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It’s Important to Know!

BP303T — Pharmaceutical Microbiology

B.Pharm Semester 3 · Unit 5 — Spoilage, preservation and animal cell culture

Unit V: Spoilage, preservation and animal cell culture

Microbial spoilage

Microbial spoilage can cause turbidity, gas, odour, colour change, phase separation, pH change, viscosity change, loss of active ingredient or toxin formation. Risk depends on water activity, nutrient availability, pH, packaging, preservative concentration, temperature and contamination route. Bacteria, yeasts and moulds may affect different formulations.

Preservation

Antimicrobial preservatives reduce growth during storage and use; they do not replace good manufacturing practice. Effectiveness depends on free preservative concentration, pH, partitioning, adsorption, compatibility, container interaction and microbial susceptibility. Preservative efficacy testing challenges the product with selected organisms and monitors recovery over time. Current test organisms and criteria are set out in the applicable pharmacopoeia.

Animal cell culture

Animal cell culture grows cells under controlled nutrient, temperature, gas and pH conditions. Primary cultures are obtained directly from tissue and have limited lifespan. Cell lines may be finite or continuous. Aseptic technique, identity testing, contamination control and passage records are essential. Applications include biological production, toxicity studies, vaccine research and tissue studies.

Unit V: Frequently asked questions

Q: Why can a preservative fail in a formulation?

A: It may be bound, partitioned, adsorbed, chemically degraded or present at a pH where its active form is reduced.

Q: What is microbial spoilage?

A: It is undesirable product change caused by microbial growth or microbial metabolism.

Q: Why is cell-line identity important?

A: Misidentified or contaminated cells can produce unreliable research or manufacturing results.

Unit V: Key takeaways

- Spoilage may be visible or may appear as loss of potency or altered quality.
- Preservatives support, but do not replace, contamination control.
- Free preservative concentration determines much of the antimicrobial effect.
- Cell culture requires controlled conditions and contamination monitoring.
- Current preservative and cell-culture criteria need verified standards.

Unit V: Practical correlation

Practical correlation: multidose product preservation. Preservative selection should be supported by formulation compatibility, container studies and an efficacy test. The required preservative system for a named product is set out in its approved specification.