

PRESERVATIVE CHALLENGE TEST

for SkinTegrity™ Hydrogel

Microconsultant, Inc.
Study Number MC-613-94

MICROCONSULT, INC.

ANTIMICROBIAL PRESERVATIVE EFFICACY TEST

DATE July 8, 1994

Study: MC-613-94

Swiss American Products
2315 Alpha Rd.
Dallas, Tx. 75244
Mr. Bill Kling

TEST MATERIAL: Eutra/Elta Dermal Gel for Wound Dressing
PRODUCT NUMBER: Lot 4255
METHOD REFERENCE MC-10

Starting Date for Preservative Efficacy Test: 6/06/94

	E. coli ATCC 8739	S. aureus ATCC 6538	P. aerug. ATCC 9027	C.albicans ATCC 10231	A. niger ATCC 16404
Inoc. level:	4.50×10^{-6}	6.1×10^{-6}	9.2×10^{-6}	8.0×10^{-5}	3.0×10^{-5}
DAY 7 COUNT	<10	<10	<10	<10	<10
DAY 14 COUNT	<10	<10	<10	<10	<10
DAY 21 COUNT	<10	<10	<10	<10	<10
DAY 28 COUNT	<10	<10	<10	<10	<10
PASS/FAIL	PASS	PASS	PASS	PASS	PASS

The sample meets the U.S.P. XXII requirements for Antimicrobial Preservative Effectiveness.

Analyst: *William F. Bryan*

Date: *7-8-94*

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Study # MC61394
Date Inoculated 6/06/94

	DAY 7 COUNTS 6/17/94				
	E. coli	S. aureus	P.aerug.	C.albic.	A.niger
Dermal Gel for Wound Dressing 4225	<10	<10	<10	<10	<10
	DAY 14 COUNTS 6/24/94				
	E. coli	S. aureus	P.aerug.	C.albic.	A.niger
Dermal Gel for Wound Dressing 4225	<10	<10	<10	<10	<10
	DAY 21 COUNTS 7/01/94				
	E. coli	S. aureus	P.aerug.	C.albic.	A.niger
Dermal Gel for Wound Dressingg 4225	<10	<10	<10	<10	<10
	DAY 28 COUNTS 7/08/94				
	E. coli	S. aureus	P.aerug.	C.albic.	A.niger
Dermal Gel for Wound Dressing 4225	<10	<10	<10	<10	<10

RESULTS: (PASS/FAIL U.S.P. XXII INTERPRETATION)

Dermal Gel for Wound Dressing 4255	Bacteria PASS	Fungi PASS	Overall PASS
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Analyst: *William F. Bryan*

Date: *7-8-94*