

STUDY REPORT

The Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay.

Project: BT – GAM – 10

GAMA Healthcare Ltd, Unit 2, The Exchange, Brent Cross Gardens, London NW4 3RJ

Originator: Suzanne O'Sullivan

Date: June 29th 2015

Product: Clinell Universal Wipes
(BT-GAM-10-01)

Sponsor Laboratory: BluTest Laboratories Ltd
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SO/IEC 17025:2005

General requirements for the competence of testing and calibration laboratories.

STUDY REPORT

STUDY TITLE

Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay

Virus: Duck Hepatitis B virus

PRODUCT IDENTITY

Clinell Universal Wipes
UF3014

AUTHOR

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STUDY COMPLETION DATE

June 23, 2015

PERFORMING LABORATORY

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SPONSOR

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PROJECT NUMBER

A18512

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STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antiviral Properties of a Product Using a Virucidal Suspension Assay

Project Number: A18512

TRF Number: BLU01050715.DHBV

TEST SUBSTANCE IDENTITY

Test Substance: Clinell Universal Wipes

Lots/Batches: UF3014

STUDY DATES

Date Sample Received: May 18, 2015

Study Initiation Date: May 22, 2015

Experimental Start Date: June 8, 2015

Experimental End Date: June 19, 2015

Study Completion Date: June 23, 2015

TEST PARAMETERS

Dilution: Ready to use (RTU)

Virus: Duck Hepatitis B virus, strain 11/14/12

Exposure Time: 1 minute

Exposure Temperature: 20±2°C (21.0°C)

Organic Soil Load: 0.3g/L Bovine Albumin (final test concentration)

Test Medium: Test medium used in this study was Leibovitz L-15 medium supplemented with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin.

Indicator Cell Cultures: primary duck hepatocytes



EXPERIMENTAL SUMMARY

The liquid to be used in testing was expressed from five towelettes using a 20 mL syringe. A suspension of virus was exposed to the product. At the pre-determined exposure time an aliquot was removed, neutralized by serial dilution, and assayed for the presence of virus. The virus control, cytotoxicity control, and neutralization control were assayed in parallel. Antiviral properties of the product were evaluated and compared at the specified concentration and time interval. 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

Under the conditions of this investigation and in the presence of a 0.3g/L Bovine Albumin organic soil load, Clinell Universal Wipes (UF3014), ready to use, demonstrated a $\geq 99.98\%$ reduction in viral titer following a 1 minute exposure time to Duck Hepatitis B virus as compared to the titer of the corresponding virus control. The log reduction in viral titer was $\geq 3.75 \log_{10}$.



STUDY RESULTS

TABLE 1: Virus Control Results

Dilution	Virus Control
	Exposure Time 1 Minute
Cell Control	0 0 0 0
10 ⁻²	+ + + +
10 ⁻³	+ + + +
10 ⁻⁴	+ + + +
10 ⁻⁵	+ + + +
10 ⁻⁶	+ + + 0
10 ⁻⁷	0 0 0 0
TCID ₅₀ /250 µL	10 ^{6.25}

(+) = Positive for the presence of test virus

(0) = No test virus recovered and/or no cytotoxicity present



TABLE 2: Effects of Clinell Universal Wipes (UF3014) Against Duck Hepatitis B Virus in Suspension Following a 1 Minute Exposure Period

Dilution	Test: Duck Hepatitis B Virus + Clinell Universal Wipes
	Exposure Time 1 Minute
Cell Control	0 0 0 0
10 ⁻²	T T T T
10 ⁻³	0 0 0 0
10 ⁻⁴	0 0 0 0
10 ⁻⁵	0 0 0 0
10 ⁻⁶	0 0 0 0
10 ⁻⁷	0 0 0 0
TCID ₅₀ /250 µL	≤10 ^{2.50}
Percent Reduction	≥99.98%
Log Reduction	≥3.75

(0) = No test virus recovered and/or no cytotoxicity present

(T) = Cytotoxicity present



TABLE 3: Cytotoxicity and Neutralization Control Results

Dilution	Cytotoxicity Control	Neutralization Control
	Clinell Universal Wipes	Duck Hepatitis B Virus+ Clinell Universal Wipes
Cell Control	0 0 0 0	0 0 0 0
10 ⁻²	T T T T	T T T T
10 ⁻³	0 0 0 0	+ + + +
10 ⁻⁴	0 0 0 0	+ + + +
TCID ₅₀ /250 µL	10 ^{2.50}	Neutralized at ≤2.50 Log ₁₀

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

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6/23/15

 Date

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