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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honors in Industrial Pharmaceutical Science
IPS 4143 Pharmacognosy I
Batch 06
4th Year 1st Semester
End Semester Examination - SEQ

Date : 12th June 2026
Time : 9.00 am – 12.00 noon

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 List **four (04)** main areas of pharmacognosy. (20 marks)

1.2 State **four (04)** current trends in pharmacognostic research. (20 marks)

1.3 Write a short note on importance of crude drugs in 'Deshiya Chikitsa' system of indigenous medicine. (30 marks)

1.4 How can omics technologies be used in the classification of natural drugs? (30 marks)

Question 02

2.1 List **four (04)** characteristics of purified drugs. (20 marks)

2.2 Differentiate between 'organized' and 'unorganized' crude drugs. (20 marks)

2.3 Outline the the six (06) major steps in common preparation method of crude drugs. (30 marks)

2.4 Complete the following table on crude drugs. (6 x 5 marks)

Crude drug	Source/ origin	Major constituent (only one is enough)	Pharmaceutical use (only one is enough)
Clove oil	A)	B)	C) .....
Cod liver oil	D)	E)	F) .....

Question 03

3.1 Classify following set of natural medicines using **two (02)** suitable classification systems. (Indicate each of the classification systems you used clearly): ginseng, turmeric, artemisinin, castor oil, cinchona (20 marks)

3.2 List **two (02)** merits of cultivation of medicinal plants. (10 marks)

3.3 State the key steps involved in the following agricultural/biotechnological techniques.

3.3.1 Plant tissue culture (25 marks)

3.3.2 Hybridization of medicinal plants (25 marks)

3.4 A herbal drug manufacturer intends to prepare a medicinal crude drug powder of *Evolvulus alsinoides* (Vishnukranthi) collected from several small farms. As a quality officer, identify **two (02)** Good Agricultural Practices (GAP)-related factors that could lead to quality failures and recommend necessary measures to improve them. (20 marks)

Question 04

4.1 List **four (04)** general properties of resins. (20 marks)

4.2 Classify tannins into **three (03)** major categories with **one (01)** suitable example for each. (20 marks)

4.3 Describe the industrial applications of resins with suitable examples. (30 marks)

4.4 Discuss **three (03)** identification tests used for tannins. (30 marks)

Question 05

5.1 State **four (04)** biological functions of lipids. (20 marks)

5.2 Differentiate between saturated fatty acids and unsaturated fatty acids using **four (04)** suitable characteristics. (20 marks)

5.3 A manufacturer reported rancidity in a fixed oil preparation during storage. As a quality assurance officer, discuss the methods used for detection of adulteration in lipids. (30 marks)

5.4 Analyze the pharmaceutical applications of natural carbohydrates with suitable examples. (30 marks)

Question 06

6.1 List **four (04)** common reasons for adulteration of crude drugs. (20 marks)

6.2 Outline the role of modern analytical techniques in the detection of adulteration in crude drugs. (20 marks)

6.3 Compare intentional adulteration with unintentional adulteration of crude drugs using suitable examples. (30 marks)

6.4 Write a short note on polysaccharides, including their classification, properties, and pharmaceutical importance. (30 marks)

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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honours in Industrial Pharmaceutical Sciences
IPS 4113 – Biopharmaceutics
Batch 06
4th year 1st semester
End Semester SEQ Examination

Date: 08th June 2026
Time: 09:00 a.m. – 12:00 noon (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. Define clinical pharmacokinetics. (15 marks)

1.2. Evaluate the reasons for necessity to introduce a new discipline named 'biopharmaceutics' in health care. (20 marks)

1.3. Write a brief description on vesicular / corpuscular transport. (15 marks)

1.4. Explain the mechanism of carrier mediated transport with examples. (20 marks)

1.5. Comment on the nature of pharmacokinetic profile of carrier mediated transport using a rate of absorption vs. concentration plot. (30 marks)

Question 02 **(100 marks)**

2.1. Enumerate **four (04)** active pharmaceutical ingredient related factors that may influence the biopharmaceutical characteristics of the drug product. (20 marks)

2.2. Partition co-efficient ($K_{m/w}$) of a drug molecule - **X** was found to be 1.02.
The other parameters observed during the absorption of **X** are as follows:
rate of diffusion ($\frac{dQ}{dt}$) = 420 µg/min, Concentration of drug in GIT (C_{GIT}) = 200 µg/mL
surface area of GI membrane (A) = 55 cm^2 Concentration of drug in plasma (C) = 100 µg/mL
Thickness of GI membrane (h) = 0.2 cm (25 marks)

Apply modified Fick's first law of diffusion and find the diffusivity (D) of a drug molecule.

2.3. The bioavailability of Phenylpropanolamine hydrochloride (PPH) was studied in 24 adult male subjects. The following data represent the mean blood PPH concentrations (ng/ml) after the oral administration of a single 25 mg dose.
Plasma concentration time profile of PPH is given below:

Time h	0.25	0.5	0.75	1	1.5	2	3	4	6	8	12	18	24
Conc ng/ml	51.33	74.05	82.91	85.11	81.76	75.51	62.98	52.32	36.08	24.88	11.83	3.88	1.27

2.3.1. Plot the graph in the provided semi-log graph paper. (20 marks)

2.3.2. Determine the elimination rate constant. (20 marks)

2.3.3. Determine the absorption rate constant. (15 marks)

Question 03 **(100 marks)**

3.1. Outline **two (2)** drug-related factors affecting the process of drug absorption. (10 marks)

3.2. Outline the characteristics of first-order absorption kinetics. (20 marks)

3.3. The following graph represents the plasma concentration of a drug after oral administration. Copy this graph to your answer script and label the following phases on the graph:

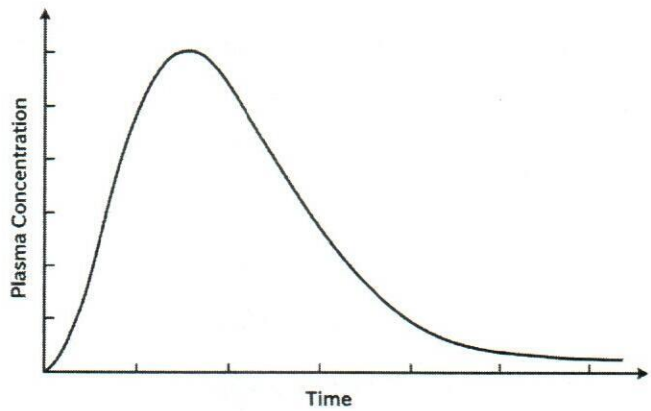
3.3.1 Absorption Phase

3.3.2 Peak Plasma Concentration (C_{max})

3.3.3 Time to Reach Peak Concentration (T_{max})

3.3.4 Distribution Phase

3.3.5 Elimination Phase (5 × 4 = 20 marks)



3.4. Analyze the concept of bioavailability by explaining their relationship to drug exposure. (20 marks)

3.5. Evaluate the clinical importance of measuring the plasma drug concentration in therapeutic drug monitoring and dose optimization. (30 marks)

Question 04 **(100 marks)**

4.1. Outline **three (3)** factors influencing drug distribution. (15 marks)

4.2. Briefly describe plasma protein binding and tissue binding with their effects on drug distribution and activity. (25 marks)

4.3. Analyze how physiological barriers affect the drug distribution. (30 marks)

4.4. Evaluate the clinical significance of the following.

4.4.1 Volume of distribution in dose design

4.4.2 Drug accumulation (2×15 marks)

Question 05 **(100 marks)**

5.1. State **two (2)** different types of clearance processes that contribute to total body clearance. (10 marks)

5.2. Outline the role of drug clearance in drug elimination. (15 marks)

5.3. Differentiate the one and two-compartment models by considering their plasma concentration–time profiles. (25 marks)

5.4. A patient in the ICU is receiving a continuous IV infusion of an antibiotic drug (Drug "X") to maintain a stable plasma concentration of it. The infusion rate is 60 mg/hr, and the measured steady-state plasma concentration (C_{ss}) of dug "X" is 12 mg/L.

5.4.1. Calculate the clearance of the drug "X". (30 marks)

5.4.2. Interpret what this value indicates about the patient's drug elimination and its implication for dosing. (20 marks)

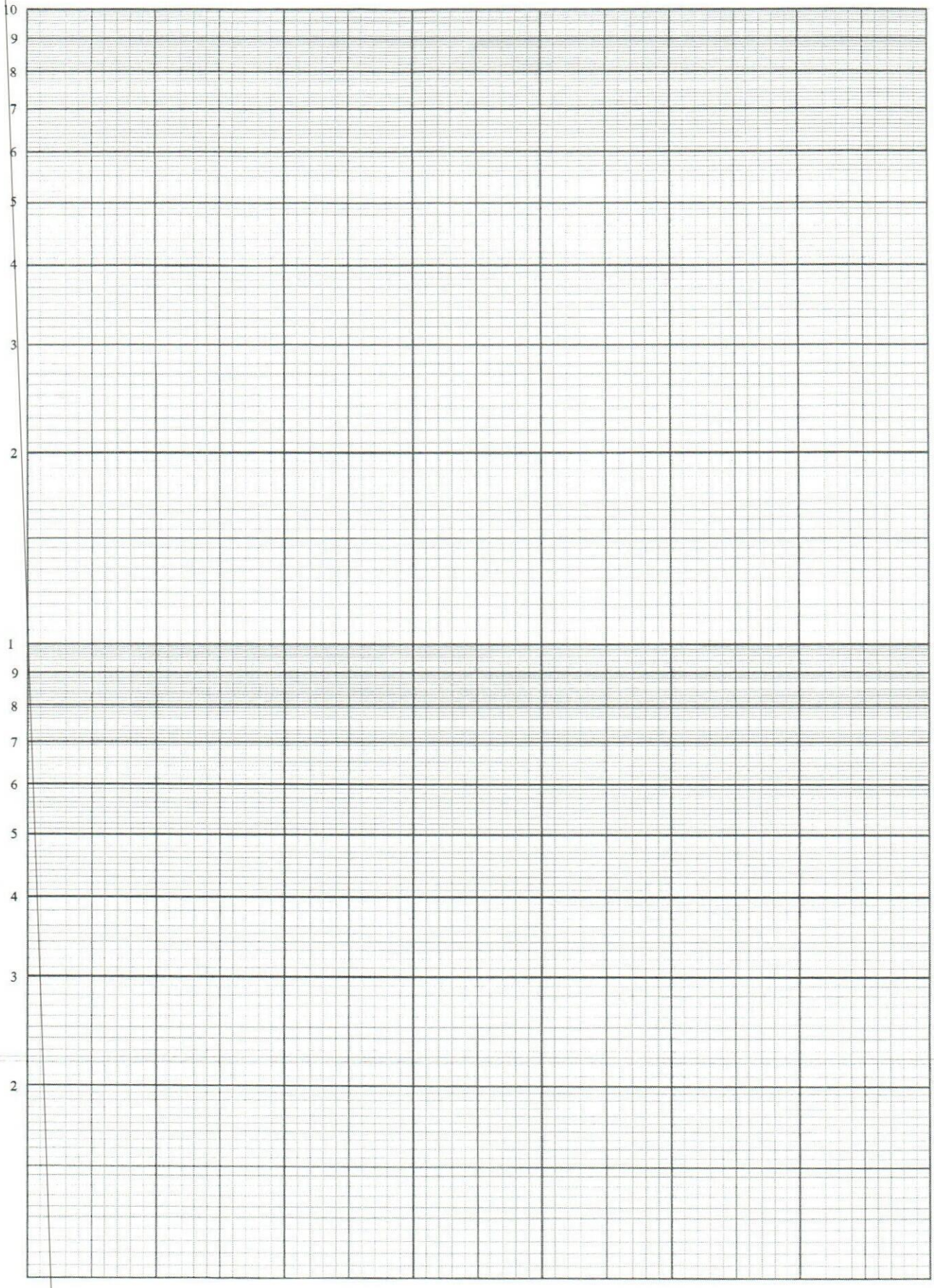
Question 06 **(100 marks)**

6.1. Critically analyze **two (02)** disadvantages of kinetic profiling using Michaelis' constant (K_m) and maximum velocity of the process (V_{max}). (25 marks)

6.2. Briefly discuss **two (02)** occasions where non-linear pharmacokinetics may be observed. (25 marks)

6.3. Mention **six (06)** factors contributing to drug-drug interactions. (25 marks)

6.4. Discuss indirect pharmacodynamic interactions. (25 marks)


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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honors in Industrial Pharmaceutical Science
IPS 4222 Pharmaceutical Jurisprudence
Batch 05
4th Year 1st Semester
End Semester Examination - SEQ (Resit)

Date : 04th of May 2026
Time : 9.00 a.m. - 12.00 noon (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 Distinguish between a 'bill' and an 'act'. (20 marks)

1.2 State ethics in pharmaceutical industry related to marketing and advertising. (25 marks)

1.3 Mention **five (05)** elements in the national medicinal drug policy (NMDP) of Sri Lanka. (25 marks)

1.4 Outline the objectives of the NMDP of Sri Lanka. (30 marks)

Question 02 **(100 marks)**

2.1 What is 'full product registration' of a cosmetic? (20 marks)

2.2 Differentiate 'controlled cosmetics' and 'general cosmetics'. (20 marks)

2.3 Outline current regulations on advertising cosmetics in Sri Lanka. (30 marks)

2.4 Write an account on pharmaceutical education in global setting. (30 marks)

Question 03 **(100 marks)**

3.1 Who is eligible to apply for drug registration with the National Medicines Regulatory Authority (NMRA) in Sri Lanka? (10 marks)

3.2 Why is it necessary to submit a site master file during the registration process of imported medicines? (20 marks)

3.3 Suppose you are planning to establish a new pharmaceutical manufacturing plant and have finalized a location for the construction.

3.3.1 State the initial documents required to be submitted to the NMRA. (20 marks)

3.3.2 What is the next step if compliance with the Authority's guidelines is confirmed? (20 marks)

3.4 "Medicines can be manufactured before the registration". Comment on this statement.

(30 marks)

Question 04 **(100 marks)**

4.1 State **five (05)** members of the medicines evaluation committee (MEC). (20 marks)

4.2 What is a physician sample? (20 marks)

4.3 A vehicle transporting articles (as per NMRA act) is stopped by authorized officers, and samples are collected and sent to an approved analyst for examination.

4.3.1 Name **three (03)** individuals who are eligible to act as authorized officers. (30 marks)

4.3.2 Write a descriptive account on other powers of an authorized officer. (30 marks)

Question 05 **(100 marks)**

5.1 Mention the drug schedule to which the following articles belong. (10 marks)

5.1.1 Barbiturates - .....

5.1.2 Alkaloids - .....

5.2. State **two (02)** educational qualifications for registration as pharmacists by Sri Lanka Medical Council (SLMC). (20 marks)

5.3 How should the remaining poisons be handled, when a pharmacist terminates their practice? (20 marks)

5.4 What are the labeling requirements for poisons and poisonous substances intended for sale? (20 marks)

5.5 How does the Ministry of Health regulate the import and export of raw or prepared opium according to the poison, opium, dangerous drug ordinance? (30 marks)

Question 06 **(100 marks)**

6.1 Categorize nutraceuticals based on their source. (20 marks)

6.2 Write a brief account on probiotics. (25 marks)

6.3 State **four (04)** objectives of consumer affairs authority. (20 marks)

6.4 A local research institute imported a new anti-diabetic medicine for clinical trials without proper authorization. The shipment was detained by the customs. The institute argues that the import was not for commercial use, therefore should be exempted from restrictions.

6.4.1 How would you address this issue as a representative of the research institute? (15 marks)

6.4.2 How would this institute get approval needed to import medicines for clinical trials in Sri Lanka in a future instance? (20 marks)

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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honors in Industrial Pharmaceutical Science
IPS 4222 Pharmaceutical Jurisprudence
Batch 05
4th Year 1st Semester
End Semester Examination - SEQ (Resit)

Date : 04th of May 2026
Time : 9.00 a.m. - 12.00 noon (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 Distinguish between a 'bill' and an 'act'. (20 marks)

1.2 State ethics in pharmaceutical industry related to marketing and advertising. (25 marks)

1.3 Mention **five (05)** elements in the national medicinal drug policy (NMDP) of Sri Lanka. (25 marks)

1.4 Outline the objectives of the NMDP of Sri Lanka. (30 marks)

Question 02 **(100 marks)**

2.1 What is 'full product registration' of a cosmetic? (20 marks)

2.2 Differentiate 'controlled cosmetics' and 'general cosmetics'. (20 marks)

2.3 Outline current regulations on advertising cosmetics in Sri Lanka. (30 marks)

2.4 Write an account on pharmaceutical education in global setting. (30 marks)

Question 03 **(100 marks)**

3.1 Who is eligible to apply for drug registration with the National Medicines Regulatory Authority (NMRA) in Sri Lanka? (10 marks)

3.2 Why is it necessary to submit a site master file during the registration process of imported medicines? (20 marks)

3.3 Suppose you are planning to establish a new pharmaceutical manufacturing plant and have finalized a location for the construction.

3.3.1 State the initial documents required to be submitted to the NMRA. (20 marks)

3.3.2 What is the next step if compliance with the Authority's guidelines is confirmed? (20 marks)

3.4 "Medicines can be manufactured before the registration". Comment on this statement.

(30 marks)

Question 04 **(100 marks)**

4.1 State **five (05)** members of the medicines evaluation committee (MEC). (20 marks)

4.2 What is a physician sample? (20 marks)

4.3 A vehicle transporting articles (as per NMRA act) is stopped by authorized officers, and samples are collected and sent to an approved analyst for examination.

4.3.1 Name **three (03)** individuals who are eligible to act as authorized officers. (30 marks)

4.3.2 Write a descriptive account on other powers of an authorized officer. (30 marks)

Question 05 **(100 marks)**

5.1 Mention the drug schedule to which the following articles belong. (10 marks)

5.1.1 Barbiturates - .....

5.1.2 Alkaloids - .....

5.2. State **two (02)** educational qualifications for registration as pharmacists by Sri Lanka Medical Council (SLMC). (20 marks)

5.3 How should the remaining poisons be handled, when a pharmacist terminates their practice? (20 marks)

5.4 What are the labeling requirements for poisons and poisonous substances intended for sale? (20 marks)

5.5 How does the Ministry of Health regulate the import and export of raw or prepared opium according to the poison, opium, dangerous drug ordinance? (30 marks)

Question 06 **(100 marks)**

6.1 Categorize nutraceuticals based on their source. (20 marks)

6.2 Write a brief account on probiotics. (25 marks)

6.3 State **four (04)** objectives of consumer affairs authority. (20 marks)

6.4 A local research institute imported a new anti-diabetic medicine for clinical trials without proper authorization. The shipment was detained by the customs. The institute argues that the import was not for commercial use, therefore should be exempted from restrictions.

6.4.1 How would you address this issue as a representative of the research institute? (15 marks)

6.4.2 How would this institute get approval needed to import medicines for clinical trials in Sri Lanka in a future instance? (20 marks)

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Beyond A Graduate

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Faculty of Health Sciences
Bachelor of Science Honors in Industrial Pharmaceutical Science
IPS 4222 Pharmaceutical Jurisprudence
Batch 05
4th Year 1st Semester
End Semester Examination - SEQ

INDEX NUMBER: .....

Date : 16th of July 2025
Time : 9.00 a.m. - 12.00 noon (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 Distinguish between a 'bill' and an 'act'. (20 marks)

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1.3 Mention **five (05)** elements in national medicinal drug policy (NMDP) of Sri Lanka. (25 marks)

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1.4 Outline the objectives of NMDP of Sri Lanka. (30 marks)

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Question 02 **(100 marks)**

2.1 What is 'full product registration' of a cosmetic? (20 marks)

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3.1 Who is eligible to apply for drug registration with the National Medicines Regulatory Authority (NMRA) in Sri Lanka? (10 marks)

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3.2 Why is it necessary to submit a site master file during the registration process of imported medicines? (20 marks)

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3.3 Suppose you are planning to establish a new pharmaceutical manufacturing plant and have finalized a location for the construction.

3.3.1 State the initial documents required to be submitted to the NMRA. (20 marks)

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(30 marks)

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Question 04 **(100 marks)**

4.1 State **five (05)** members of the medicines evaluation committee (MEC). (20 marks)

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4.2 What is a physician sample? (20 marks)

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4.3 A vehicle transporting articles (as per NMRA act) is stopped by authorized officers, and samples are collected and sent to an approved analyst for examination.

4.3.1 Name **three (03)** individuals who are eligible to act as authorized officers. (30 marks)

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4.3.2 Write a descriptive account on other powers of an authorized officer. (30 marks)

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Question 05 **(100 marks)**

5.1 Mention the drug schedule to which the following articles belong. (10 marks)

5.1.1 Barbiturates - .....

5.1.2 Alkaloids - .....

5.2. State **two (02)** educational qualifications for registration as pharmacists by Sri Lanka Medical Council (SLMC). (20 marks)

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5.3 How should the remaining poisons be handled, when a pharmacist terminates their practice? (20 marks)

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5.4 What are the labeling requirements for poisons and poisonous substances intended for sale? (20 marks)

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5.5 How does the Ministry of Health regulate the import and export of raw or prepared opium according to the poison, opium, dangerous drug ordinance? (30 marks)

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Question 06 **(100 marks)**

6.1 Categorize nutraceuticals based on their source. (20 marks)

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6.2 Write a brief account on probiotics. (25 marks)

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6.3 State **four (04)** objectives of consumer affairs authority. (20 marks)

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6.4 A local research institute imported a new anti-diabetic medicine for clinical trials without proper authorization. The shipment was detained by the customs. The institute argues that the import was not for commercial use, therefore should be exempted from restrictions.

6.4.1 How would you address this issue as a representative of the research institute? (15 marks)

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6.4.2 How would this institute get approval needed to import medicines for clinical trials in Sri Lanka in a future instance? (20 marks)

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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honours in Industrial Pharmaceutical Sciences
IPS 4133 Pharmaceutical Biotechnology
Batch – 04
4th Year 1st Semester
End semester Special Repeat SEQ Examination

Date : **02.06.2025**
Time : **9.00 am. – 12.00 pm. (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. Define the process DNA replication. (25 marks)

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1.2. State the types enzymes involves in the DNA replication mechanism. (25 marks)

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1.3. Outline the DNA replication mechanism. (25 marks)

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1.4. Compare and contrast leading and lagging strands. (25 marks)

QUESTION 02 **(100 marks)**

2.1. Define the term spontaneous DNA mutation. (25 marks)

2.2. Briefly describe spontaneous DNA mutation and induced DNA damages. (25 marks)

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2.3. Briefly outline the base excision and nucleotide excision DNA damage repair mechanisms. (50 marks)

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QUESTION 03 **(100 marks)**

3.1 Define the term of "polymerase chain reaction". (10 marks)

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3.2 Outline the steps of polymerase chain reaction. (25 marks)

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3.3 Outline the steps of sanger sequencing method. (30 marks)

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3.4 State the importance of the next generation sequencing method. (35 marks)

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QUESTION 04 **(100 marks)**

4.1 Mention the sources of enzymes and discuss their limitations. (20 marks)

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4.2 Briefly describe the human insulin production via recombinant biotechnology. (25 marks)

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4.3 Mention four applications of pharmaceutical biotechnology. (25 marks)

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4.4 Briefly describe the therapeutic uses of pharmaceutical biotechnology products. (30 marks)

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QUESTION 05 **(100 marks)**

5.1 Define the term "central dogma of life". (20 marks)

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5.2 Briefly define the terms transcription and translation in protein synthesis. (25 marks)

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5.3 Outline the process of translation in central dogma of life. (25 marks)

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5.4 Outline the template strand and RNA strand of given coding strand. (30 marks)
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QUESTION 06 **(100 marks)**

6.1 Define the term recombinant DNA technology. (10 marks)

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6.2 State the basic events of gene cloning. (25 marks)

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6.3 Write the short notes on following topics.

6.3.1 Restriction endonuclease enzyme (20 marks)

6.3.2 Vector (20 marks)

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6.4 Outline a selection method of host cells which have acquired recombinant vector. (25 marks)

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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Bachelor of Science Honors in Industrial Pharmaceutical Science
IPS 4143 Pharmacognosy I
Batch 04
4th Year 1st Semester
End Semester (Resit) Examination - SEQ

INDEX NUMBER: .....

Date : 30th of May 2025
Time : 9.00 a.m. - 12.00 noon (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 List **four (04)** tannin-containing plant sources. (20 marks)

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1.2 State **five (05)** types of carbohydrates with pharmaceutical uses. (25 marks)

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1.3 Differentiate the characteristics of fats and oils. (30 marks)

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1.4 Outline pharmaceutical uses of different types of lipid derivatives. (25 marks)

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Question 02 **(100 marks)**

2.1 Distinguish between organized and unorganized drugs. (20 marks)

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2.2 List **four (04)** important alkaloids extracted form *Cinchona* spp. (20 marks)

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2.3 Define the following terms related to herbal drug industry.

2.3.1 Inferiority of substances (15 marks)

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2.3.2 Admixture (15 marks)

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2.4 Outline different methods used in isolation of resins. (30 marks)

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Question 03 **(100 marks)**

3.1 List **four (04)** animal-based crude drugs. (20 marks)

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3.2 What is "indirect adulteration" of herbal medicines? (20 marks)

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3.3 Mention the method used in quantitative microscopy for crude drug evaluation. (30 marks)

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3.4 Outline **three (03)** different ways used to classify crude drugs. (30 marks)

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Question 04 **(100 marks)**

4.1 What are the parameters involved in biological evaluation of crude drugs? (20 marks)

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4.2 List **four (04)** Good Manufacturing Practice (GMP) of the herbal drug industry. (20 marks)

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4.3 State advantages and disadvantages of the use of crude drugs. (30 marks)

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4.4 What is the importance of better cultivation of medicinal plants? (30 marks)

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Question 05 **(100 marks)**

5.1 What is "*in situ* conservation of medicinal plants"? (20 marks)

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5.2 What are the disadvantages of the asexual propagation of medicinal plants? (20 marks)

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5.3 State **five (05)** key features of plant kingdom members. (30 marks)

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5.4 Why do the stomata absent in plant roots? (30 marks)

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Question 06 **(100 marks)**

6.1 State the **four (04)** whorls of typical angiosperm flowers. (20 marks)

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6.2 List different shapes of flowers belonging to family Apocynaceae, giving examples. (20 marks)

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6.3 Differentiate pharmacopeia, botanical floras, and monographs. (30 marks)

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6.4 Mention different modifications in some plants to perform special functions. (30 marks)

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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 (Special Resit)

INDEX NUMBER: .....

Date : **28th of May 2025**
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. State the importance of appendices in pharmaceutical quality control. (20 marks)

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1.2. List **05** responsibilities of British Pharmacopeia Commission (BPC). (30 marks)

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1.3. Outline the elements of pharmaceutical products distribution system. (20 marks)

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1.4. Write a short note on distribution records. (30 marks)

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Question 02 **(100 marks)**

2.1. State **05** key functions of the quality assurance. (20 marks)

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2.2. State **five (05)** advantages of following Good Manufacturing Practices. (20 marks)

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2.3. What is the purpose of following Good Laboratory Practices (GLPs)? (25 marks)

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2.4. How you are going to handle toxic substances in a laboratory? (25 marks)

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Question 03 **(100 marks)**

3.1. A batch of coated tablets were tested for disintegration according to the USP guidelines. One tablet out from the six tablets fail to disintegrate in the intestinal fluid after immersing for an hour.

3.1.1. As a quality control executive what will be your next steps. (30 marks)

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3.2. What is the difference between the disintegration testing procedures for uncoated tablets and enteric-coated tablets? (20 marks)

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3.3. What is the importance of conducting friability test for tablets? (30 marks)

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3.4. State the acceptance criteria for a batch when one capsule fails to disintegrate during the disintegration test. (20 marks)

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Question 04 **(100 marks)**

4.1. Mention the importance of measuring zeta potential in a pharmaceutical emulsion. (30 marks)

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4.2. List **04** functions of a packaging material. (20 marks)

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4.3. State the possible interactions that may occur between primary packaging and the included pharmaceutical product. (20 marks)

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4.4. State the importance of conducting following quality control tests for pharmaceutical liquid dosage forms.

4.4.1. Phase separation. (10 marks)

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4.4.2. Thermal stress. (10 marks)

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4.2.3. Re-dispersibility. (10 marks)

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Question 05 **(100 marks)**

5.1. A batch of the pain relief injection has been identified with serious adverse effects following patient complaints. The collected samples were sent to the regulatory authorities to check the quality of the medication.

5.1.1. How does the company assess the quality of its medication independently, aside from regulatory authorities? (30 marks)

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5.2. Differentiate between analytical work sheet and the analytical test report. (30 marks)

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5.3. What is certificate of analysis (COA)? (20 marks)

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5.4. State the purpose of quality management system in a quality control laboratory.(20 marks)

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Question 06 **(100 marks)**

6.1. A batch of the pain relief injection has been identified with serious adverse effects following patient deaths. They are using water as a solvent to dissolve the drug during the manufacturing.

6.1.1. Identify the possible cause of the patient's death and the associated adverse effects.

(20 marks)

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6.1.2. Provide a suggestion to solve this problem. (20 marks)

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6.2. Following table shows the results of the rabbit test for an injection.

1st Group of rabbits	Initial Temperature	Temperature after 30 mins	Temperature after 60 mins	Temperature after 90 mins	Temperature after 120 mins	Temperature after 180 mins
Rabbit 01	38.0°C	38.1°C	38.2°C	38.2°C	38.3°C	38.2°C
Rabbit 02	38.1°C	38.2°C	38.3°C	38.2°C	38.2°C	38.1°C
Rabbit 03	38.0°C	38.2°C	38.4°C	38.4°C	39.3°C	38.3°C

Use the following table as the reference to interpret the results.

NUMBER OF RABBITS	MATERIAL PASSED IF SUM OF RESPONSE DOES NOT EXCEED.	MATERIAL FAILED IF SUM OF RESPONSE EXCEEDS.
3 RABBITS	1.15C	2.65C
6 RABBITS	2.80C	4.30C
9 RABBITS	4.45C	5.95C
12 RABBITS	6.10C	7.60C

6.2.1. Comment on the acceptance of the batch giving the reasons. (20 marks)

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6.2.2. What is the next step you have to done after this procedure? (20 marks)

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6.3. What is the importance of conducting growth promotion test prior conducting the sterility test? (20 marks)

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Faculty of Health Sciences
Bachelor of Science Honours in Industrial Pharmaceutical Sciences
IPS 4113 – Biopharmaceutics
Batch – 04 & 05 (Special Re-sit)
4th year 1st semester
End Semester SEQ Examination

INDEX NUMBER: .....

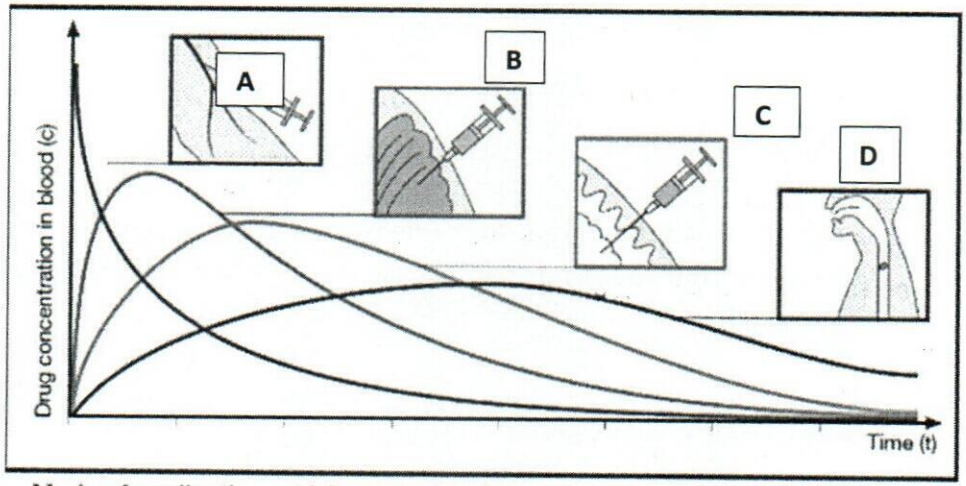
Date: 26th May 2025
Time: 09.00 a.m. – 12.00 p.m. (Three hours)

INSTRUCTIONS TO CANDIDATES

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

Question 1 **(100 marks)**

1.1. Below graph shows the drug plasma concentration – time profiles obtained for the various roots of administration.



Mode of application and time course of drug concentration

a) Identify the different routes of administration – A, B, C & D depicted above. (10 marks)

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b) State the advantages and disadvantages of the above-mentioned routes in terms of bioavailability. (20 marks)

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c) Draw the log concentration – time profile for the route **A**. (20 marks)

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d) Write down the equation relevant to the above log concentration – time profile and explain how you find out the elimination rate constant (K_{el}) and the initial drug plasma concentration (C_0) from the above graph. (30 marks)

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1.2. State how the following factors affect drug distribution. (20 marks)

a) Extent of binding to the plasma proteins

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b) Ionization at physiological pH

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Question 2 **(100 Marks)**

2.1. Define the following terms.

a) Disposition (10 marks)

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b) Distribution of drugs (10 marks)

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c) Differentiate between plasma protein-drug binding and tissue protein-drug binding. (20 marks)

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d) Develop the relationship between perfusion rate & tissue distribution half-life. (30 marks)

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e) Mention the different fluid compartments available in the body and their method of determination (30 marks)

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Question 3 **(100 marks)**

3.1. Define the following terms

a) Absolute bioavailability (15 marks)

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b) Relative bioavailability (15 marks)

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3.2. State the API related factors affecting the bioavailability of orally administered drugs. (40 marks)

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3.3. Following data is obtained for 4 different formulations of Pentoxifylline in volunteers of average weight 50 kg.

Drug Product	Dose (mg /kg)	AUC (mg.hr/liter)	Dose in mg/50kg
I.V solution	1.2	450	
Oral solution	4.0	822	
Oral capsule	4.0	736	
Oral SR tablet	8.0	1040	

Fill the blank column of the above table. (20 marks)

3.4 Define Biopharmaceutics. (10 marks)

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Question 4 **(100 Marks)**

4.1. Illustrate the process of excretion of drugs using a suitable diagram. (30 marks)

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

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

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Question 5 **(100 Marks)**

5.1. Define the following pharmacokinetic parameters.

a) C_{max} (10 marks)

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b) t_{max} (10 marks)

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c) AUC (10 marks)

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5.2 Outline the Wagner – Nelson method for estimation of absorption rate constant. (40 marks)

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5.3 Write a descriptive account of one compartment open model extravascular administration (30 marks)

Question 6

6.1 Compare and contrast the following terms

a) Compartmental vs. non-compartmental pharmacokinetic analysis (10 marks)

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b) Caternary vs. Mammillary Model (10 marks)

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6.2. 100 mg of drug X is given by an intravenous bolus injection and drug plasma concentration was measured in different time intervals as follows.

Time (hr)	C_p (mg/L)	
0	8	
1	7.09	
2	6.29	
3	5.58	
4	4.95	
6	3.89	
9	2.71	
12	1.89	
18	0.92	
24	0.44	

Using the above primary measurements,

a) Plot the zero-order kinetic graph (approximately) (10 marks)

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b) Fill the blank column in the above table with the data required to plot first order-kinetic curve. (20 marks)

6.3. The following data for decomposition of two drugs, A and B are given in the table below:

Time (hr)	Drug – A (mg)	Drug – B (mg)	
0.5	379	181.2	
1.0	358	164.0	
1.5	337	148.6	
2.0	316	134.6	
3.0	274	110.4	
4.0	232	90.6	
6.0	148	61.0	
8.0	64	41.0	

Assume Drug – A undergoes zero-order decomposition and Drug – B undergoes first order decomposition. Then,

a) Plot the respective graph for Drug – B, after filling the blank column in the above table (30 marks)

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b) What is the rate constant for decomposition? (10 marks)

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c) What is their half-life? (10 marks)

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Faculty of Health Sciences

Bachelor of Science Honours in Industrial Pharmaceutical Sciences

IPS 4133 Pharmaceutical Biotechnology

Batch – 05

4th Year 1st Semester

End Semester SEQ Examination

Date : **07th of February 2025**
Time : **9.00 am. – 12.00 pm. (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 1 **(100 Marks)**

1.1 Define the term of "Okaszaki fragment" in DNA replication process. (25 marks)

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1.2 State the enzymes and proteins involved in the DNA replication process. (25 marks)

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1.3 Briefly outline the formation of leading strand and lagging strand. (25 marks)

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1.4 "DNA shortening take place during each DNA replication of the cell", state your opinion and the reasons for your statement. (25 marks)

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QUESTION 02 **(100 Marks)**

2.1 State the basic events in gene cloning. (25 marks)

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2.2 State the important features that you consider during the selection of a molecular vector.

(25 marks)

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2.3 Mention the function of restriction enzyme in molecular cloning. (25 marks)

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2.4 Differentiate the two methods of selection of host cells which acquired recombinant vector based on the vector type. (25 marks)

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QUESTION 03 **(100 Marks)**

3.1 Define the term post-transcriptional modification. (25 marks)

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3.2 State 3 (three) modifications and functions that take place in the post transcriptional modification. (25 marks)

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3.3 Briefly outline the translation process of central dogma of life. (25 marks)

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3.4 Differentiate the two-termination process that takes place in translation. (25 marks)

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QUESTION 04 **(100 Marks)**

4.1 Define the term of "gene sequencing". (25 marks)

4.2 Differentiate the function of the deoxyribonucleoside triphosphates (dNTPs) and. dideoxynucleotides (ddNTPs). (25 marks)

4.3 Outline the method of chain termination in the sanger sequencing process. (25 marks)

4.4 State the principle of pyrosequencing method. (25 marks)

QUESTION 05 **(100 marks)**

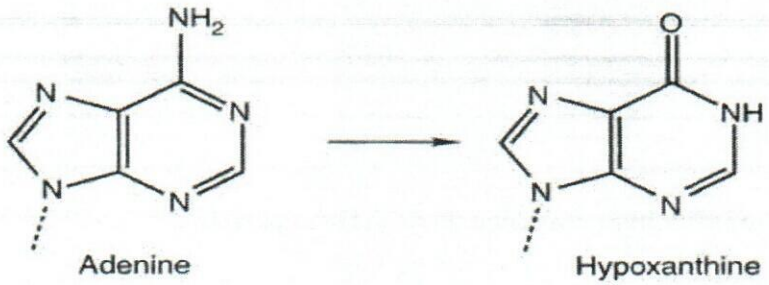
5.1 What are the structural components of the lac operon? (20 marks)

5.2. Illustrate the regulation of lac operon in the presence of lactose in the cell. (20 marks)

5.3. State the main components of the PCR technique. (20 marks)

5.4. Outline the significance of the PCR technique in the pharmaceutical industry, providing a specific example. (40 marks)

QUESTION 06 **(100 marks)**



6.1 Identify the type of mutation shown above. (10 marks)

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6.2 Discuss the environmental and genetic factors that can lead to the occurrence of mutations. (20 marks)

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6.3 Differentiate between missense and frameshift mutations, providing examples. (20 marks)

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6.4 Write short notes on the following:

6.4.1 Spontaneous mutations and their causes. (25 marks)

6.4.2 Base excision repair mechanism. (25 marks)

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Faculty of Health Sciences
Bachelor of Science Honours in Industrial Pharmaceutical Sciences
IPS 4133 Pharmaceutical Biotechnology

Batch – 05
4th Year 1st Semester
End Semester SEQ Examination

Date : **07th of February 2025**
Time : **9.00 am. – 12.00 pm. (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 1 **(100 Marks)**

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1.4 "DNA shortening take place during each DNA replication of the cell", state your opinion and the reasons for your statement. (25 marks)

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QUESTION 02 **(100 Marks)**

2.1 State the basic events in gene cloning. (25 marks)

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(25 marks)

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QUESTION 03 **(100 Marks)**

3.1 Define the term post-transcriptional modification. (25 marks)

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3.3 Briefly outline the translation process of central dogma of life. (25 marks)

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3.4 Differentiate the two-termination process that takes place in translation. (25 marks)

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QUESTION 04 **(100 Marks)**

4.1 Define the term of "gene sequencing". (25 marks)

4.2 Differentiate the function of the deoxyribonucleoside triphosphates (dNTPs) and. dideoxynucleotides (ddNTPs). (25 marks)

4.3 Outline the method of chain termination in the sanger sequencing process. (25 marks)

4.4 State the principle of pyrosequencing method. (25 marks)

QUESTION 05 **(100 marks)**

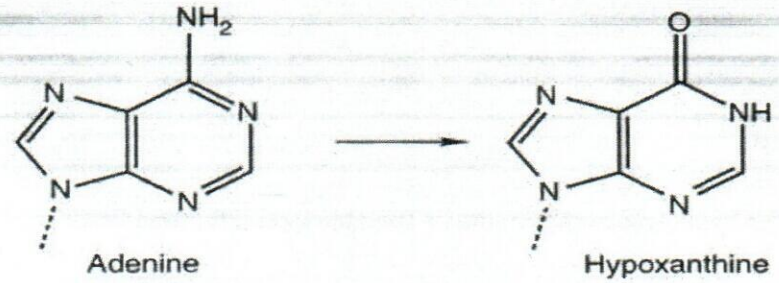
5.1 What are the structural components of the lac operon? (20 marks)

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5.4. Outline the significance of the PCR technique in the pharmaceutical industry, providing a specific example. (40 marks)

QUESTION 06 **(100 marks)**



6.1 Identify the type of mutation shown above. (10 marks)

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6.2 Discuss the environmental and genetic factors that can lead to the occurrence of mutations. (20 marks)

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6.3 Differentiate between missense and frameshift mutations, providing examples. (20 marks)

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6.4 Write short notes on the following:

6.4.1 Spontaneous mutations and their causes. (25 marks)

6.4.2 Base excision repair mechanism. (25 marks)

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Faculty of Health Sciences
Bachelor of Science Honors in Industrial Pharmaceutical Science
IPS 4143 Pharmacognosy I
Batch 05
4th Year 1st Semester
End Semester Examination - SEQ

INDEX NUMBER: .....

Date : 05th of February 2025
Time : 9.00 a.m. - 12.00 noon (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 What is pharmacognosy and its scope? (20 marks)

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1.2 Write a brief introduction to Complementary and Alternative Medicine (CAM). (30 marks)

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1.3 State **three (03)** different ways used to classify crude drugs. (30 marks)

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1.4 How do you determine the moisture content of a crude drug? (20 marks)

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Question 02 **(100 marks)**

2.1 What is 'saponification value' of a fat/ oil? (20 marks)

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2.2 State the differences between fixed oils and essential oils. (40 marks)

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2.3 Sketch suitable biosynthesis pathway for fatty acids, starting from acetyl CoA. (40 marks)

Question 03 **(100 marks)**

3.1 What is the main difference in the chemical constituents of the two varieties of almond (*Prunus amygdalus*); sweet almond and bitter almond? (30 marks)

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3.2 Write a brief account of gelatin, a natural protein. (20 marks)

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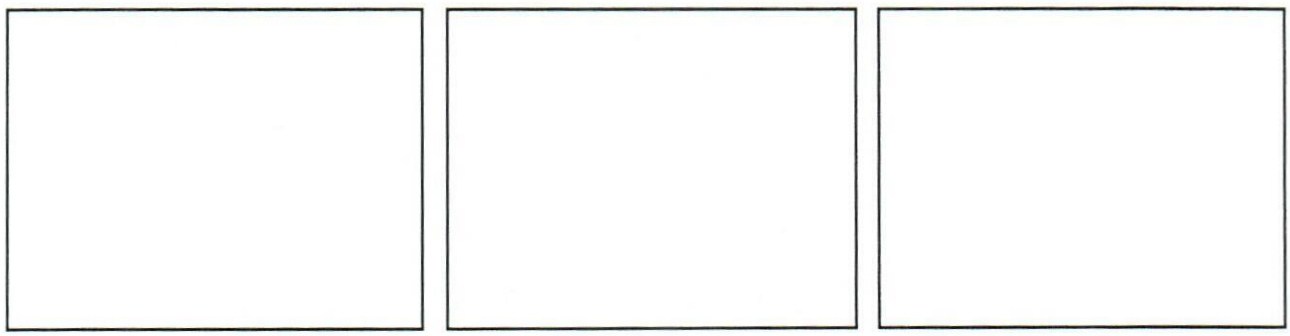
3.3 Name **three (03)** different chemical tests for proteins. (20 marks)

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3.4 Indicate **three (03)** different chemically modified cellulose, giving the structure of the groups used for their modification. (30 marks)



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Question 04 **(100 marks)**

4.1 What are the parameters involved in the **biological** evaluation of crude drugs? (30 marks)

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4.2 State the methods used in quantitative microscopy for crude drug evaluation. (35 marks)

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4.3 How does the unintentional adulteration happen in crude drug formulation? (35 marks)

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Question 05 **(100 marks)**

5.1 What is the concept of *in situ* conservation of medicinal plants? (35 marks)

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5.2 What are the disadvantages of the asexual propagation of medicinal plants? (30 marks)

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5.3 Give the key steps involved in Good Manufacturing Practice (GMP) of the herbal drug industry. (35 marks)

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Question 06 **(100 marks)**

6.1 Name **two (02)** major chemical classes of tannins. (20 marks)

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6.2 Illustrate chemical structures of **two (02)** phytoconstituents found in Arjuna (*Terminalia arjuna*). (30 marks)

6.3 Outline a common isolation procedure for tannins and name **one (01)** identification test. (50 marks)

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Examination Department
30 JAN 2025
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Faculty of Health Sciences
Bachelor of Science Honours in Industrial Pharmaceutical Sciences
IPS 4123 – Pharmaceutical Quality Control
Batch – 05
4th year 1st semester
End Semester SEQ Examination

INDEX NUMBER: .....

Date : **30th of January 2025**
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. State the importance of appendices in pharmaceutical quality control. (20 marks)

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.....

1.2. List **05** responsibilities of British Pharmacopeia Commission (BPC). (30 marks)

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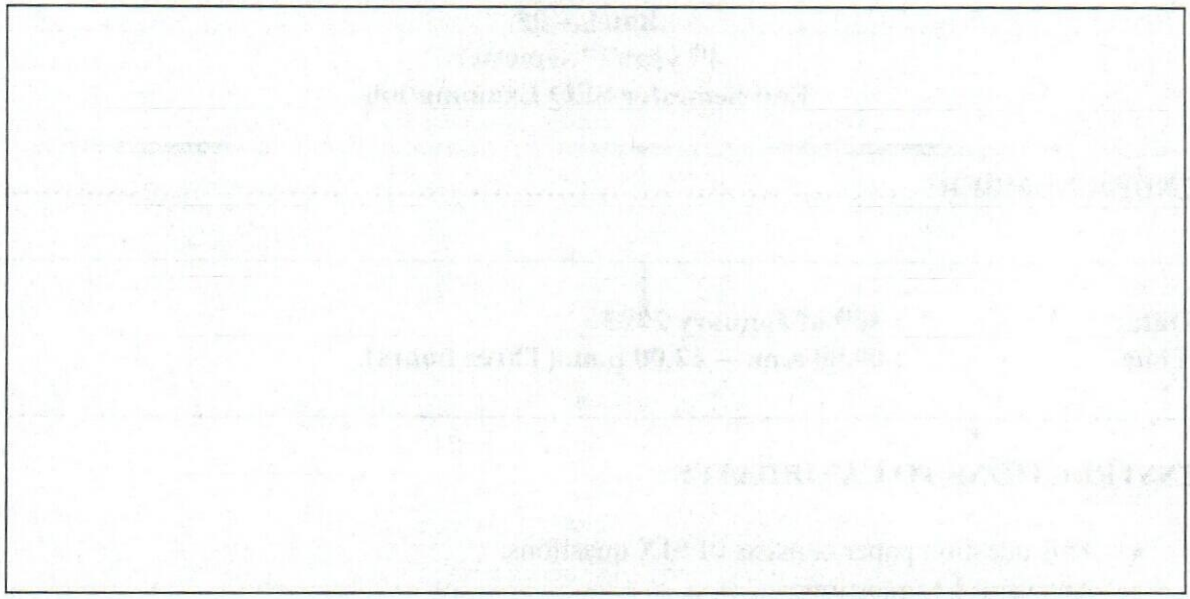
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1.3. Draw the elements of pharmaceutical products distribution system. (15 marks)



1.4. Write a short note on distribution records. (35 marks)

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Question 02 **(100 marks)**

2.1. XPharm is a reputed pharmaceutical company. But recently, due to increased production demands, the company speed up manufacturing processes and release their products into the market continuously. After some time, there are certain cases reported of withholding of certain batches of XPharm's drugs from the several pharmacies and hospitals.

2.1.1. Identify the reason for withholding the batches of drugs. (20 marks)

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2.1.2. Provide the necessary suggestions to solve this problem. (30 marks)

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2.2. What is the purpose of following Good Laboratory Practices (GLPs)? (25 marks)

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2.3. How you are going to handle toxic substances in a laboratory? (25 marks)

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Question 03 **(100 marks)**

3.1. A batch of coated tablets were tested for disintegration according to the USP guidelines. Two tablets from the tested 6 samples fail to disintegrate in the intestinal fluid after immersing for an hour.

3.1.1. As a quality control executive what will be your next steps. (30 marks)

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3.1.2. How do you evaluate whether the sample adheres to the USP guidelines? (20 marks)

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3.2. Write the procedure to disintegration of the enteric coated tablets. (20 marks)

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3.3. What is the importance of conducting friability, thickness, and hardness tests for tablets? (30 marks)

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Question 04 **(100 marks)**

4.1. Mention the importance of measuring zeta potential in a pharmaceutical emulsion. (20 marks)

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4.2. List **04** functions of a packaging material. (10 marks)

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4.3. State the possible interactions that may occur between primary packaging and the included pharmaceutical product. (20 marks)

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4.4. A pharmaceutical company has developed a new liquid oral formulation for a pediatric cough syrup. Before releasing the product to the market, the company conducted the uniformity of content test for the developed formulation.

4.4.1. State how you would conduct the test according to the BP guidelines. (20 marks)

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4.4.2. According to the results, you observed that more than 3 individual contents are outside the limits of 75% - 125%. Comment on your decision about quality of the above product.

(10 marks)

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4.5. Write a short note on the CAPA concept used in modern quality systems of CGMPs.

(20 marks)

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Question 05 **(100 marks)**

5.1. A batch of the pain relief injection has been identified with serious adverse effects following patient complaints. The collected samples were sent to the regulatory authorities to check the quality of the medication.

5.1.1. How does the company assess the quality of its medication independently, aside from regulatory authorities?

(30 marks)

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5.2. Differentiate between analytical work sheet and the analytical test report. (30 marks)

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5.3. What is certificate of analysis (COA)? (20 marks)

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5.4. State the purpose of quality management system in a quality control laboratory.(20 marks)

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Question 06 **(100 marks)**

6.1. What are the **04** types of water for injections (WFI)? (20 marks)

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6.2. State the purpose of using WFI to prepare parenteral formulations? (20 marks)

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6.3. Following table shows the results of the rabbit test for an injection. (30 marks)

1st Group of rabbits	Initial Temperature	Temperature after 30 mins	Temperature after 60 mins	Temperature after 90 mins	Temperature after 120 mins	Temperature after 180 mins
Rabbit 01	38.0°C	38.2°C	38.3°C	38.5°C	38.9°C	39.2°C
Rabbit 02	38.1°C	38.2°C	38.3°C	38.4°C	38.5°C	38.6°C
Rabbit 03	38.0°C	38.1°C	38.4°C	38.6°C	39.0°C	38.3°C

Use the following table as the reference to interpret the results.

NUMBER OF RABBITS	MATERIAL PASSED IF SUM OF RESPONSE DOES NOT EXCEED.	MATERIAL FAILED IF SUM OF RESPONSE EXCEEDS.
3 RABBITS	1.15C	2.65C
6 RABBITS	2.80C	4.30C
9 RABBITS	4.45C	5.95C
12 RABBITS	6.10C	7.60C

6.3.1. Comment on the acceptance of the batch giving the reasons.

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6.4. What is the importance of conducting growth promotion test prior conducting the sterility test? (20 marks)

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