SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES COIMBATORE

CASE STUDY BASED PUZZLE

BP502T: INDUSTRIAL PHARMACY I

TOPIC: SOFT GELATIN CAPSULE

Case Study 6: Leakage of Soft Gelatin Capsules

A batch of soft gelatin capsules containing a liquid fill showed leakage after a few weeks of storage.

Puzzles / Questions

1. What interaction between shell and fill may cause leakage?
2. Why is base adsorption important in soft gelatin capsules?
3. What is the minim/gram factor, and how does it affect formulation?
4. Suggest formulation changes to prevent leakage.

Case Study 7: Shell Deformation During Storage

Soft gelatin capsules stored at high temperature became sticky and lost shape.

Puzzles / Questions

1. Which component of the shell is responsible for this behavior?
2. How does moisture content affect shell stability?
3. What are the ideal storage conditions for soft gelatin capsules?
4. Which stability testing parameter would detect this issue?

Case Study 8: Inconsistent Fill Weight

During encapsulation, variation in fill volume was observed.

Puzzles / Questions

1. Which physical property of fill material affects fill uniformity?
2. Why are suspensions more challenging than solutions?
3. Which in-process control ensures uniform fill?
4. How does capsule size influence fill accuracy?

Case Study 9: Drug Degradation Inside Soft Gelatin Capsules

A moisture-sensitive drug showed reduced potency during stability testing.

Puzzles / Questions

1. Why are soft gelatin capsules unsuitable for some drugs?
2. Which shell component contributes to moisture content?
3. Suggest suitable alternatives to soft gelatin capsules.
4. Which stability study condition confirms this degradation?

Case Study 10: Capsule Size Selection

A patient complained about difficulty swallowing a soft gelatin capsule.

Puzzles / Questions

1. How are soft gelatin capsule sizes designated?
2. Which factors influence capsule size selection?
3. How can dose adjustment help reduce capsule size?
4. What role does patient compliance play in capsule design?

C. Pellets – Case Study Puzzles

Case Study 11: Poor Pellet Sphericity

Pellets produced by extrusion–spheronization were irregular and elongated.

Puzzles / Questions

1. Which formulation factor affects pellet shape?
2. What is the role of microcrystalline cellulose in pelletization?
3. Which equipment parameter influences sphericity?
4. How can pellet quality be improved?

Case Study 12: Wide Pellet Size Distribution

Pellets showed large variation in size, affecting capsule filling uniformity.

Puzzles / Questions

1. Which pelletization process is most likely used here?
2. How does screen size affect pellet diameter?
3. Which test evaluates pellet size distribution?
4. Why is uniform pellet size important in modified-release formulations?

Case Study 13: Dose Dumping from Pellet-Based Capsules

A modified-release pellet formulation showed rapid drug release.

Puzzles / Questions

1. What could be the cause related to coating?
2. Which pellet coating defects lead to dose dumping?
3. Name equipment used for pellet coating.
4. How is dissolution testing useful in detecting this problem?

Case Study 14: Equipment Selection for Pellet Manufacture

A company wants to scale up pellet production from lab to industry.

Puzzles / Questions

1. Which pelletization techniques are suitable for large-scale production?
2. Compare extrusion–spheronization and fluidized bed pelletization.
3. Which equipment ensures better control over pellet size?
4. What challenges occur during scale-up?

Case Study 15: Stability Issues in Pellet Formulations

Pellets showed aggregation during long-term storage.

Puzzles / Questions

1. What role does moisture play in pellet stability?
2. Which excipients help prevent aggregation?
3. How does packaging influence pellet stability?
4. Which stability test predicts this problem?