



STUDY REPORT

Study Title

ASTM E1052: Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension

Product Identity

Cold Sore Night
Lot: RD09292021

Test Microorganism

Herpes simplex virus 1, HF strain, ATCC VR-260

Study Identification Number

NG18658

Author

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Study Completion Date

08NOV2021

Testing Facility

Microchem Laboratory
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Study Sponsor

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RESULTS (cont)

Table 3: Test Results for Lot: RD09292021

	Test Results – Lot: RD09292021		
	Replicate #1	Replicate #2	Replicate #3
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻²	0 + 0 0	0 0 0 0	0 0 0 0
10 ⁻³	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁴	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁵	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁶	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁷	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁸	0 0 0 0	0 0 0 0	0 0 0 0
TCID ₅₀ per 0.1 ml	1.75 log ₁₀	≤1.50 log ₁₀	≤1.50 log ₁₀
Avg. TCID ₅₀ per 0.1 ml	≤ 1.60 log ₁₀		
Log ₁₀ Reduction	≥5.32 log ₁₀		
Percent Reduction	≥ 99.9995 %		

Table 4: Test Substance Cytotoxicity and Neutralization Control Results

	Cytotoxicity	Neutralization
10 ⁻³	0 0 0 0	+ + + +
10 ⁻⁴	0 0 0 0	+ + + +
10 ⁻⁵	0 0 0 0	+ + + +
TCID ₅₀ per 0.1 ml	≤1.50 log ₁₀ *	≤1.50 log ₁₀

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed;
 T = Cytotoxicity observed; N/A = not applicable; † Taking cytotoxicity and neutralization controls into account;
 *Cytotoxicity control results reported as TCD₅₀ per 0.1 ml



STUDY CONCLUSION

The purpose of the study was to determine the virucidal efficacy of Cold Sore Night (Lot: RD09292021) against Herpes simplex virus 1, HF strain, ATCC VR-260, with no additional organic soil load supplementation, virus was tested as propagated., at a contact time of 1 hour and exposure temperature of room temperature (23.5–24.1 ° C and 36–38% RH).

The Virus Control demonstrated an average viral titer of 6.92 log₁₀ TCID₅₀ per 0.1 ml.

Taking the cytotoxicity and neutralization control results into consideration, the evaluated test substance, Cold Sore Night, demonstrated a ≥ 5.32 log₁₀ reduction ($\geq 99.9995\%$) in viral titer for Lot: RD09292021.

No test substance cytotoxicity was detected the lots of test substance assayed, ≤ 1.50 log₁₀ TCD₅₀ per 0.1 ml.

The Test Substance Neutralization Control demonstrated that the test substance was neutralized at ≤ 1.50 log₁₀ TCID₅₀ per 0.1 ml.