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MICROBIOLOGICAL REPORT



Report Date: 01/23/18
Date Received: 11/07/17
Date Completed: 01/19/18
Project #: 1030185
P.O.#: Not Specified
Reference #: 11120-063;
11228-121

SAMPLE DESCRIPTION

<u>ACCESSION #</u>	<u>SAMPLE:</u>	<u>LOT #:</u>	<u>BATCH #:</u>
1030197	S.P. Hydrosol (Sandalwood) (Stability Sample: Time 0, Ambient)	Not Specified	Not Specified

TEST PERFORMED:

Validation Test for the Antimicrobial
Preservative Effectiveness Test

BTS METHOD #

M115.R13

REFERENCE:

United States Pharmacopeia 40, <51>

Antimicrobial Effectiveness Test (Category 2)

M101.R14

United States Pharmacopeia 40, <51>

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 brasiliensis</i>	(mold)	DNB	1:10	33	31	94
<i>Candida albicans</i>	(yeast)	DNB	1:10	144	121	84
<i>Escherichia coli</i>	(bacteria)	DNB	1:10	59	48	81
<i>Pseudomonas aeruginosa</i>	(bacteria)	DNB	1:10	61	63	103
<i>Staphylococcus aureus</i>	(bacteria)	DNB	1:10	38	39	103

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 brasiliensis</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

<u>MICROORGANISM</u>		<u>INITIAL</u>	<u>COLONY FORMING UNITS/gm</u>	
		<u>INOCULUM/gm</u>	<u>14 DAYS</u>	<u>28 DAYS</u>
<i>Aspergillus brasiliensis</i>	(mold)	1.4E6	65	<10
<i>Candida albicans</i>	(yeast)	1.2E5	<10	<10
<i>Escherichia coli</i>	(bacteria)	1.7E6	<10	<10
<i>Pseudomonas aeruginosa</i>	(bacteria)	1.4E6	<10	<10
<i>Staphylococcus aureus</i>	(bacteria)	1.3E6	<10	<10

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

LOG REDUCTION FROM INITIAL INOCULUM

	<u>14 DAYS</u>	<u>28 DAYS</u>
<i>Aspergillus brasiliensis</i>	4.3	5.1
<i>Candida albicans</i>	4.1	4.1
<i>Escherichia coli</i>	5.2	5.2
<i>Pseudomonas aeruginosa</i>	5.1	5.1
<i>Staphylococcus aureus</i>	5.1	5.1

CONCLUSION:

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



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