



**MICROBIOLOGICAL REPORT**

R&R Lotion, Inc.  
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**Report Date:** 01/27/09  
**Date Received:** 12/15/08  
**Date Completed:** 01/26/09  
**Project #:** 607903  
**P.O.#:** 100  
**Reference #:** 5831-097; 5791-181

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**SAMPLE DESCRIPTION**

<b><u>ACCESSION #</u></b>	<b><u>SAMPLE:</u></b>	<b><u>LOT #:</u></b>	<b><u>BATCH #:</u></b>	<b><u>QTY:</u></b>
607903	IC Lotion	100	100	2

**TEST PERFORMED:**

Validation Test for the Antimicrobial  
Preservative Effectiveness Test

**BTS METHOD #**

M115.R09

**REFERENCE:**

United States Pharmacopeia 31, <51>

Antimicrobial Effectiveness Test (Category 2)

M101.R10

United States Pharmacopeia 31, <51>

**PLATING MEDIA:**

Microbial Content Test Agar (Bacteria)  
Sabouraud Dextrose Agar (Yeast and Mold)

**ANTIMICROBIAL PRESERVATIVE EFFECTIVENESS VALIDATION TEST**

<u>Test Microorganism</u>		<u>Diluent</u>	<u>Dilution</u>	<u>Inoculum CFU/plate</u>	<u>Microbial Recovery CFU/plate</u>	<u>Percent Recovery</u>
<i>Aspergillus niger</i>	(mold)	DNB	1:10	15	19	127
<i>Candida albicans</i>	(yeast)	DNB	1:10	46	46	100
<i>Escherichia coli</i>	(bacteria)	DNB	1:10	38	51	134
<i>Pseudomonas aeruginosa</i>	(bacteria)	DNB	1:10	41	60	146
<i>Staphylococcus aureus</i>	(bacteria)	DNB	1:10	64	45	70

CFU = colony forming units

DNB = D/E Neutralizing Broth

**CONCLUSION:**

The antimicrobial preservative properties present in the sample can be neutralized under the test conditions described below:

	<u>DILUENT</u>	<u>DILUTION</u>
<i>Aspergillus niger</i>	DNB	1:10
<i>Candida albicans</i>	DNB	1:10
<i>Escherichia coli</i>	DNB	1:10
<i>Pseudomonas aeruginosa</i>	DNB	1:10
<i>Staphylococcus aureus</i>	DNB	1:10

**ANTIMICROBIAL PRESERVATIVE EFFECTIVENESS TEST****RESULTS:****TABLE SUMMARY**

<b><u>MICROORGANISM</u></b>		<b><u>INITIAL INOCULUM/gm</u></b>	<b>COLONY FORMING UNITS/gm</b>	
			<b><u>14 DAYS</u></b>	<b><u>28 DAYS</u></b>
<i>Aspergillus niger</i>	(mold)	4.1E5	<10	<10
<i>Candida albicans</i>	(yeast)	1.8E5	<10	<10
<i>Escherichia coli</i>	(bacteria)	1.5E6	<10	<10
<i>Pseudomonas aeruginosa</i>	(bacteria)	8.0E5	<10	<10
<i>Staphylococcus aureus</i>	(bacteria)	9.3E5	<10	<10

**Note: Numbers in the report such as 2.3E5 are an alternate exponential format for  $2.3 \times 10^5$ .**

**LOG REDUCTION FROM INITIAL INOCULUM**

	<b><u>14 DAYS</u></b>	<b><u>28 DAYS</u></b>
<i>Aspergillus niger</i>	4.6	4.6
<i>Candida albicans</i>	4.3	4.3
<i>Escherichia coli</i>	5.2	5.2
<i>Pseudomonas aeruginosa</i>	4.9	4.9
<i>Staphylococcus aureus</i>	5.0	5.0

**CONCLUSION:**

The above test results meet the current USP Category 2 Criteria of Acceptance for the Antimicrobial Preservative Effectiveness Test.



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