier type and exposure time, was used to calculate the average log and percent reductions in viral titer for the corresponding test replicates. The average titer of the zero time virus control replicates was also used for calculating the average log and percent reductions.

Appropriate test substance cytotoxicity and neutralization controls were run concurrently.

Per Sponsor's direction, the study was not required to be conducted under US EPA 40 CFR Part 160 or US FDA 21 CFR Part 58.

CONCLUSION

Stainless Steel Carriers – 3 Hour Exposure

Under these test conditions, Mobile Disinfection Unit M.D.U demonstrated no average reduction in viral titer following a 3 hour exposure time to Murine Norovirus on stainless steel carriers, as compared to the average titer of the 3 hour dried virus control on stainless steel carriers.

The average log reduction in viral titer was 0.57 $\log_{10}$, as compared to the average titer of the zero time virus control on stainless steel carriers. The average percent reduction in viral titer was 73.1%, as compared to the average titer of the zero time virus control on stainless steel carriers.

Cotton Fabric Carriers – 3 Hour Exposure

Under these test conditions, Mobile Disinfection Unit M.D.U demonstrated a 0.32 $\log_{10}$ average reduction in viral titer following a 3 hour exposure time to Murine Norovirus on cotton fabric carriers, as compared to the average titer of the 3 hour dried virus control on cotton fabric carriers. The average percent reduction in viral titer was 52.1%, as compared to the average titer of the 3 hour dried virus control on cotton fabric carriers.

The average log reduction in viral titer was 1.17 $\log_{10}$, as compared to the average titer of the zero time virus control on cotton fabric carriers. The average percent reduction in viral titer was 93.2%, as compared to the average titer of the zero time virus control on cotton fabric carriers.

Stainless Steel Carriers – 6 Hour Exposure

Under these test conditions, Mobile Disinfection Unit M.D.U demonstrated no average reduction in viral titer following a 6 hour exposure time to Murine Norovirus on stainless steel carriers, as compared to the average titer of the 6 hour dried virus control on stainless steel carriers.

The average log reduction in viral titer was 0.87 $\log_{10}$, as compared to the average titer of the zero time virus control on stainless steel carriers. The average percent reduction in viral titer was 86.5%, as compared to the average titer of the zero time virus control on stainless steel carriers.

Cotton Fabric Carriers – 6 Hour Exposure

Under these test conditions, Mobile Disinfection Unit M.D.U demonstrated a 1.00 $\log_{10}$ average reduction in viral titer following a 6 hour exposure time to Murine Norovirus on cotton fabric carriers, as compared to the average titer of the 6 hour dried virus control on cotton fabric carriers. The average percent reduction in viral titer was 90.0%, as compared to the average titer of the 6 hour dried virus control on cotton fabric carriers.

The average log reduction in viral titer was 1.85 $\log_{10}$, as compared to the average titer of the zero time virus control on cotton fabric carriers. The average percent reduction in viral titer was 98.6%, as compared to the average titer of the zero time virus control on cotton fabric carriers.

STUDY RESULTS

TABLE 1: Input Virus Control Results

Dilution	Input Virus Control
Cell Control	0 0
10^{-1}	+ +
10^{-2}	+ +
10^{-3}	+ +
10^{-4}	+ +
10^{-5}	+ +
10^{-6}	+ +
10^{-7}	+ +
10^{-8}	+ 0
PFU_{50}/250 µL	$10^{8.00}$

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 2: Zero Time Virus Control Results on Stainless Steel and Cotton Fabric Carriers

Dilution	Zero Time Virus Control			
	Stainless Steel Carriers		Cotton Fabric Carriers	
	Replicate #1	Replicate #2	Replicate #1	Replicate #2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-1.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-2.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-3.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-4.3}$	+ + + +	+ + + +	+ + + +	+ 0 0 0
$10^{-5.3}$	+ + + +	+ + + +	+ 0 0 0	0 0 0 0
$10^{-6.3}$	+ + + +	0 + + +	0 0 0 0	0 0 0 0
$10^{-7.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-8.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
PFU_{50}/250 µL	$10^{6.80}$	$10^{6.55}$	$10^{5.05}$	$10^{4.05}$
Average PFU_{50}/250 µL	$10^{6.69}$		$10^{4.79}$	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 3: Dried Virus Control Results - 3 Hour Exposure

Dried Virus Control Results Following a 3 Hour Exposure on Stainless Steel and Cotton Fabric Carriers

Dilution	Dried Virus Control - 3 Hour Exposure			
	Stainless Steel Carriers		Cotton Fabric Carriers	
	Replicate #1	Replicate #2	Replicate #1	Replicate #2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-1.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-2.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-3.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-4.3}$	+ + + +	+ + + +	0 0 0 0	0 0 + 0
$10^{-5.3}$	+ + + +	+ + + +	0 0 0 0	0 0 0 0
$10^{-6.3}$	0 0 + 0	0 0 0 +	0 0 0 0	0 0 0 0
$10^{-7.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-8.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
PFU_{50}/250 µL	$10^{6.05}$	$10^{6.05}$	$10^{3.80}$	$10^{4.05}$
Average PFU_{50}/250 µL	$10^{6.05}$		$10^{3.94}$	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 4: Dried Virus Control Results - 6 Hour Exposure

Dried Virus Control Results Following a 6 Hour Exposure on Stainless Steel and Cotton Fabric Carriers

Dilution	Dried Virus Control - 6 Hour Exposure			
	Stainless Steel Carriers		Cotton Fabric Carriers	
	Replicate #1	Replicate #2	Replicate #1	Replicate #2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-1.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-2.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-3.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-4.3}$	+ + + +	+ + + +	0 0 + 0	0 0 0 0
$10^{-5.3}$	+ + + +	+ + + +	0 0 0 0	0 0 0 0
$10^{-6.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-7.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-8.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
PFU_{50}/250 µL	$10^{5.80}$	$10^{5.80}$	$10^{4.05}$	$10^{3.80}$
Average PFU_{50}/250 µL	$10^{5.80}$		$10^{3.94}$	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

TABLE 5: Test Results - 3 Hour Exposure

Effects of Mobile Disinfection Unit M.D.U. Following a 3 Hour Exposure to Murine Norovirus on Stainless Steel and Cotton Fabric Carriers

Dilution	Test: Murine Norovirus + Mobile Disinfection Unit M.D.U. 3 Hour Exposure			
	Stainless Steel Carriers		Cotton Fabric Carriers	
	Replicate #1	Replicate #2	Replicate #1	Replicate #2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-1,3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-2,3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-3,3}$	+ + + +	+ + + +	+ + 0 0	+ + + +
$10^{-4,3}$	+ + + +	+ + + +	0 0 0 0	0 0 0 0
$10^{-5,3}$	+ + + +	+ + + +	0 0 0 0	0 0 0 0
$10^{-6,3}$	0 0 + +	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-7,3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-8,3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
PFU_{50}/250 µL	$10^{6.30}$	$10^{5.80}$	$10^{3.30}$	$10^{3.80}$
Average PFU_{50}/250 µL	$10^{6.12}$		$10^{3.62}$	
Average Log Reduction*	No Reduction		0.32 Log_{10}	
Average Percent Reduction*	No Reduction		52.1%	
Average Log Reduction**	0.57 Log_{10}		1.17 Log_{10}	
Average Percent Reduction**	73.1%		93.2%	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present
(*) = Based on the average titer of the 3 hour dried virus control for the corresponding carrier type
(**) = Based on the average titer of the zero time virus control for the corresponding carrier type

TABLE 6: Test Results - 6 Hour Exposure

Effects of Mobile Disinfection Unit M.D.U. Following a 6 Hour Exposure to Murine Norovirus on Stainless Steel and Cotton Fabric Carriers

Dilution	Test: Murine Norovirus + Mobile Disinfection Unit M.D.U. 6 Hour Exposure			
	Stainless Steel Carriers		Cotton Fabric Carriers	
	Replicate #1	Replicate #2	Replicate #1	Replicate #2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-1.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-2.3}$	+ + + +	+ + + +	+ + + +	+ + + +
$10^{-3.3}$	+ + + +	+ + + +	0 0 0 0	0 0 + 0
$10^{-4.3}$	+ + + +	+ + + +	0 0 0 0	0 0 0 0
$10^{-5.3}$	0 0 + +	+ + + +	0 0 0 0	0 0 0 0
$10^{-6.3}$	0 0 0 0	0 0 0 +	0 0 0 0	0 0 0 0
$10^{-7.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
$10^{-8.3}$	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
PFU_{50}/250 µL	$10^{5.30}$	$10^{6.05}$	$10^{2.80}$	$10^{3.05}$
Average PFU_{50}/250 µL	$10^{5.82}$		$10^{2.94}$	
Average Log Reduction*	No Reduction		1.00 Log_{10}	
Average Percent Reduction*	No Reduction		90.0%	
Average Log Reduction**	0.87 Log_{10}		1.85 Log_{10}	
Average Percent Reduction**	86.5%		98.6%	

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present
(*) = Based on the average titer of the 6 hour dried virus control for the corresponding carrier type
(**) = Based on the average titer of the zero time virus control for the corresponding carrier type

TABLE 7: Cytotoxicity and Neutralization Control Results

Dilution	Cytotoxicity Control		Neutralization Control	
	Stainless Steel Carrier	Cotton Fabric Carrier	Stainless Steel Carrier	Cotton Fabric Carrier
Cell Control	0 0	0 0	0 0	0 0
$10^{-1,3}$	0 0	0 0	+ +	+ +
$10^{-2,3}$	0 0	0 0	+ +	+ +
$10^{-3,3}$	0 0	0 0	+ +	+ +
TCD_{50}/250 µL	$\leq 10^{0.80}$	$\leq 10^{0.80}$	See Below	See Below

(+) = Positive for the presence of test virus
(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control (neutralization control) indicate that neutralization took place for both the stainless steel and cotton fabric carriers exposed to Mobile Disinfection Unit M.D.U. at a PFU_{50}/250 µL of ≤ 0.80 $\log_{10}$.

PREPARED BY:

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7-16-14

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