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FINAL REPORT

ANTIMICROBIAL SUSCEPTIBILITY TEST - ZONE OF INHIBITION

PROCEDURE NO. STP0124 REV 01
PROTOCOL DETAIL SHEET NO. 200803429 REV 01

LABORATORY NO. 452816

PREPARED FOR:

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QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58) [ ] USEPA (40 CFR PART 160)

ANTIMICROBIAL SUSCEPTIBILITY TEST - ZONE OF INHIBITION

LABORATORY NO. 452816

1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above.

2. In accordance with the Good Laboratory Practice Regulations, the Zone Measurement phase(s) of this study was inspected by the Quality Assurance Unit on: 09 Jan 2009. The findings of the inspection(s) were reported to the Study Director and to Management on: 12 Jan 2009.

3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard testing procedures are accurately described, and that the reported results accurately reflect the raw data.

4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

Michael Neilson
Wellance T. Naeata
Dr. Jerry Nelson
Jeff Hills

QUALITY ASSURANCE: _____ DATE: 14 Jan 2009

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ANTIMICROBIAL SUSCEPTIBILITY TEST - ZONE OF INHIBITION

LABORATORY NUMBER:	452816
PROCEDURE NUMBER:	STP0124 REV 01
PROTOCOL DETAIL SHEET NUMBER:	200803429 REV 01
SAMPLE SOURCE:	EnzySurge
SAMPLE IDENTIFICATION:	Refer to Tables 1-2 P.O. #1008
DEVIATIONS:	None
PROTOCOL APPROVAL DATE:	16 Dec 2008
SAMPLE RECEIVED DATE:	26 Nov 2008
LAB PHASE START DATE:	16 Dec 2008
LAB PHASE COMPLETION DATE:	12 Jan 2009
REPORT ISSUE DATE:	13 Jan 2009

INTRODUCTION:

This report details the procedures used for screening products for antimicrobial activity. The challenge organisms for this study were *Staphylococcus aureus*, ATCC #6538, and *Escherichia coli*, ATCC #8739. The test procedure was an adaptation of the disk diffusion (Kirby-Bauer) method for antibiotic susceptibility testing.

PROCEDURES:

Culture Preparation: Mueller-Hinton broth was inoculated with *S. aureus* and *E. coli* from stock cultures and incubated for 18-24 hours at 30-35°C. The test organisms were standardized using physiological saline to achieve a cell density equivalent to a McFarland Standard of 0.5. The inoculum was used within 15 minutes after standardization.

Test Performance: A sterile cotton swab was dipped into the standardized inoculum, rotated several times, and pressed firmly on the inside wall of the tube above the fluid level to remove excess inoculum from the swab. The swab was streaked over the entire surface of the Mueller-Hinton agar plate three times, with the plate rotated approximately 60° each time, then a final sweep was made around the agar rim. The lid was left ajar for no longer than 15 minutes to allow any excess surface moisture to be absorbed. Sterile disks were placed on the agar plates using a pair of sterile forceps. One disk was placed in the center of each plate, pressing firmly so that the sample stayed in place and contacted the agar surface evenly. Each disk was inoculated with approximately 0.1 mL of the sample. For the negative controls, each disk was inoculated with sterile purified water.

The plates were incubated at 30-35°C for approximately 24 hours. The samples were transferred to freshly prepared plates and incubated for approximately 24 hours. This procedure was repeated until plates showed no zone of inhibition. The diameters of the zones of inhibition (if present) for each product were measured using calibrated calipers sensitive to 0.01 mm. The complete zone of inhibition, including the diameter of the sample, was measured.

RESULTS:

Test results can be found in Tables 1-2.

CONCLUSION:

Interpretation of the data is the responsibility of the sponsor and no conclusion can be made by Nelson Laboratories, Inc. (NLI).

DATA DISPOSITION:

The raw data and final report from this study are archived at NLI or an approved off-site location.

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

Technical Reviewer

Wellance T. Naeata, B.S.
Study Director

13 Jan 2009
Study Completion Date

jzw

TABLE 1. Results
Zone of Inhibition Measurements
Sample Identification: Silver Stream Lot #SIL-001271008
Silver Buffered Solution 250ml Active ingredient: Each ml contains Silver Nitrate 0.1mg
Time Point: 24 hours

TEST ORGANISM		DIAMETER OF THE ZONE INCLUDING SAMPLE (mm)
Staphylococcus aureus ATCC #6538	1	16.24
	2	16.34
	3	15.33
Escherichia coli ATCC #8739	1	14.14
	2	16.28
	3	12.53

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EnzySurge
Lab Number 452816

Antimicrobial Susceptibility Test - Zone of Inhibition

TABLE 2. Results
Zone of Inhibition Measurements
Sample Identification: Silver Stream Lot #SIL-001271008
Silver Buffered Solution 250ml Active ingredient: Each ml contains Silver Nitrate 0.1mg
Time Point: 48 hours

TEST ORGANISM		DIAMETER OF THE ZONE INCLUDING SAMPLE (mm)
Staphylococcus aureus ATCC #6538	1	No Zone
	2	No Zone
	3	No Zone
Escherichia coli ATCC #8739	1	No Zone
	2	No Zone
	3	No Zone