RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES
Final Year B.Pharm

Advanced Industrial Pharmacy
(Revised Scheme 4)

QUESTION PAPER BANK

Chapter - 1 BIOPHARMACEUTICAL CLASSIFICATION SYSTEMS (5)

SHORT ESSAY (5 Marks)

1. Explain the BCS classification of drugs with examples.
2. Define bioavailability. Explain any three approaches to improve the bioavailability of the poorly soluble drugs.
3. Explain the concept of inclusion complexes.
4. Define solid dispersions. Explain any one method of preparation of solid dispersions.
5. Define complexation technique. Explain any one method of preparation of inclusion complexes.
6. Define bioavailability. Explain how the bioavailability of poorly soluble drugs can be improved?
7. Explain the following approaches: a) Solid dispersion b) Complexation technique.

Chapter - 2 CONTROLLED DRUG DELIVERY SYSTEMS: (10 + 2)

LONG ESSAY (10 Marks)

1. Explain the various requirements of drug candidate to be selected for formulation into controlled drug delivery system.
2. Explain the principle involved in the design of controlled drug delivery systems.
3. Define microencapsulation. Write the applications of microencapsulation. Explain phase separation – coacervation technique.
4. Describe the various physicochemical and pharmaceutical factors to be considered in selection of a drug candidate for controlled delivery formulations.
5. Write the concept of controlled drug delivery systems. Explain the approaches for the Controlled release formulations based on diffusion.
6. Write the concept of controlled drug delivery systems. Explain the approaches for the Controlled release formulations based on dissolution.
7. Write the concept of controlled drug delivery systems. Explain the approaches for the Controlled release formulations based on ion exchange technique.

SHORT ANSWERS (2 Marks)

1. Define controlled drug delivery systems with examples.
2. What are the advantages and disadvantages of controlled drug delivery systems?
3. Define core and coat materials with respect to microencapsulation.
4. Define microencapsulation technique.
5. Define dissolution and diffusion.
6. Write the applications of microencapsulation.
7. Name any two polymers used in the reservoir type of controlled drug delivery formulations.
8. Name any two polymers used in the matrix type of controlled drug delivery formulations.
9. Name any two ion exchange resins used in controlled drug delivery formulations.
10. Name the techniques of microencapsulation.
11. Define half life and protein binding.
12. How the half life influence the design of controlled drug delivery systems.
13. How the protein binding influence the design of controlled drug delivery systems.

Chapter - 3 A) NOVEL DRUG DELIVERY SYSTEMS B) TARGETED DRUG DELIVERY SYSTEMS (10 + 5 + 5 + 2)

LONG ESSAYS (10 Marks)

1. Define NDDS. Explain the advantages and formulation of ocular drug delivery systems.
2. What is transdermal DDS? Explain the different formulation approaches for transdermal DDS.
3. What is an implant? Explain the formulation of implants with a suitable example.
4. Define liposome. Explain the different methods of preparation of liposomes.
5. Define nanoparticle? Write the importance of nanoparticles in target drug delivery systems with suitable examples.
6. What are buccal DDS? Explain the formulation of buccal drug delivery system.
7. What are the advantages and disadvantages of nasal DDS? With the help of a neat labeled diagram explain the physiology of the nasal cavity with reference to nasal drug absorption.
8. Explain the methods of preparation and applications of microsphere with suitable examples.
9. Describe all the criteria to be considered for the selection of drugs to be formulated into a transdermal DDS with examples.
10. What are vesicular DDS of niosomes? Explain the advantages, disadvantages and applications.
11. What are targeted DDS? Explain the different approaches of targeting.

SHORT ESSAYS (5 Marks)

1. Explain the characteristics of ocular drug delivery systems.
2. What is ocular DDS? Explain its advantages, disadvantages and ideal requirements for ocular drug delivery systems.
3. Explain concept, advantages and disadvantages of nanoparticles.
4. Explain concept, advantages and disadvantages of liposomes.
5. Explain concept, advantages and disadvantages of implants.
6. Write a note on the formulation of buccal drug delivery systems.
7. Define ocular drug delivery system. Explain different types of ocular DDS.
8. What is nasal drug delivery system? Write about its advantages and disadvantages.
9. Define nanoparticles. Explain its importance in targeted drug delivery systems.
10. What are niosomes? Write its applications in target drug delivery system.
11. Explain any two formulation approaches for transdermal drug delivery systems.
12. Define microspheres. Explain any two methods of microsphere preparation.
13. Describe the components of transdermal DDS.
14. Differentiate between novel and conventional drug delivery systems.

SHORT ANSWERS (2 Marks)

1. Define buccal drug delivery systems.
2. What is transdermal drug delivery?
3. Enumerate the different types of ocular dosage forms.
4. What are the ideal requirements for ocular drug delivery systems?
5. Define liposomes?
6. Define niosomes.
7. Explain the advantages of nasal drug delivery systems.
8. What is nasal DDS?
9. Define microspheres.
10. Define nanoparticles.
11. How nanoparticles are used as target drug delivery systems.
12. What are pressure sensitive adhesives? Give examples.
13. Define ocular drug delivery systems.
14. What are implants?
15. Give examples for implant drug delivery systems.
16. Name two marketed transdermal products.

Chapter -4 PILOT PLANT SCALE UP (10 + 2)

LONG ESSAY (10 marks)

1. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.
2. Explain the protocol for pilot plant scale up for tablets production.
3. What are the various general requirements for setting up a pilot plant for pharmaceutical preparations?
4. Explain how the development of master formula records and batch manufacturing records play an important role in pilot plant scale up studies.

SHORT ANSWERS (2 Marks)

1. What is pilot plant?
2. Describe master formula records.
3. What is a batch manufacturing record? What are the different parts in batch manufacturing record?
4. Explain the contents of batch manufacturing record.
5. Describe the personnel requirements in a pilot plant.
6. What is technology transfer?
7. Describe the benefits of pilot plant scale up studies.
8. Name any four general requirements for pilot plant construction.
9. What are the contents of master formula records?

Chapter -5 PHARMACEUTICAL PACKAGING (5 + 2)

SHORT ESSAY (5 Marks)

1. Explain the different types of pharmaceutical packaging materials?
2. Define and explain primary and secondary packing materials.
3. Define pharmaceutical packaging materials. What are their advantages and disadvantages?
4. What are the criteria for the selection of pharmaceutical packaging materials?
5. What are the materials used for the construction of containers and closures?
6. Explain glass as the container for the pharmaceutical packaging.
7. Explain metal as the container for the pharmaceutical packaging.
8. Explain plastic as the container for the pharmaceutical packaging.
9. Explain rubber as the container for the pharmaceutical packaging.
10. Explain the quality control tests conducted for glass as pharmaceutical packaging materials.
11. Explain the quality control tests conducted for metal as pharmaceutical packaging materials.
12. Explain the quality control tests conducted for plastic as pharmaceutical packaging materials.
13. Explain the quality control tests conducted for rubber as pharmaceutical packaging materials.

SHORT ANSWERS (2 Marks)

1. Define pharmaceutical packaging with examples.
2. Define primary packing materials with examples.
3. Define secondary packing materials with examples.
4. Define containers with examples.
5. Define closures and closure liners with examples.
6. What are the advantages and disadvantages of glass as the pharmaceutical packaging material?
7. What are the advantages and disadvantages of metal as the pharmaceutical packaging material?
8. What are the advantages and disadvantages of plastic as the pharmaceutical packaging material?
9. What are the advantages and disadvantages of rubber as the pharmaceutical packaging material?
10. Name the types of glass used as the pharmaceutical packaging materials.
11. Define glass transition temperature.

Chapter - 6: CURRENT GOOD MANUFACTURING PRACTICES (CGMP): (5+2+2)

SHORT ESSAY (5 marks)

1. Explain the salient features of USFDA with respect to approval of pharmaceutical formulations.
2. Describe the guidelines mentioned under MHRA for quality manufacture of pharmaceutical formulations.
3. Write the cGMP requirements of schedule M as per D & C Act.
4. Explain the salient features of USFDA with respect to manufacture of finished products.
5. Explain the objectives, role and structure of TGA.
6. Explain the objectives, role and structure of MHRA.

SHORT ANSWERS (2 Marks)

1. What is cGMP? Write the significance of implementation of cGMP.
2. What are the objectives of D & C Act.
3. What is USFDA? Write any two functions of USFDA.
4. What is MHRA? Write any two functions of MHRA.
5. What is TGA? Write any two functions of TGA.
6. What are therapeutic goods as per TGA guidelines?
7. What are the objectives of USFDA guidelines?
8. What are the objectives of MHRA guidelines?
9. What are the objectives of TGA guidelines?
10. Define Active Pharmaceutical Ingredient and Finished Product as per USFDA.

Chapter - 7: VALIDATION: (10 + 2)

LONG ESSAY (10 Marks)

1. Explain various types of validation. Discuss suitable validation procedure for mixing operation.
2. Explain the process validation. Describe the protocol of process validation of compression of tablets.
3. Describe the various steps involved in the process validation of the mixing operation on a planetary mixer.
4. Describe the various steps involved in the process validation of the mixing operation on a sigma blade mixer.
5. Define validation. Explain the prospective and concurrent validation.
6. Define validation. Explain the retrospective validation and revalidation.
7. Define validation. Explain the significance of validation in pharmaceutical operations with respect to mixing and compression.

SHORT ANSWER (2 Marks)

1. Define validation.
2. Define process validation.
3. Why do we have to perform process validation?
4. What are the objectives of process validation?
5. What is the importance of process validation?
6. Name different types of validation.
7. Define prospective validation.
8. Define concurrent validation.
9. Define retrospective validation.
10. Define revalidation.
11. Name four types of process validation.
12. What are the three stages of process validation?
13. What are the typical activities of process design?
14. What is meant by process qualification?
15. What is meant by continued process verification?
16. Define validation master plan.
17. Define validation protocol.
18. Define validation report.
19. Define sampling plan.
20. Name the critical process parameters in validation of mixing.
21. Name the critical process parameters in validation of compression.

Chapter - 8: BIOSTATISTICS (5 + 2)

SHORT ESSAY (5 Marks)

1. Define biostatistics. What is the significance of biostatistics in pharmacy?
2. Define biostatistics. Explain different types of data distribution.
3. Define biostatistics. Explain the measurement of central tendency distribution with respect to average, mean, median and mode.
4. Define and explain average, mean, median and mode with examples.
5. Explain variation of mean and standard deviation with examples.
6. Explain variance and coefficient of variation with examples.
7. Define biostatistics. Explain the standard error of mean.
8. Describe the procedure for the measurement of the spread of data range?
9. Define variation of mean, standard deviation, variance and coefficient of variation.

SHORT ANSWERS (2 Marks)

1. Define biostatistics.
2. Define data distribution.
3. Define central tendency distribution.
4. Define median and mode.
5. What are the differences between median and mode?
6. Define variation of mean.
7. Define standard deviation.
8. Define variance.
9. Define coefficient of variation.
10. What is meant by standard error of mean?

Chapter - 9: ICH GUIDELINES AND QbD (2 + 2)

SHORT ANSWERS (2 Marks)

1. Define ICH. What is the purpose of ICH guidelines?
2. What are the advantages of ICH guidelines?
3. Name various zones as per ICH guidelines.
4. What is the basis of classification of zones as per ICH guidelines?
5. What are the quality guidelines as per ICH?
6. What are the safety guidelines as per ICH?
7. What are the efficacy guidelines as per ICH?
8. Classify zones for long term stability testing as per ICH guidelines.
9. Classify zones for accelerated stability testing as per ICH guidelines.
10. Classify zones for intermediate stability testing as per ICH guidelines.
11. Define accelerated and intermediate testing?
12. Define long term and accelerated testing?
13. Define QbD.
14. What are the benefits of QbD?
15. What are the tools of QbD?
16. What are the components of QbD?
17. What are the advantages of implementing QbD?
18. What are the challenges of adopting QbD?