

UNIT-V

Microbial stability evaluation of formulations



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Evaluation of microbial stability of formulation

- Microbial stability of a formulation is **dependent on effectiveness of its preservative**. **Chemical assay and biological assay may assure effectiveness of preservative but it may lose its activity due to presence of other ingredients in the formulation.**

- Some formulations **do not require preservative** because they act as **self-preservative**. Some formulation does not require preservative because it contains antimicrobial agents like antibiotics as ingredient.
- Some formulation may contain **high sugar concentration, salt concentration** and may act as **self preservative**.
- So, the **ability of the formulation to protect itself from microbial growth must ascertain to determine microbial stability** of the formulation. It is done by **preservative efficacy test**.

- Basic principle of this test is **to inoculate products with different types of specified microorganism with specific quantity.**
- Little amount of inoculated product is removed at a specific interval. Then viable count of this withdrawn sample is determined.
- United States Pharmacopoeia, European Pharmacopoeia etc recommends this type of tests.

- The concentration of the test organism should be 10^5 - 10^6 cells per ml or gm.
- Total microbial count is performed in 0 hr, 6 hrs, 24 hrs, 48 hrs. 7 days, 14 days and 28 days.
- British pharmacopeia recommends test even after 28 days.

- Different bacterial species are used for this purpose. They are ***Staphylococcus aureus***, ***Pseudomonus aeruginosa*** and ***E.coli***.
- Different fungus species are also used. They are ***Candida albicans***, ***Aspergillus niger*** etc. This test allows to add designated micro-organisms if required.

- After withdrawal of sample and before viable count, sample is mixed with chemicals **which can deactivate preservative** because presence of even **very minute quantity of preservative may hamper microbial viable count.**
- There are two types of performance criteria. **Criteria A is desired and recommended** where as **criteria B is satisfactory in justified cases.**