Analytical Report: ABE59366
Eurofins Sample Number: NJ23AA8083-1
Version: 1

Nuvoe Pty Ltd
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Alexandria, NSW 2015
AU

Client Account Number: A01509847177
Eurofins Quote Number: XC8UPH23002601

Eurofins Sample Number NJ23AA8083-1

Original Received Date:	21-Feb-2023
Description:	GLP Report for Nuvoe Pod & Bottle - UV-C Water Purifier Efficacy Study
Containers Submitted:	1 Unit(s)

Analysis

Protocol or Final Report Writing

Refer to Attachment # 1

Method: Protocol
Analysis Date: 29-Mar-2023

Supplemental Information

Samples were tested as received. Specifications (if) reported are as provided by the client.

Contracted Company: Eurofins ams Laboratories (Sydney)

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SampleReceiptAMS@eurofins.com

TGA Licence No: MI-2021-LI-08995-1 APVMA Licence No: 6241
Questions about this report should be directed to your project manager or the general email listed above.

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EFFICACY STUDY OF NUVOE POD AND BOTTLE
STUDY REPORT

This study was undertaken to assess the Nuvoe Pod & Bottle efficacy against *Escherichia coli* and hence qualify its use as a water purifier. This study followed AS/NZS 4276.7 and client's approved protocol No. NJ23AA1847-1. Triplicate testing was performed on three individual Nuvoe Pod & Bottle systems on 'Bottle' mode. An average of 4 log reductions (99.994%) of the challenge organism was achieved in this study.

Devices Submitted for the study
1x NUV121LWW Nuvoe Pod & Bottle – Lunar White (Lot #A)
2x NUV121MBQ Nuvoe Pod & Bottle – Midnight Black (Lot #B/C)

INTRODUCTION

This study was undertaken to assess the Nuvoe Pod & Bottle efficacy against *Escherichia coli* and hence qualify its use as a water purifier. This study followed AS/NZS 4276.7 and client's approved protocol No. NJ23AA1847-1. Triplicate testing was performed on three individual Nuvoe Pod & Bottle systems using the 3-minute Deep Clean UV-C cycle.

This study was carried out by Eurofins BioPharma Product Testing – Sydney (Eurofins ams Laboratories Pty Ltd), 179 Magowar Road, GIRRAWEEN, NSW 2145 Australia. Eurofins ams Laboratories Pty Ltd is licensed by the Australian Therapeutic Goods Administration for analysis and testing (Licence No: MI-2021-LI-08995-1) and GMP Licence No. MI-2022-LI-06073-1, Australian Pesticide and Veterinary Medicines Authority (Licence No. 6241), registered with Food and Drug Administration USA (DUNS No. 754742088 and Facility Establishment Identifier No. 3006635869). Certified by the office of Gene Technology Regulator (PC2 Laboratory) (Certificate No. 4820).

METHOD

Organisms preparation

E.coli ATCC 11775 was obtained from Eurofins ams Laboratories culture curator, its ID was confirmed prior to use. The culture was sub-culured onto TSA plate and incubated at 37°C±2°C for 18-24 hours. The growth was then suspended in PEP to make bacterial test suspension of approximately 10^8CFU/mL (N). Validation suspension (Nv) was prepared by diluting the test suspension (N) in PEP to obtain 10-100CFU. Both test suspension (N) and validation suspension (Nv) were prepared on the day of use.

Device preparation

Each of the bottles were sanitized prior to use using 2% Proxitane for 30 minutes and were rinsed three times in sterile de-ionised water (DW). Each of the Pods were sprayed with 70% Ethanol and left to dry in BSC prior to use.

Efficacy Test

Efficacy testing was performed on each of the three Nuvoe Pod & Bottles, labelled as Lot "A", "B", and "C" – see Figure 1. Neutralisation validation, Negative and triplicate Positive controls were also performed as part of the study.

The Pod was set to 'Bottle Mode' and installed into the Bottle. Each Bottle was filled with 600mL of *E.Coli* inoculated water. It was then shaken for 6 seconds to activate the 3 minute "Deep Clean" UV-C cleaning cycle. At the end of the cycle, serial dilutions were prepared, filtered, plated and then incubated for 36-48 hours at 37°C±2°C. All colonies recovered from each plate were then counted and recorded.

Figure 1: Nuvoe Pod and Bottle systems

RESULTS

Neutraliser study

The Neutralisation study showed 48CFU was inoculated and 47CFU was recovered in the Neutralisation validation. Therefore, rinsing once with 50mL Peptone Tween Water (PTW) has successfully shown to be a suitable method in recovering surviving organism (calculated recovery rate was 97.92%). Refer to Table 1 for result.

Efficacy study

An average of 3.05 x 10^6 CFU/mL *E.coli* was inoculated into each of the three Nuvoe Pod & Bottles. The average recovered surviving organism at the end of the "Bottle" mode was 1.92 x 10^2 CFU/mL. Therefore the calculated average log reduction was 4.20 (99.994%). Refer to Table 2 for result.

Table 1. Neutralisation Validation

RESULT		
Positive control (CFU)	**Validation count (CFU)**	**Recovery rate (%)**
48	47	97.92
Validated method	Wash once with 50mL of PTW	

Table 2. Efficacy Test Results

<table>
<tr><th colspan="6">RESULT</th></tr>
<tr><th colspan="3">Positive Control</th><th colspan="3">Test result</th><th rowspan="2">Log reduction (% Reduction)</th></tr>
<tr><th>Replicate</th><th>CFU/mL</th><th>Average (CFU/mL) (log_{10})</th><th>Batch</th><th>CFU/mL</th><th>Average (CFU/mL) (log_{10})</th></tr>
<tr><td>1</td><td>2.95 x 10^6</td><td rowspan="3">3.05 x 10^6 (6.48)</td><td>A</td><td>1.89 x 10^2</td><td rowspan="3">1.92 x 10^2 (2.28)</td><td rowspan="3">4.20 (99.994)</td></tr>
<tr><td>2</td><td>3.15 x 10^6</td><td>B</td><td>2.38 x 10^2</td></tr>
<tr><td>3</td><td>3.05 x 10^6</td><td>C</td><td>1.50 x 10^2</td></tr>
<tr><td colspan="5">Negative control (CFU)</td><td colspan="2"><1</td></tr>
</table>

Conclusion

Each of the three Nuvoe Pod & Bottles had achieved a minimum of 4 log reductions when challenged with 6 log of *E.coli* and run using the 3 minute 'Deep Clean' UV-C cycle.

There were no growth obtained from the Negative control, indicating the Nuvoe Pod and Bottle were sufficiently sanitised.

All three Positive controls obtained at least 10^6 CFU/mL, indicating a sufficient organism was used.

Neutralisation validation study obtained a recovery of 97.92%, indicating the recovery method used within the study was suitable.