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BP303T — Pharmaceutical Microbiology

B.Pharm Semester 3
3 hrs/week · 4 credits · 45 hours · 100 marks (25 internal + 75 end-semester, 3 hr paper)

Complete notes — all 5 units in one PDF

- Unit 1 — Introduction to microbiology and bacterial growth
- Unit 2 — Bacterial identification and sterilisation
- Unit 3 — Fungi, viruses, disinfectants and sterility testing
- Unit 4 — Aseptic areas and microbiological assay
- Unit 5 — Spoilage, preservation and animal cell culture

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B.Pharm Semester 3 · Unit 1 — Introduction to microbiology and bacterial growth

Unit I: Introduction to microbiology and bacterial growth

Scope and history

Microbiology studies microorganisms and their interactions with hosts, materials and environments. Pharmaceutical microbiology applies this knowledge to contamination control, sterile products, antimicrobial testing, fermentation, quality systems and public health. Historical development includes microscopy, germ theory, pure culture methods and aseptic practice. Specific dates and attribution should be checked against the prescribed history text.

Prokaryotes and eukaryotes

Prokaryotic cells lack a membrane-bound nucleus and usually have a simpler internal organisation. Bacteria have a cell membrane, cytoplasm, ribosomes and a cell wall in many species. Eukaryotic microorganisms have a nucleus and membrane-bound organelles. Fungi are eukaryotic; viruses are acellular particles that require a host cell for replication.

Bacterial morphology and nutrition

Bacteria may be spherical, rod-shaped, curved or spiral, and may occur singly, in pairs, chains or clusters. Structures such as capsule, flagella, pili, endospore and cell wall influence survival, movement, attachment and staining. Nutrients provide carbon, nitrogen, minerals, growth factors and energy. Culture media may be defined, complex, selective, differential, enriched or enrichment media.

Growth and cultivation

In a closed culture, the growth curve has lag, log, stationary and decline phases. Temperature, pH, oxygen, water activity, nutrients and osmotic conditions affect growth. Pure cultures are isolated by dilution, streaking, spreading or other separation methods, then preserved by refrigeration, deep freezing, drying or other validated approaches. Anaerobes require removal or exclusion of oxygen. Exact preservation conditions should be checked against the prescribed text for each organism.

Measurement and microscopy

Total counts include living and non-living cells, while viable counts estimate cells able to form colonies under defined conditions. Phase-contrast microscopy improves contrast in living unstained cells. Dark-field microscopy uses scattered light to view thin organisms. Electron microscopy provides greater resolution but requires specialised preparation and does not show ordinary living growth.

Unit I: Frequently asked questions

Q: Why is the log phase important?

A: Cells divide actively and show relatively uniform physiology, so this phase is useful for studying growth and antimicrobial effects.

Q: What is a pure culture?

A: It is a culture derived from one organism or one type of organism under the stated identification criteria.

Q: What is the difference between total and viable count?

A: Total count includes cells regardless of viability, while viable count estimates cells that can grow under the test conditions.

Unit I: Key takeaways

- Pharmaceutical microbiology links microorganisms with product quality and patient safety.
- Prokaryotes and eukaryotes differ in cell organisation.
- Media composition and physical conditions determine cultivation.
- Growth commonly passes through four phases in a closed culture.
- Count and microscopy methods answer different questions.

Unit I: Practical correlation

Practical correlation: culture media. A laboratory should select media and incubation conditions that support the target organism while limiting contamination. The exact medium and incubation schedule are set out in the current practical manual for the test organism.

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B.Pharm Semester 3 · Unit 2 — Bacterial identification and sterilisation

Unit II: Bacterial identification and sterilisation

Staining and biochemical identification

Simple staining improves cell shape and arrangement. Gram staining separates many bacteria into Gram-positive and Gram-negative groups according to cell-envelope behaviour during decolourisation and counterstaining. Acid-fast staining detects organisms with lipid-rich cell walls that resist ordinary decolourisation. Staining quality depends on smear thickness, fixation, reagent condition and timing.

Biochemical tests identify metabolic traits. The IMViC group includes indole, methyl red, Voges-Proskauer and citrate tests. A biochemical result must be interpreted with controls, culture purity and the complete identification scheme rather than one reaction alone.

Sterilisation principles

Sterilisation means removal or destruction of all forms of viable microbial life as defined by the method and validation system. Moist heat damages essential components through denaturation and hydrolysis. Dry heat acts through oxidation and requires different time-temperature conditions. Filtration removes organisms from heat-sensitive liquids or gases but does not destroy them.

Chemical sterilants act through oxidation, alkylation or other chemical injury. Gaseous methods can penetrate packaged materials but require exposure control and residue assessment. Radiation can damage nucleic acids. Mechanical cleaning reduces bioburden and supports, but is not by itself, sterilisation.

Indicators and validation

Physical records, chemical indicators and biological indicators provide different evidence. Biological indicators use resistant spores appropriate to the process. Validation must consider load, packaging, cold spots, exposure, equipment performance and routine monitoring. The organism, cycle parameters and acceptance criteria are set out in the validated procedure for each process.

Unit II: Frequently asked questions

Q: What is the main basis of Gram staining?

A: It is the differential retention of the primary stain after decolourisation, related to cell-envelope structure.

Q: Why is filtration not the same as sterilisation by heat?

A: Filtration physically removes retained organisms and requires filter integrity, while heat inactivates organisms by thermal damage.

Q: Why are biological indicators used?

A: They challenge a process with resistant spores and provide direct evidence that the process can achieve the required microbial inactivation.

Unit II: Key takeaways

- Staining is useful only when smear preparation and controls are adequate.
- IMViC tests are interpreted as a pattern, not as isolated facts.
- Sterilisation method depends on material, load and process compatibility.
- Indicators support monitoring and validation.
- Cleaning, process control and documentation work together.

Unit II: Practical correlation

Practical correlation: autoclave cycle review. A release decision should consider cycle records, load configuration, indicator results and deviations. Exact cycle parameters and biological indicator selection are set out in the validated procedure.

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B.Pharm Semester 3 · Unit 3 — Fungi, viruses, disinfectants and sterility testing

Unit III: Fungi, viruses, disinfectants and sterility testing

Fungi and viruses

Fungi are eukaryotes that may grow as yeasts, moulds or dimorphic forms. Moulds produce hyphae and mycelia; yeasts commonly reproduce by budding. Fungal identification may use morphology, culture, microscopy and biochemical or molecular methods.

Viruses contain genetic material within a protein coat and may have a lipid envelope. They replicate by entering susceptible host cells and using host and viral functions. Viral survival outside the host depends on envelope, temperature, moisture, radiation and surface conditions. Exact virus classification should be checked against the prescribed text where required.

Disinfectants and antiseptics

Disinfectants are applied to inanimate surfaces, while antiseptics are used on living tissue under appropriate conditions. Activity depends on concentration, contact time, temperature, pH, organic matter, microbial load, biofilm and organism resistance. Common classes include alcohols, phenolics, halogens, oxidising agents, aldehydes, quaternary ammonium compounds and biguanides. Product-specific claims and concentrations should be taken from the product monograph.

Sterility testing

Sterility testing is performed on representative samples using validated media and incubation conditions. Membrane filtration is suitable for many filterable products; direct inoculation is used when filtration is unsuitable. Controls are needed for media fertility, method suitability and environmental conditions. A negative test does not prove that every unit is sterile; it provides evidence under the sampling plan.

Unit III: Frequently asked questions

Q: How do yeasts differ from moulds?

A: Yeasts are usually unicellular and reproduce by budding, while moulds grow as multicellular hyphae forming a mycelium.

Q: Why is contact time important for a disinfectant?

A: Microbial injury accumulates over time, so insufficient contact can leave viable organisms.

Q: Why must a sterility test include controls?

A: Controls show whether media, technique, environment or the product itself could cause a false result.

Unit III: Key takeaways

- Fungi are eukaryotes and viruses require host cells for replication.
- Disinfectant performance depends on organism and environmental conditions.
- Sterility tests require method suitability and representative sampling.
- A negative result has meaning only within a validated procedure.
- Product-specific disinfectant claims require verified sources.

Unit III: Practical correlation

Practical correlation: sterility testing. A laboratory should prevent accidental contamination through gowning, environmental monitoring, controls and aseptic handling. The product-specific test method is set out in the applicable pharmacopoeia.

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B.Pharm Semester 3 · Unit 4 — Aseptic areas and microbiological assay

Unit IV: Aseptic areas and microbiological assay

Aseptic areas

An aseptic area controls viable and non-viable contamination during operations where later sterilisation may not be possible. Design considers personnel and material flow, pressure relationships, surfaces, cleaning, air supply, filtration and monitoring. Laminar airflow equipment provides a controlled unidirectional stream over a work zone when correctly operated.

Clean-area classification uses airborne particle and microbial monitoring criteria. Classification systems and limits can differ by standard and activity and should be checked against the current applicable standard. Personnel are a major contamination source, so gowning and behaviour are central controls.

Contamination control

Contamination can enter through personnel, raw materials, equipment, air, water, packaging or poor process flow. Environmental monitoring may include airborne particles, viable air sampling, surface sampling, settle plates and personnel monitoring. A trend is often more informative than one isolated result.

Microbiological assay

Microbiological assays estimate biological activity by comparing a test preparation with a reference preparation. A cylinder-plate or diffusion assay measures zones of inhibition, while a turbidimetric assay measures growth response. Parallelism, linearity, precision, controls and reference standard suitability are important. Assay-specific calculations and acceptance criteria are set out in the applicable pharmacopoeia.

Unit IV: Frequently asked questions

Q: Why is personnel control important in an aseptic area?

A: People shed particles and microorganisms, so gowning, movement and technique directly affect contamination risk.

Q: What is the purpose of laminar airflow?

A: It supplies a controlled unidirectional air stream that helps protect exposed sterile materials in the work zone.

Q: What does a microbiological assay measure?

A: It estimates biological activity by comparing the response produced by a test sample with that produced by a reference.

Unit IV: Key takeaways

- Aseptic design controls air, people, materials and movement.
- Laminar airflow protects a work zone only when operated correctly.
- Environmental monitoring should be interpreted as a trend.
- Microbiological assays require reference standards and suitable controls.
- Clean-area limits depend on the applicable standard.

Unit IV: Practical correlation

Practical correlation: environmental monitoring. An investigation should consider location, activity, personnel, cleaning, sampling method and historical trend rather than treat one result in isolation. Alert and action levels are set out in the facility standard.

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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.