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It’s Important to Know!

BP302T — Physical Pharmaceutics I

B.Pharm Semester 3 · Unit 5 — pH, buffers and isotonic solutions

Unit V: pH, buffers and isotonic solutions

pH and measurement

pH is a logarithmic expression related to hydrogen-ion activity. A pH meter uses an indicator electrode and a reference system, with calibration against appropriate standard buffers. Temperature, junction potential, electrode condition and sample composition affect the result. Colour indicators provide approximate rather than universal values.

Buffers

A buffer resists a change in pH after addition of a small amount of acid or base. It usually contains a weak acid and its conjugate base, or a weak base and its conjugate acid. The Henderson-Hasselbalch equation links pH with pKa and the ratio of conjugate base to acid, within its assumptions. Buffer capacity depends on total concentration, ratio and proximity of pH to pKa.

Buffers support stability, solubility, preservative action, comfort and biological compatibility. A buffer can also accelerate degradation or reduce solubility if selected poorly.

Isotonic solutions

An isotonic solution has an effective osmotic pressure compatible with the intended biological site. Tonicity differs from simple molar concentration because solute dissociation and membrane permeability matter. Sodium chloride equivalent, freezing-point depression and other validated methods can be used to adjust tonicity. The method and target depend on route and are set out in the applicable pharmacopoeia.

Unit V: Frequently asked questions

Q: What is buffer capacity?

A: It is the amount of strong acid or base needed to change the pH of a specified buffer system by a defined amount.

Q: Why should pH be measured after calibration?

A: Calibration relates the electrode response to known standards and helps identify slope or offset errors.

Q: Why is isotonicity important for parenteral or ophthalmic products?

A: A large osmotic difference can cause discomfort, tissue irritation or cell-volume changes at sensitive biological sites.

Unit V: Key takeaways

- pH is related to hydrogen-ion activity and must be measured under controlled conditions.
- Buffers resist pH change but have finite capacity.
- Buffer selection must balance pH, stability, solubility and compatibility.
- Tonicity depends on effective osmotic behaviour, not only concentration.
- Adjustment calculations require the intended route and validated method.

Unit V: Practical correlation

Practical correlation: ophthalmic formulation. pH and tonicity should be adjusted within a range compatible with the eye while preserving drug stability and antimicrobial control. The acceptable product range is set out in the approved specification.