

Test Report

REPORT NO: UO/2017/6008

Date : 2017/08/18

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CAP Global Limited

Room 1504,15/F, Ricky Centre, No.36 Chong Yip Street, Kwun Tong, Hong Kong

The following sample(s) was/were submitted and identified by/on behalf of applicant as:

Sample Name: Sora

Applicant : CAP Global Limited

JP No.: JP2017060345

Sample Condition: Please refer to the photo for sample shown at the last page of this report.

MFG: ---

EXP: ---

Date of Sample Receive 2017/06/09

Date of Testing : 2017/06/09 to 2017/08/18

Test Requested: The challenge tests for the sample are to assess the preservative effectiveness.

Purpose: According to USP <51>, it refers to the five test microorganisms, including *Escherichia coli* (BCRC 11634 ; ATCC 8739), *Staphylococcus aureus* (BCRC 10451 ; ATCC 6538P), *Pseudomonas aeruginosa* (BCRC 11633 ; ATCC 9027), *Candida albicans* (BCRC 21538 ; ATCC10231) and *Aspergillus brasiliensis* (BCRC 30506 ; ATCC 16404). The challenge tests for the sample are to assess the preservative effectiveness.

Test Method : With reference to U.S. Pharmacopeia <51> Antimicrobial Effectiveness Testing.

Test Results : -Please refer to next page(s)-

Signed for and on behalf of
SGS Taiwan Ltd.

Yuan-Min Wen
Manager



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Test Results

Procedure :

Sample was handled under sterile environment and operated with aseptic technique during preparation.

First, the test was conducted in five sterile containers of suitable size into which a sufficient volume of the sample has been transferred. Inoculate each container with one of the prepared and standardized inoculum, and mix. The volume of the suspension inoculum used is between 0.5% and 1.0% of the volume of the sample. The concentration of test microorganisms that is added to the sample are such that the final concentration of the test preparation after inoculation is between 1×10^5 and 1×10^6 CFU /mL of the product.

Incubation the inoculated containers for 7, 14, 21, 28 days at the appropriate condition specified in Table 1. Count and record any changes observed in appearance at these condition. Using the calculated concentrations of CFU/mL present at the start of the test, calculate the change in \log_{10} values of the concentration of CFU/mL for each microorganism at the applicable test intervals, and express the changes in terms of log reductions.

Table1 : Culture Conditions for Inoculum Preparation

Organism	Suitable Medium	Incubation Temperature(°C)	Inoculum Incubation Time	Microbial Recovery Incubation Time
<i>Escherichia coli</i>	TSA	32.5±2.5	18~24 hrs	3~5 days
<i>Pseudomonas aeruginosa</i>	TSA	32.5±2.5	18~24 hrs	3~5 days
<i>Staphylococcus aureus</i>	TSA	32.5±2.5	18~24 hrs	3~5 days
<i>Candida albicans</i>	SDA	22.5±2.5	44~52 hrs	3~5 days
<i>Aspergillus brasiliensis</i>	SDA	22.5±2.5	6~10 days	3~7 days

超微量工業安全實驗室
Ultra Trace Industrial Safety Hygiene

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Test Results

<u>Organism</u>	<u>Original inoculum (CFU/mL)</u>	<u>Contact time</u>	<u>Counts of the sample at contact time (CFU/mL)</u>	<u>Log reductions (R)</u>
<i>Escherichia coli</i>	5.50×10^5	7 days	<1	>3
		14 days	<1	>3
		21 days	<1	>3
		28 days	<1	>3
<i>Staphylococcus aureus</i>	2.18×10^5	7 days	<1	>3
		14 days	<1	>3
		21 days	<1	>3
		28 days	<1	>3
<i>Pseudomonas aeruginosa</i>	3.00×10^5	7 days	<1	>3
		14 days	<1	>3
		21 days	<1	>3
		28 days	<1	>3
<i>Candida albicans</i>	3.75×10^5	7 days	<1	>3
		14 days	<1	>3
		21 days	<1	>3
		28 days	<1	>3
<i>Aspergillus brasiliensis</i>	2.20×10^5	7 days	<1	>3
		14 days	<1	>3
		21 days	<1	>3
		28 days	<1	>3

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