CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honours in Industrial Pharmaceutical Sciences
IPS 4123 – Pharmaceutical Quality Control
Batch – 04
4th year 1st semester
End Semester SEQ Examination

INDEX NUMBER: .....

Date	**: 14th March 2024**
Time	**: 09.00 a.m. – 12.00 p.m. (Three hours)**

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.

Question 01 **(100 marks)**

1.1. What is the importance of the Quality Assurance (QA) department in a pharmaceutical manufacturing plant? (20 marks)
1.2. State **05** main areas in which you have to follow Good Manufacturing Practices in a pharmaceutical manufacturing plant. (10 marks)
1.3. Briefly describe the **03** objectives of following Good Laboratory Practices. (30 marks)
1.4. Describe the importance of following GMP in a pharmaceutical manufacturing area. (40 marks)

Question 02 **(100 marks)**

2.1. What is a quality management system in a quality control laboratory? (10 marks)
2.2. Briefly describe how you are going to control your documents as a head of the quality control laboratory. (30 marks)
2.3. Write short notes on the following.
2.3.1. Handling of incoming samples for the quality analysis. (20 marks)
2.3.2. Samples collection from in-process manufacturing. (20 marks)
2.4. What is the importance of retained samples of a particular pharmaceutical product? (20 marks)

Question 03 **(100 marks)**

3.1. State **05** responsibilities of British Pharmacopoeia Commission (BPC). (20 marks)
3.2. State the content available in the Pharmacopieal appendices. (15 marks)
3.3. Outline the elements of pharmaceutical products distribution system. (30 marks)
3.4. Write short notes on the following.
3.4.1. Distribution channels. (15 marks)
3.4.2. Distribution records. (20 marks)

Question 04 **(100 marks)**

4.1. Write all the quality test parameters considered in the following quality control tests according to United States Pharmacopeia.
- 4.1.1. Disentigration test for uncoated tablets. (15 marks)
- 4.1.2. Dissolution test for uncoated tablets. (15 marks)
- 4.1.3. Uniformity of weight for uncoated tablets. (15 marks)

4.2. Briefly describe the importance of conducting following quality control tests for pharmaceutical liquid dosage forms.
- 4.2.1. Phase separation. (10 marks)
- 4.2.2. Thermal stress. (10 marks)
- 4.2.3. Re-dispersibility. (10 marks)

4.3. Outline the method followed in *in vitro* skin irritant test for pharmaceutical creams. (25 marks)

Question 05 **(100 marks)**

5.1. State **05** determinants of medicine quality. (10 marks)

5.2. Briefly describe the **05** advantages of the LAL test over the rabbit test when testing pyrogens. (20 marks)

5.3. What is the importance of conducting a growth promotion test when you are doing the sterility test? (20 marks)

5.4. In addition to the foregoing medium tests, before conducting a sterility test on a product,
- 5.4.1. How you are going to determine the product's level of bacteriostatic and fungistatic activity? (30 marks)
- 5.4.2. If the product has bacteriostatic or fungistatic activity, how you are going to continue the sterility test? (20 marks)

Question 06 **(100 marks)**

6.1. State **04** considerations that should consider obtaining the required quality of packaging by the quality management system. (20 marks)

6.2. Briefly describe the process "sampling" when assuring the quality of pharmaceutical packaging. (15 marks)

6.3. Outline the classification of drug recalling. (20 marks)

6.4. Write short notes on the following.
- 6.4.1. Corrective and Preventive Action. (25 marks)
- 6.4.2. Quality by Design and Product Development. (20 marks)

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INDEX NUMBER:.....

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Time: 09.00 a.m. – 12.00 p.m. (Three hours)

INSTRUCTIONS TO CANDIDATES

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Question 1 **(100 Marks)**

1.1. Define Biopharmaceutics. (10 marks)
1.2. Classify and enumerate the biopharmaceutic factors influencing the bioavailability of a drug from its dosage form. (20 marks)
1.3. Briefly describe the different routes of drug administration in terms of bioavailability, stating their advantages and disadvantages. (30 marks)
1.4. Describe Fick's First Law of Diffusion and its application. (40 marks)

Question 2 **(100 Marks)**

2.1. Define the following terms.
  2.1.1. Disposition (10 marks)
  2.1.2. Distribution of drugs (10 marks)
2.2. Differentiate between plasma protein-drug binding and tissue protein-drug binding. (20 marks)
2.3. Develop the relationship between perfusion rate & tissue distribution half-life. (30 marks)
2.4. Describe the different fluid compartments available in the body. (30 marks)

Question 3 **(100 Marks)**

3.1. Classify the chemical pathways of drug metabolism. (30 marks)
3.2. State **05** factors affecting biotransformation of drugs. (10 marks)
3.3. Briefly describe the enzyme induction by giving examples (20 marks)
3.4. Describe the causes of non-linearity in each ADME (absorption, distribution, metabolism, and excretion) (40 marks)

Question 4 **(100 Marks)**

4.1. Write the process of excretion of drugs illustrating a suitable diagram. (30 marks)

4.2. Briefly describe the non-renal excretion pathways. (30 marks)

4.3. Write a descriptive account of renal clearance and the factors affecting it. (40 marks)

Question 5 **(100 Marks)**

5.1. Define the terms.

5.1.1. Object drug (10 marks)

5.1.2. precipitant drug (10 marks)

5.2. Write a brief note on pharmacokinetic drug-drug interactions and their types with suitable examples. (40 marks)

5.3. Derive the equation to determine the concentration and half-life of a drug undergoing zero-order kinetics. (40 marks)

Question 6 **(100 Marks)**

6.1. Define the following pharmacokinetic parameters.

6.1.1. C_{max} (10 marks)

6.1.2. t_{max} (10 marks)

6.1.3. AUC (10 marks)

6.2. Briefly describe the Wagner – Nelson method for estimation of absorption rate constant. (40 marks)

6.3. Describe one compartment open model extravascular administration. (30 marks)