rpc
SCIENCE & ENGINEERING

921 College Hill Rd. Fredericton, NB Canada E3B 6Z9

Antimicrobial Effectiveness Testing - USP<51>

Non-sterile dosage forms of pharmaceutical products, food product formulations with a specific type of processing and packaging and various type of cannabis products typically have preservatives added to them in order to protect them from microbial contamination. Preservatives are antimicrobial additives that are incorporated into product formulations to help maintain the quality of a product by inhibiting and reducing microbial contamination.

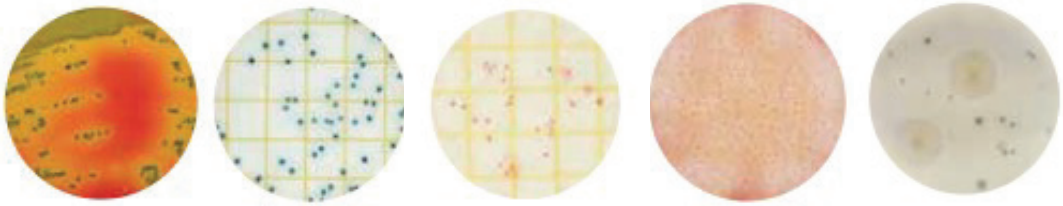
The USP <51> Antimicrobial Effectiveness Testing, also known as the Preservative Efficacy Test or Microbial Challenge Study, is performed to determine if the chosen preservative is appropriate for a product formulation. It is also carried out as part of a stability study to ascertain whether a preservative system is still effective up to the expiration date of a product. Testing is performed according to compendial requirements in both USP <51> and EP 5.1.3.

To evaluate the antimicrobial effectiveness of a product, the product is inoculated with a prescribed quantity of specified microorganisms.

The following common five USP test organisms (3 bacteria and 2 fungi) are used in this study:

1. *E. coli*
2. *P. aeruginosa*
3. *S. aureus*
4. *C. albicans*
5. *A. brasiliensis*

Client isolates or other target organisms can also be used. The effectiveness of the preservative is evaluated by comparing the initial level of microorganisms to the test sample at various time intervals over a period of 28 days at a specified temperature. Reduction of microorganisms is calculated logarithmically. RPC scientists interpret the data and provide a report to the client in a timely fashion.



Contact

For more information on preservation testing, antimicrobial performance, and turn-around time, please contact:

Dr. Attiq Rehman, MSc, PhD
Director of Bioscience
Tel: 506.452.1365
Toll Free: 1.800.563.0844
info@rpc.ca

RPC's Quality Management System is registered to ISO 9001:2015.