

## 1. Long-Term Stability Studies

**Q1.** What is the primary purpose of long-term stability studies?

- A. To identify degradation pathways
- B. To provide real-time data on product behavior over its shelf life
- C. To predict shelf life quickly
- D. To test packaging materials

**Answer:** B

**Justification:** Long-term studies are conducted under recommended storage conditions (e.g., 25°C/60% RH for 12–24 months) and provide real-time evidence for expiry dates and storage conditions.

## 2. Accelerated Stability Studies

**Q2.** Accelerated stability studies are typically conducted under which conditions?

- A. 25°C/60% RH
- B. 30°C/65% RH
- C. 40°C/75% RH
- D. 21°C/45% RH

**Answer:** C

**Justification:** Accelerated studies use elevated stress conditions (40°C/75% RH for 6 months) to predict degradation patterns quickly and support early shelf-life estimation.

## 3. Intermediate Stability Studies

**Q3.** When are intermediate stability studies required?

- A. When long-term studies are inconclusive
- B. When accelerated studies show significant changes
- C. When photostability studies fail
- D. When stress testing is incomplete

**Answer:** B

**Justification:** Intermediate studies (30°C/65% RH for 6 months) bridge accelerated and long-term data when accelerated studies reveal significant changes.

## 4. Stress Testing

**Q4.** What is the main role of stress testing in stability studies?

- A. To confirm expiry dates
- B. To identify degradation pathways and impurities
- C. To validate packaging labels
- D. To support regulatory submissions

**Answer:** B

**Justification:** Stress testing under extreme conditions (heat, humidity, oxidation, pH, light) identifies degradation pathways and stability-limiting factors.

## 5. Photostability Testing

**Q5.** Which ICH guideline specifically addresses photostability testing?

- A. Q1A(R2)
- B. Q1B
- C. Q1C
- D. Q1E

**Answer:** B

**Justification:** ICH Q1B defines protocols for testing drug sensitivity to light, ensuring proper packaging and labeling (e.g., “Protect from light”).

## 6. Accelerated Regulatory-Compliant Considerations

**Q6.** Extrapolated shelf life from accelerated studies is acceptable only if:

- A. Supported by validated analytical methods and statistical evaluation
- B. Conducted under stress conditions
- C. Confirmed by photostability data
- D. Approved by packaging manufacturers

**Answer:** A

**Justification:** Regulatory bodies accept extrapolated shelf life only when scientifically justified, supported by validated methods, and robust statistical analysis.

## 7. Climatic Zones

Q7. Which climatic zone is most relevant for India?

- A. Zone I (Temperate)
- B. Zone II (Subtropical)
- C. Zone III (Hot/Dry)
- D. Zone IVb (Hot/Humid)

**Answer: C**

**Justification:** India falls under Zone III (Hot/Dry, 30°C/65% RH), requiring stability protocols aligned with this climatic condition.

## 8. Documentation Requirements

Q8. Which of the following is NOT a required element of stability documentation?

- A. Stability protocol
- B. Raw data and summary tables
- C. Graphical trends
- D. Marketing strategy

**Answer: D**

**Justification:** Documentation must include protocol, raw data, graphical trends, and justification of shelf life, but marketing strategy is not part of stability compliance.

## 9. Regulatory Expectations

Q9. Stability data is required for which of the following submissions?

- A. New Drug Applications (NDAs)
- B. Abbreviated NDAs (ANDAs)
- C. Post-approval changes
- D. All of the above

**Answer: D**

**Justification:** Stability data supports NDAs, ANDAs, and post-approval changes, ensuring product quality, safety, and efficacy.

## 10. Common Pitfalls

**Q10.** Which of the following is a common pitfall in stability studies?

- A. Using validated methods
- B. Including all time points
- C. Ignoring zone-specific requirements
- D. Providing graphical trends

**Answer:** C

**Justification:** Common pitfalls include incomplete documentation, non-validated methods, unjustified extrapolation, and ignoring zone-specific requirements for global submissions.