



Ensuring Medical Device
Safety and Compliance™

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Confidential
MG120-000

GARY W. WINCH
SELECT FABRICATORS, INC
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PALMYRA, NY

14522

Lab No. 03G 07684 00
P.O. No. 283
ID No. 1176-BGJ GLP
Lot 102703 MT
Revised Page

REVISED REPORT
DETERMINING ANTIMICROBIAL ACTIVITY OF IMMOBILIZED ANTIMICROBIAL AGENTS
(ASTM E2149-01) (GLP)

Test Article: MedTex 180

The test article was received on 10-31-03.

Sample Size: $1.00 \pm 0.01\text{g}$
Target Inoculum Level: $(1.5 - 3.0) \times 10^5 \text{ CFU/ml}$

Sample Identification / Test Organisms	Organism Count (CFU/ml)		Percent Reduction
	Zero Time	24 Hour	
MedTex 180 / <i>Staphylococcus aureus</i> ATCC 6538	1.8×10^5	< 10	99.99
<i>S. aureus</i> Control	1.9×10^5	7.9×10^5	NR
MedTex 180 / <i>Pseudomonas aeruginosa</i> ATCC 9027	1.5×10^5	1.6×10^3	98.93
<i>P. aeruginosa</i> Control	1.7×10^5	1.5×10^7	NR
MedTex 180 / <i>Escherichia coli</i> ATCC 8739	1.9×10^5	< 10	99.99
<i>E. coli</i> Control	1.9×10^5	2.1×10^7	NR
MedTex 180 / <i>Staphylococcus aureus</i> ATCC 33591	2.1×10^5	< 10	99.99
<i>S. aureus</i> Control	2.2×10^5	4.8×10^5	NR
MedTex 180 / <i>Enterococcus faecalis</i> ATCC 51575	2.1×10^5	< 10	99.99
<i>E. faecalis</i> Control	2.0×10^5	1.4×10^5	30.00
MedTex 180 / <i>Candida albicans</i> ATCC 10231	1.7×10^5	< 10	99.99
<i>C. albicans</i> Control	1.7×10^5	1.8×10^5	NR

NR = No Reduction



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Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

Comment: Stability Testing: Marketed Product Stability characterized by its labeling. (per sponsor).
Expiration Date: Stable for duration of testing (per sponsor).
Sample Disposition: Any remaining sample was retained in NAMSA archives.

The study initiated by Protocol Lab No. 03G 07684 00 signature on 11-24-03 was conducted in accordance with the Provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR58. A certificate of Quality Assurance Inspections was issued with this report.

This report has been revised to include the GLP stability and disposition statements. The conclusions are not affected.

Record Storage: All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

Test Facility: NAMSA, 3400 Cobb International Blvd., Kennesaw, GA 30152-7601

jsm

Date Completed 12-18-03

Approved By


Season A. Weaver, B.S., M.S.