超微量工業安全實驗室

Ultra Trace Industrial Safety Hygiene

Test Report

REPORT NO: UO/2017/6008 **Date： 2017/08/18**

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

SGS TAIWAN LTD SGS TAIWAN

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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(℃)	Inoculum Incubation Time	Microbial Recovery Incubation Time
Escherichia coli	TSA	32.5±2.5	18~24 hrs	3~5 days
Pseudomonas aeruginosa	TSA	32.5±2.5	18~24 hrs	3~5 days
Staphylococcus aureus	TSA	32.5±2.5	18~24 hrs	3~5 days
Candida albicans	SDA	22.5±2.5	44~52 hrs	3~5 days
Aspergillus brasiliensis	SDA	22.5±2.5	6~10 days	3~7 days

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Test Results

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