

<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 $>1 \times 10^5$ 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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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

Prepared by  Approved by  Date 2020/04/20
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Raw data are archived by Labs-Mart Inc. Results shown relate only to samples submitted and tested.
Labs-Mart Inc. assumes no liability for the use of the results by any party.

Testing may be completed at other Labs-Mart locations.

Statement of conformity only applies to tests currently presented on our scope of accreditation. All required parts of the standard (17025) applicable to a test laboratory are met. Accreditation is location and parameter specific. The tests listed in this report may not be included in the current scope of accreditation.

The sample(s) were provided by the customer as listed on this report and therefore results reported apply to the samples as received.

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