NELSON LABORATORIES

Sponsor:
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Antimicrobial Susceptibility Test - Zone of Inhibition GLP Report

Test Article:	Batch #SSG241017
Purchase Order:	1728
Study Number:	999694-S01
Study Received Date:	30 Oct 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0124 Rev 02 Customer Specification Sheet (CSS) Number: 201707795 Rev 01
Deviation(s):	None

Summary: 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.

Results:

Zone of Inhibition Measurement:

Test Organism	Test Article Replicate	Diameter of the Zone Including Test Article (mm)
S. aureus	1	19.28
	2	18.87
	3	18.88
	Control 1	No Zone
	Control 2	No Zone
	Control 3	No Zone
E. coli	1	15.82
	2	20.14
	3	17.26
	Control 1	No Zone
	Control 2	No Zone
	Control 3	No Zone

Study Director — Wellance T. Naeata, B.S.

26 Jan 2018
Study Completion Date

999694-S01

Test Method Acceptance Criteria: The data are reported by Nelson Laboratories, LLC (NL) and the sponsor performs any statistical analysis and determines the acceptance criteria.

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 Sterile water (PURW) to achieve a cell density equivalent to a 0.5 McFarland standard.

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 3 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. The test article was applied to a sterile disk and placed on the agar plates using a pair of sterile forceps. For the negative control plates, a disk was placed on each agar plate and inoculated with PURW. The plates were incubated at 30-35°C for 18-24 hours. The diameters of the zones of inhibition (if present) for each product were measured using calibrated calipers. The complete zone of inhibition, including the diameter of the test article, was measured.

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Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	15 Jan 2018
Phase Inspected by Quality Assurance: Sample Plating	22 Jan 2018
Audit Results Reported to Study Director	23 Jan 2018
Audit Results Reported to Management	23 Jan 2018

Scientists	Title
Thomas Pace	Supervisor
Wellance Naeata	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

26 JAN 2018
Date

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