<USP>51 Testing March-April 2020

The USP Chapter 51 Preservative Challenge Test is the most common method used to gauge preservative effectiveness. Much like a Preservative Challenge Screen, it is used to evaluate the effect of preservatives in cosmetics, personal care products, and drug products. Preservatives are antimicrobial ingredients that are added to aqueous product formulations to help maintain the safety of the product by inhibiting the growth and reducing the amount of microbial contaminants.

The USP <51> challenge test utilizes 5 microorganisms (3 bacteria and 2 fungi) for challenge testing. Each of the microorganisms are known strains of pathogenic microorganisms and they represent a wide range of microbial physiologies.

The first time a product is challenge tested for antimicrobial effectiveness under the USP <51> method, a neutralization and recovery validation is required to ensure that the microorganisms are able to be recovered from the product if they are present.

SUMMARY OF THE USP <51> CHALLENGE TEST PROCEDURE

Prior to initiation of USP <51>, the product should be evaluated using the USP <61> - Microbial Enumerations Test for the presence of pathogens after manufacturing.

- The product is separated out into 5 containers, each being challenged with one of the 5 method-specified microorganisms (S. aureus ATCC 6538, E. coli ATCC 8739, *P. aeruginosa* ATCC 9027, C. albicans ATCC 10231, and A. brasiliensis ATCC 16404) at a concentration of $>1x10^5$CFU/g or ml.
- The initial concentration of each microorganism is determined by inoculating a control substance and using standard dilution and plating techniques.
- At the time of test initiation, a separate volume, typically 1 ml or 1 g, of the product is diluted in a volume of chemical neutralizer broth, to be used in the neutralization and recovery validation.
- The inoculated product is held at room temperature for a period of no less than 28 days.

For bacteria: Not less than 2.0 log reduction (growth reduction) from the initial count at 14 days and no increase from the 14 days count to 28 days
For yeast; no increase from initial calculated count from 14 and 28 days
For mold; no increase from initial calculated count from 7 and 28 days

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REPORT # 87854-1

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Date 4/20/2020

Received 2020/03/16

DABOMB.ME HEAVY DUTY CLEANER (87854-1)

Test	Specification	Test Result	Method	Analyst	Date	Loc.
Antimicrobial Effectiveness	N/A	Present (Pass)	USP <51>	OM	2020/04/19	AB

Labs-Mart Testing Locations:

AB - 1938 94 Street, Edmonton, AB, Canada

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Date 2020/04/20