



NON-GLP STUDY REPORT

STUDY TITLE

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

Virus: SARS-Related Coronavirus 2

PRODUCT IDENTITY

Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998)
Lot 4314

TRF NUMBER

BGP001060220.SARS2

AUTHOR

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STUDY COMPLETION DATE

July 9, 2020

PERFORMING LABORATORY

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PROJECT NUMBER

A29968



STUDY REPORT

GENERAL STUDY INFORMATION

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

Project Number: A29968

TRF Number: BGP001060220.SARS2

TEST SUBSTANCE IDENTITY

Test Substance: Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998)

Lot/Batch: Lot 4314

STUDY DATES

Date Sample Received: May 11, 2020

Study Initiation Date: June 19, 2020

Experimental Start Date: June 24, 2020

Experimental End Date: July 1, 2020

Study Completion Date: July 9, 2020

TEST PARAMETERS

Dilution: Ready to use (RTU)

Virus: SARS-Related Coronavirus 2, BEI Resources NR-52281, Strain Isolate USA-WA1/2020

Exposure Time: 30 seconds

Exposure Temperature: Room temperature (18.0°C)

Organic Soil Load: 1% fetal bovine serum

Test Medium: Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 2.0 mM L-glutamine, 0.1 mM NEAA and 1.0 mM sodium pyruvate

Indicator Cell Cultures: Vero E6



EXPERIMENTAL SUMMARY

A suspension of virus was exposed to the use dilution of 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 controls, cytotoxicity controls, and neutralization controls were assayed in parallel. To aid in the removal of the cytotoxic effects to the cell cultures the 10^{-2} dilution was passed through a Sephadex column utilizing the syringe plunger prior to titration, and then was also passed through one additional Sephadex column following titration. Antiviral properties of the product were evaluated and compared at the specified concentrations and time intervals.

CONCLUSION

Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998) [Lot 4314], ready to use, demonstrated a $\geq 99.9\%$ reduction in viral titer following a 30 second exposure time to SARS-Related Coronavirus 2 as compared to the titer of the corresponding virus control. The log reduction in viral titer was $\geq 3.00 \log_{10}$.



STUDY RESULTS

TABLE 1: Virus Control Results

Dilution	Virus Control
	Exposure Time 30 seconds
Cell Control	0 0 0 0
10 ⁻²	+ + + +
10 ⁻³	+ + + +
10 ⁻⁴	+ 0 + +
10 ⁻⁵	+ 0 0 0
10 ⁻⁶	0 0 0 0
10 ⁻⁷	0 0 0 0
TCID ₅₀ /100 µL	10 ^{4.50}

(+) = Positive for the presence of test virus

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



TABLE 2: Effects of Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998) [Lot 4314] Against SARS-Related Coronavirus 2 in Suspension Following a 30 Second Exposure Time

Dilution	Test: SARS-Related Coronavirus 2 + Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998) [Lot 4314]
	Exposure Time 30 seconds
Cell Control	0 0 0 0
10 ⁻²	0 0 0 0
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 /100 µL	≤10 ^{1.50}
Percent Reduction	≥99.9%
Log Reduction	≥3.00 log ₁₀

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



TABLE 3: Cytotoxicity and Neutralization Control Results

Dilution	Cytotoxicity Control	Neutralization Control
	Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998) [Lot 4314]	SARS-Related Coronavirus 2 + Biocence W.S. Liquid Botanical Human OTC Drug (NDC# 59998) [Lot 4314]
Cell Control	0 0 0 0	0 0 0 0
10 ⁻²	0 0 0 0	++++
10 ⁻³	0 0 0 0	++++
10 ⁻⁴	0 0 0 0	++++
TCD ₅₀ /100 µL	≤10 ^{1.50}	Neutralized at a TCID ₅₀ /100 µL of ≤1.50 Log ₁₀

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

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7-9-2020

 Date

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