GENEVA
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FOR THE MEDICAL INDUSTRY WORLDWIDE
P.O. Box 140 • 1001 Proctor Drive • Elkhorn, WI 53121-0140
Phone: (262) 723-5669 • **Fax:** (262) 723-4015
www.genevalabs.com

SteriWeb Medical, LLC

Omnicide PHMB (0.5%) Gel
Lot No.: N/A

Antimicrobial Effectiveness Test (USP)
(GLP)

December 9, 2013

JN13J1514

The following results/conclusions relate only to the items tested. This report cannot be reproduced except in full without the written approval of the testing laboratory.

JN13J1514

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SECTION 1

TEST PROTOCOL

GLP0002*

JN13J1514

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GLP PROTOCOL

Antimicrobial Effectiveness Test
(USP)

SPONSOR: SteriWeb Medical, LLC
6715 NE 63rd Street, Suite 417
Vancouver, WA 98661

P.O. NO.: Bradley Burnam

TEST ARTICLE: Omnicide PHMB (0.5%) Gel

LOT/ID.: N/A

Signing of this protocol constitutes your approval of the procedure outlined on the following pages.

STUDY DIRECTOR: Maribeth A. Cousin
Dr. Maribeth Cousin
Study Director/Sp. Microbiology
Geneva Laboratories, Inc.

STUDY INITIATION DATE: 10/29/13

SPONSOR: Bradley Burnam
SteriWeb Medical, LLC

DATE: 10/30/13

13-111

GENEVA LABORATORIES, INC.

PROTOCOL FOR ANTIMICROBIAL EFFECTIVENESS TEST

Title 21 CFR Part 58
Good Laboratory Practice for a Nonclinical Laboratory Study

§ 58.120 PROTOCOL

1). TITLE

USP Antimicrobial Effectiveness Test
Geneva Laboratories Procedure No.: MI1007*

2). PURPOSE

To demonstrate the effectiveness of the antimicrobial system in a test article.

3). IDENTIFICATION OF

	Name	CAS/Code (Lot No.)
Test Article:	Omnicide PHMB (0.5%) Gel	N/A

4). SPONSOR

SteriWeb Medical, LLC
6715 NE 63rd Street, Suite 417
Vancouver, WA 98661
ATTN.: Mr. Brad Burnam

*Denotes Current Revision

5). TEST FACILITY

Geneva Laboratories, Inc.
Proctor Drive at McKenzie Lane
P.O. Box 140
Elkhorn, WI 53121-0140

6). TEST SYSTEM

Pseudomonas aeruginosa (ATCC 9027)
Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 8739)
Candida albicans (ATCC 10231)
Aspergillus brasiliensis (ATCC 16404)
Additional Microorganisms included in AET at the request of the customer:
Vancomycin-Resistant Enterococci (VRE) [*Enterococcus faecalis* (ATCC 700802)]
Carbapenem-Resistant Enterobacteriaceae (CRE) [*Klebsiella pneumoniae* (ATCC BAA-1705)]
Methicillin-Resistant *Staphylococcus aureus* (MRSA) [*Staphylococcus aureus* (ATCC 33591)]

7). TEST SYSTEM IDENTIFICATION

Each tube or other container will be marked with markers or labeled tape.

8). DESCRIPTION OF EXPERIMENTAL DESIGN

Three of the five USP indicator microorganisms address the growth of bacteria, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Escherichia coli*. *Candida albicans* is a representative yeast and *Aspergillus brasiliensis* is a mold. The microorganisms are harvested under the current USP guidelines to assure viability. The following microorganisms will be added to the AET at the request of the customer: VRE *Enterococcus faecalis*, CRE *Klebsiella pneumoniae*, and MRSA *Staphylococcus aureus*.

The test article is inoculated at a concentration of 1×10^5 to 1×10^6 CFU microorganisms per unit of product. At 14 and 28 days after inoculation, a portion of the test article as determined by validation is plated to determine the viability of the microorganisms. Molten, tempered Tryptic Soy Agar with Lecithin and Polysorbate 80 is used for bacterial counts and molten, tempered Sabouraud Dextrose Agar is used for fungal counts. The plates are gently swirled and allowed to solidify.

The Tryptic Soy Agar plates are incubated at 32.5 ± 2.5°C for 3-5 days and the Sabouraud Dextrose Agar plates are incubated at 22.5 ± 2.5°C for 3-7 days. After incubation, each plate is counted to determine the number of CFU present. The counts are averaged and multiplied by the dilution factor that was necessary to achieve a count close to 30 to 300 CFU per plate.

The bacterial counts, under Category 2, must not have less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days. For the yeast and mold counts, there must be no increase from the initial calculated count at 14 and 28 days.

9.) SAMPLE SIZE OF TEST AND CONTROL ARTICLES

Twenty grams of sample per microorganism.

10). DOSAGE OF TEST AND CONTROL ARTICLES

N/A

11). TYPE AND FREQUENCY OF TEST MEASUREMENTS

The sponsor has determined the test article to fall under Category 2. This sets the frequency of testing at 14 and 28 days after inoculation.

12). RECORDS TO BE MAINTAINED

All raw data that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of that study will be maintained in the Geneva Laboratories archives.

13). PROPOSED STATISTICAL METHODS

Duplicate platings are done and the results are averaged.

14). REVISIONS TO PROTOCOL

All changes in or revisions of an approved protocol and the reasons for the change will be documented, signed and dated by the Study Director and maintained with the protocol.

SECTION 2

TEST REPORT/STUDY PERSONNEL

JN13J1514
PE-2-F

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REPORT TO: Mr. Brad Burnam
SteriWeb Medical, LLC
6715 NE 63rd Street, Suite 417
Vancouver, WA 98661

TEST ARTICLE: Omnicide PHMB (0.5%) Gel

P.O. NO.: Bradley Burnam

DATE RECEIVED/INITIATED/COMPLETED: 10-28-13 | 11-05-13 | 12-06-13

TEST PROCEDURE: USP Antimicrobial Effectiveness Test (GLP)
Ref. Geneva Laboratories Proc. No. MI1007K
and Ref. Validation JN13J1515

CONCLUSION: The preservative is effective as defined by the criteria in USP <51> for Category 2.

1. Bacteria
   Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.
2. Yeast and Mold
   No increase from the initial calculated count at 14 and 28 days.

Vancomycin-resistant enterococci (VRE) [*Enterococcus faecalis* (ATCC 700802)], carbapenem-resistant Enterobacteriaceae (CRE) [*Klebsiella pneumoniae* ATCC BAA-1705)], and methicillin-resistant *Staphylococcus aureus* (MRSA) [*Staphylococcus aureus* (ATCC 33591)] were added to the AET.
See results on page 2.

ANALYST: Kimberly Rader DATE: 12-6-13

ACCEPTED BY: Maribeth A. Cousin DATE: 12/06/13
Technical Reviewer

Q.A. SIGNATURE: Chelsea Rodriguez DATE: 12-9-13

The following results/conclusions relate only to the items tested. This report cannot be reproduced except in full without the written approval of the testing laboratory.

JN13J1514

	S. aureus	E. coli	P. aeruginosa	C. albicans	A. brasiliensis	S. aureus (MRSA)	E. faecalis (VRE)	K. pneumoniae (CRE)
Initial count (CFU/mL)	445,000	467,500	530,000	450,000	240,000	152,500	322,500	465,000
Initial Log	5.6484	5.6698	5.7243	5.6532	5.3802	5.1833	5.5085	5.6675
DAY 14 CFU/g recovered	<100	<100	<100	<100	3,150	<100	<100	<100
log	2.0000	2.0000	2.0000	2.0000	3.4983	2.0000	2.0000	2.0000
log reduction from initial	3.65	3.67	3.72	3.65	1.88	3.18	3.51	3.67
DAY 28 CFU/g recovered	<100	<100	<100	<100	2,850	<100	<100	<100
log	2.0000	2.0000	2.0000	2.0000	3.4548	2.0000	2.0000	2.0000
log reduction from initial	3.65	3.67	3.72	3.65	1.93	3.18	3.51	3.67

GENEVA LABORATORIES, INC.

Sp. Microbiology Department
Test Personnel

Dr. Maribeth Cousin -- Director of Special Microbiology

Kimberly Restivo -- Analyst

Chelsea Rodriguez -- QA Special Microbiology

Justin Lien -- QA/QC Supervisor

SECTION 3

QUALITY ASSURANCE AUDIT REPORT & STATEMENT

GENEVA LABORATORIES, INC.
GLP AUDIT SCHEDULE REPORT, TEST ID AND CERTIFICATION

SPONSOR: SteriWeb Medical, LLC
6715 NE 63rd Street, Suite 417
Vancouver, WA 98661

TEST ARTICLE: Omnicide PHMB (0.5%) Gel
Lot No. N/A

NATURE OF STUDY: Antimicrobial Effectiveness Test (USP)

REFERENCE: Geneva Laboratories Procedure No.: MI1007K

TEST SYSTEM: *Pseudomonas aeruginosa* (ATCC 9027), *Aspergillus brasiliensis* (ATCC 16404), *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 8739), *Candida albicans* (ATCC 10231), Additional Microorganisms included in AET at the request of the customer: Vancomycin-Resistant Enterococci (VRE) [*Enterococcus faecalis* (ATCC 700802)], Carbapenem-Resistant Enterobacteriaceae (CRE) [*Klebsiella pneumoniae* (ATCC BAA-1705)], Methicillin- Resistant *Staphylococcus aureus* (MRSA) [*Staphylococcus aureus* (ATCC 33591)]

TEST STATUS:
Study Initiated: 10-29-13
Test Initiated: 11-05-13
Test Completed: 12-06-13
Study Completed: 12-09-13

AUDIT DATES: See Table I

COMMENTS INCLUDING DEVIATIONS AND PROBLEMS: Under the condition of the study, the preservative is effective as defined by the criteria in USP <51> for category 2. Three (3) additional microorganisms were added to the study per sponsor request.

My review of the study documents indicates that the facilities, equipment, personnel, methods, practices, records and controls are in conformance with the GLP Regulations. This final report accurately describes the methods and standard operating procedures used and the raw data generated during the course of the study.

The copies of the protocols and records of Quality Assurance inspections have been transferred to the Geneva Laboratories GLP archive and will be maintained as long as indicated in 21 CFR Part 58 §58.195 paragraph a) and b).

QA INSPECTOR: _____ DATE: 12.9.13

QA SIGNATURE: _____ DATE: 12.9.2013

TABLE I

QUALITY ASSURANCE AUDIT DATES

INSPECTED BY INSPECTION DATE	STUDY SEGMENT INSPECTED	DATE FINDINGS WERE WRITTEN FOR MANAGEMENT AND STUDY DIRECTOR
C.R./11-05-13	Sample Preparation and Inoculation	11-05-13
C.R./11-19-13	Day 14 Plating	11-19-13
C.R./11-22-13	Day 14 Plate Count	11-22-13
C.R./12-03-13	Day 28 Plating	12-06-13
C.R./12-06-13	Day 28 Plate Count	12-06-13
C.R./12-09-13	Raw Data Review	12-09-13
C.R./12-09-13	Final Report Review	12-09-13

*C.R. Chelsea Rodriguez

QA AUDITOR: Chelsea Rodriguez DATE: 12.9.13

QA MANAGEMENT: _____ DATE: 12.9.2013

SECTION 4

COMPLIANCE/ARCHIVE STATEMENTS

GLP0001*

GENEVA LABORATORIES, INC.
STUDY DIRECTOR COMPLIANCE STATEMENT

SPONSOR: SteriWeb Medical, LLC
6715 NE 63rd Street, Suite 417
Vancouver, WA 98661

PROTOCOL: Antimicrobial Effectiveness Test (USP)

TEST ARTICLE: Omnicide PHMB (0.5%) Gel
Lot No. N/A

STUDY INITIATION DATE: 10-29-13 STUDY COMPLETION DATE: 12-09-13

After a review of the pertinent raw data, I am led to conclude the test results were accurately recorded and verified, correctly analyzed, interpreted and all applicable GLP Regulations of 21 CFR Part 58 for Non-Clinical Laboratory Studies were followed.

All raw data, documentation, protocols, specimens and final reports are retained for orderly storage and expedient retrieval as recommended in the 21 CFR Part 58 §58.190.

STUDY DIRECTOR: Maribeth A. Cousin DATE: 12/09/13
Sp. Microbiology

GLP0002*

GENEVA LABORATORIES, INC.
GLP COORDINATOR ARCHIVE STATEMENT

SPONSOR: SteriWeb Medical, LLC
6715 NE 63rd Street, Suite 417
Vancouver, WA 98661

PROTOCOL: Antimicrobial Effectiveness Test (USP)

TEST ARTICLE: Omnicide PHMB (0.5%) Gel
Lot No. N/A

STUDY INITIATION DATE: 10-29-13 STUDY COMPLETION DATE: 12-09-13

For the purpose of information retrieval, we are informing you of our storage procedure of specimens and records.

Specimens and a copy of the final report are stored in the archives of Geneva Laboratories, Inc. Fragile specimens will be retained so long as the quality of the preparation affords evaluation.

Raw data for the above listed test compiled by Geneva Laboratories is stored at Geneva Laboratories (or an alternate archive location) for not less than five (5) years.

GLP COORDINATOR: Lori Smith DATE: 12.9.13