

Certificate of Analysis

Page 1 of 6 Analytical Report: AAK83329 Eurofins Sample Number: FQ20AA3579-1 Version: 1

Client Account Number: A00905133OBN Eurofins Quote Number: X9NBPH20008401

Offshoot (NZ) Ltd 34 Rosemont Road Waihi Waihi, 3610 NZ

Eurofins Sample Number FQ20AA3579-1

BioPharma Product Testing

Original Received Date: Description: Containers Submitted: 27-Aug-2020 Offshoot Wipes, 500mL 1 Bottle(s)

Analysis

Time Kill Test

Refer to Attachment # 1 Method: TMD 110, EN 1276 Analysis Date: 22-Oct-2020

Analysis Date: 22-061-2020

Testing of virucidal activity of disinfectants by surface carrier technique

Refer to Attachment # 2

Method: TMCV 006, ASTM E1053 Analysis Date: 29-Sep-2020

Supplemental Information

For FQ20AA3579-1:

Solution provided is added to wipes.

Instead of providing wipes for "squeezing" solution out, client has provided the solution added.

Eurofins BPT Testing Facility	Test
Eurofins ams Laboratories Pty Ltd	Testing of virucidal activity of disinfectants by surface
8, Rachael Close	carrier technique
Silverwater, NSW 2128	Time Kill Test
AUSTRALIA	

Contracted Company: Eurofins BioPharma Product Testing NZ Ltd

35 O'Rorke Road, Penrose, Auckland 1061 New Zealand nzbiopharma@eurofins.com

Medsafe GMP certificate number TT60-200-16-3

Questions about this report should be directed to your project manager or the general email listed above.



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Reviewed and electronically signed for Data Reviewer Approval by Teresa Susanto, Laboratory Manager- Sterility for Eurofins ams Laboratories Pty Ltd, on 06-Nov-2020 17:39:58 UTC+13:00 Reviewed and electronically signed for Project Manager Authorized by Derek Radford, Business Unit Manager for Eurofins BioPharma Product Testing NZ Ltd, on 09-Nov-2020 08:51:55 UTC+13:00

Test Conditions		
Test Concentration	Neat	
Contact Time	5 Minutes	
Neutraliser/ Dilution	T6 1:10	
Test Conditions	Dirty (0.3% BSA)	
Test Temperature	Room Temperature	

<u>RESULTS</u>

Table 1: Surviving organisms after exposure to the Product under Test				
	Inoculum Control Count	Surviving Test Organisms 5 Minutes		
Organism				
	CFU/mL	CFU/mL	Log reduction	
	(Log ₁₀)	(Log ₁₀)	Log reduction	
MRSA	7.15 x 10 ⁷	<10		
ATCC 33591	(7.85)	<(1.00)	>6.85	
K.pneumoniae	3.75 x 10 ⁷	<10		
ATCC 2146	(7.57)	<(1.00)	>6.57	
C.albicans	1.02 x 10 ⁷	<10	>C 01	
ATCC 10231	(7.01)	<(1.00)	>6.01	
Aspergillus	4.20 x 10 ⁶	2.75 x 10 ²	4.18	
ATCC 16404	(6.62)	(2.44)	4.10	
S.aureus	2.50 x 10 ⁷	<10	>6.40	
ATCC 6538	(7.40)	<(1.00)	~0.40	

E.coli	2.40 x 10 ⁷	<10	NG 29	
NCTC 10538	(7.38)	<(1.00)	>6.38	
P.aeruginosa	4.70 x 10 ⁷	<10	>6.67	
ATCC 15442	(7.67)	<(1.00)	>0.07	
S.typhimurium	1.04 x 10 ⁸	<10	>7.02	
	(8.02)	<(1.00)	>1.02	
L.monocytogenes	3.25 x 10 ⁷	<10	>6.51	
	(7.51)	<(1.00)		

CFU = Colony Forming Unit

Table 2 Neutralisation Validation Results					
Organisms	Validation suspension (Nv)	Experimental condition (A)	Neutralizer control (B)	Method validation (C)	Pass/Fail
MRSA ATCC 33591	38	52	50	56	Pass
K.pneumoniae ATCC 2146	36	35	40	35	Pass
<i>C.albicans</i> ATCC 10231	10	10	9	11	Pass
Aspergillus ATCC 16404	5	6	9	10	Pass
S.aureus ATCC 6538	36	34	40	39	Pass

E.coli	25	28	24	37	Pass
NCTC 10538	23	20	21		1 435
P.aeruginosa	36	42	34	34	Pass
ATCC 15442					
S.typhimurium	55	65	52	37	Pass
L.monocytogenes	86	62	50	79	Pass

A, B & C must be \geq 0.5Nv

COMMENTS: The product showed greater than 6 log reduction against MRSA, *K.pneumoniae, C.albicans, S.aureus, E.coli, P.aeruginosa* and *L.monocytogenes,* greater than 7 log reduction against *S.typhimurium* and 4.18 log reduction against *Aspergillus* at 5 Minutes contact time.

CONDITIONS						
Virus Strain	Murine hepatitis virus (MHV) -1 ATCC/VR-261					
Cell Substrate	A9 cells ATCC/CCL- 1.4					
Test Concentration	Neat					
Contact Time	10 minutes					
Test Temperature	Room temperature					
Test Condition	Dirty 5% FBS (Fetal Bovine Serum)					
Neutraliser	3 cc Sephadex Gel in PBS (Phosphate Buffer Saline)					

RESULTS: TABLE 1: MHV-1 test/control results for 10 minutes contact

Virus Dilution	Number of Inoculated Wells	Virus Control	Cytotoxicity	Neutralisation	Test Sample
10-1	4	4+/4	С	С	С
10-2	4	4+/4	С	С	С
10 ⁻³	4	4+/4	0+/4	4+/4	0+/4
10-4	4	4+/4	N/A	N/A	0+/4
10 ⁻⁵	4	4+/4	N/A	N/A	0+/4
10 ⁻⁶	4	2+/4	N/A	N/A	0+/4
10-7	4	2+/4	N/A	N/A	N/A
10 ⁻⁸	4	1+/4	N/A	N/A	N/A
Log ₁₀	-	6.75	2.5	2.5	2.5
Log ₁₀ Reduction of Virus after Treatment			4.2	5	

Note: Presence of virus in each response is recorded as "+" Absence of virus in each response is recorded as "0" Cytotoxic response is recorded as "C" Calculated virus titre = 10^{6.75}TCID_{50/0.1ml} (6.75 log₁₀) Cell control - 4 wells with healthy cell monolayer

* The Reed & Muench LD50 Method was used for determining the virus titre endpoint.

CONCLUSIONS:

Considering the cytotoxicity and neutralisation test results, the sample has shown virucidal efficacy against MHV-1 by achieving 4.25 log reduction in virus concentration after 10 minutes exposure period at room temperature.