Code No: G-13046/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Analysis) (Main & Backlog) Examination, December 2024

Subject: Modern Bioanalytical techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Explain the general principle and procedures involved in extraction of drugs from biological matrices by liquid-liquid extraction method. (10)
   (b) Write a note on protein precipitation method. (5)
2. (a) Explain different validation parameters for bioanalytical methods according to USFDA guidelines. (10)
   (b) Write a note on SPE sorbents. (5)
3. (a) Discuss Biopharmaceutical factors affecting drug bioavailability. (10)
   (b) Write the Biopharmaceutics classification system defined by FDA. (5)
4. (a) Explain about different Pharmacokinetic and Pharmacodynamic drug interactions with examples. (10)
   (b) Write the importance and applications of Toxicokinetic studies. (5)
5. (a) Write about principles, instrumentation, and applications of flow cytometry. (9)
   (b) Write about cryopreservation and storage of cells. (6)
6. (a) Write about in-vivo and in- vitro methods for checking the cellular permeability of new drug products. (8)
   (b) Discuss about Cytochrome P450 based drug interactions. (7)
7. (a) Explain different study designs in bioequivalence studies. (10)
   (b) Differentiate absolute and relative bioavailability with illustrative examples and equations. (5)
8. (a) Write about Rat liver microsomes and Human Liver microsomes. (5)
   (b) Discuss about different approaches for identification of metabolites. (10)

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Code No. G-13048/PCI

M. Pharmacy II - Semester (PCI) (Pharma Analysis) (Main & Backlog) Examination, December 2024

Subject: Herbal and Cosmetic Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Discuss the pharmacokinetic and pharmacodynamics issues related to herbal drugs. [10]
   (b) Differentiate between herbal drugs and conventional drugs. [5]
2. (a) Explain the determination of pesticide residues and microbial contamination in herbal formulations? [8]
   (b) Define adulteration and explain various types of adulteration of herbal drugs? [7]
3. (a) Explain DNA Finger printing techniques in identification of drugs of natural origin? [7]
   (b) Explain with an example the Ayurvedic Pharmacopoeia of India? [8]
4. (a) Explain WHO guidelines for safety monitoring of natural medicine. [10]
   (b) Write notes on bio drug-drug interactions with suitable examples. [5]
5. (a) Explain the Indian standard specification laid down for sampling and testing of dental products. [8]
   (b) Write a note on analysis of Lipsticks as per BIS. [7]
6. Write notes on
   (a) Explain the Comparative study of IP and USP with an example? [10]
   (b) Determination of Saponification value of cosmetic products. [5]
7. Write about International patent law applicable for herbal drugs and natural products. [15]
8. Discuss the quality of raw materials and general methods of analysis of raw materials used in cosmetic manufacture as per BIS? [15]

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Code No: G-13046/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Analysis) (Main & Backlog) Examination, December 2024

Subject: Modern Bioanalytical techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Explain the general principle and procedures involved in extraction of drugs from biological matrices by liquid-liquid extraction method. (10)
   (b) Write a note on protein precipitation method. (5)
2. (a) Explain different validation parameters for bioanalytical methods according to USFDA guidelines. (10)
   (b) Write a note on SPE sorbents. (5)
3. (a) Discuss Biopharmaceutical factors affecting drug bioavailability. (10)
   (b) Write the Biopharmaceutics classification system defined by FDA. (5)
4. (a) Explain about different Pharmacokinetic and Pharmacodynamic drug interactions with examples. (10)
   (b) Write the importance and applications of Toxicokinetic studies. (5)
5. (a) Write about principles, instrumentation, and applications of flow cytometry. (9)
   (b) Write about cryopreservation and storage of cells. (6)
6. (a) Write about in-vivo and in- vitro methods for checking the cellular permeability of new drug products. (8)
   (b) Discuss about Cytochrome P450 based drug interactions. (7)
7. (a) Explain different study designs in bioequivalence studies. (10)
   (b) Differentiate absolute and relative bioavailability with illustrative examples and equations. (5)
8. (a) Write about Rat liver microsomes and Human Liver microsomes. (5)
   (b) Discuss about different approaches for identification of metabolites. (10)

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Backlog

Code No: G-13047/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Analysis) (Main & Backlog) Examination, December 2024

Subject: Quality control and Quality assurance

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Write about Total quality management. (5)
   (b) Describe concept and components of Quality control and Quality assurance. (10)
2. (a) Write about CDER and CBER. (5)
   (b) Write a detailed note on requirements and guidelines of GMP (schedule M) in Pharma industries. (10)
3. (a) Define IPQC. (2)
   (b) Explain in detail IPQC tests for Tablets. (13)
4. (a) Write a short note on good documentation practice guidelines. (5)
   (b) What are the different types of audits? Explain in detail about audit methods. and techniques involved in it. (10)
5. (a) Write about mix-up and cross contamination. (5)
   (b) Add a note on Processing of intermediates and bulk products. (5)
   (c) Explain Aseptic process control. (5)
6. Write about the following
   (a) Protocol for conduct of non-clinical testing (5)
   (b) Quality control of creams (5)
   (c) Calculation of yields (5)
7. (a) Explain Master formula and Batch formula records. (10)
   (b) Write a short note on SOP. (5)
8. (a) Discuss Good laboratory practices for quality control laboratory in detail. (12)
   (b) Add a note on Electronic data. (3)

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Code No: G-13045/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Analysis) (Main & Backlog) Examination, December 2024

Subject: Advanced Instrumental Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. Explain about method development and trouble shooting process in HPLC.
2. (a) Discuss about Ion-exchange chromatography?
   (b) Explain about head space sampling and columns used in Gas chromatography.
3. (a) Write the principle and applications of Super critical fluid chromatography.
   (b) Explain about characteristics and methods of capillary electrophoresis.
4. Explain about fragmentation modes in mass spectrometry?
5. (a) Write about
   (i) spin-spin coupling and
   (ii) Relaxation process in NMR
   (b) Write in detail about COSY.
6. (a) Write about Nano Liquid Chromatography.
   (b) Discuss in detail about detectors used in Gas chromatography.
7. (a) Explain about various parameters used in HPLC.
   (b) Discuss about 2D NMR.
8. (a) Explain about Quadrpole and Time of flight in MS analysis?
   (b) Write about 13 C-NMR?

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Code No: F-7223/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II-Semester (PCI) (Backlog) Examination, June 2024

Subject: Advanced Instrumental Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Explain about method development and trouble shooting in HPLC.
   (b) Write about Chiral analysis of Pharmaceuticals using HPLC

2. (a) Discuss about Ion-exchange chromatography?
   (b) Explain about head space sampling and columns used in Gas chromatography

3. (a) Write the principle and applications of Super critical fluid chromatography
   (b) Explain about characteristics and methods of capillary electrophoresis?

4. Explain about fragmentation modes in mass spectrometry?

5. (a) Write about a) spin-spin coupling and b) relaxation process in NMR?
   (b) Write in detail about COSY?

6. (a) Write about Nano Liquid Chromatography?
   (b) Discuss in detail about detectors used in Gas chromatography?

7. (a) Explain about various parameters used in HPLC.
   (b) Discuss about 2D NMR.

8. (a) Explain about Quadrpole and Time of flight in MS analysis.
   (b) Write about 13 C-NMR?

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Code No: F-7224/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) II-Semester (PCI) (Backlog) Examination, June 2024

Subject: Modern Bio Analytical Techniques

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Write about the following sample preparation techniques. [6]
   (i) Solid phase extraction
   (ii) Liquid liquid extraction
   (b) Explain the Bioanalytical method validation as per USFDA guidelines. [9]

2. (a) Discuss Biopharmaceutical factors affecting drug bioavailability. [10]
   (b) Write the Biopharmaceutics classification system defined by FDA. [5]

3. (a) What is enzyme inhibition? Discuss drug interactions due to enzyme inhibition with examples. [7]
   (b) Discuss drug-protein binding interaction with examples. [8]

4. (a) Write about principles, instruments, and applications of flow cytometry. [9]
   (b) Write about cryopreservation and storage of cells. [6]

5. (a) Explain different study designs in bioequivalence studies. [10]
   (b) Differentiate absolute and relative bioavailability with illustrative examples and equations. [5]

6. (a) Discuss the importance and applications of Toxicokinetic studies. [8]
   (b) Write about the basic equipment used in the cell culture lab. [7]

7. (a) Discuss different approaches for the identification of metabolites. [10]
   (b) Write a short note on the clinical significance of bioequivalence studies. [5]

8. (a) Describe the compendial methods of dissolution testing. [7]
   (b) Write about in-vivo and in-vitro methods for checking the cellular permeability of new drug products. [8]

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Code No: F-7225/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) II - Semester (PCI) (Backlog) Examination, June 2024

Subject: Quality control and Quality assurance

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. Write a detailed note on requirements and guidelines of GMP (schedule M) in Pharma industries? [15]

2. Write a short note on the following
   (a) Quality control. [5]
   (b) Quality assurance. [5]
   (c) Non clinical testing. [5]

3. Define IPQC. Explain in detail about various IPQC tests for
   (a) Tablets [8]
   (b) Ophthalmics [7]

4. Explain
   (a) Batch formula Record [8]
   (b) Master formula Record [7]

5. Write a short note on the following
   (a) Expiry date calculation [5]
   (b) Limitations of production [5]
   (c) Calculation of yields [5]

6. Explain the various CPCSEA (CCSEA – New non enclature) guidelines for laboratory animal facility. [15]

7. Describe the quality control test for containers, closures and secondary packing materials? [15]

8. Write a note on
   (a) Sanitation of manufacturing premises [5]
   (b) Drug product inspection. [5]
   (c) Production record review. [5]

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Code No. F-7226/ PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm Analysis) II - Semester (PCI) (Backlog) Examination, June 2024
Subject: Herbal and Cosmetic Analysis

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. **(75 Marks)**

1. (a) How Herbal medicines are differentiated from Conventional Drugs?
   (b) Discuss about Standardization of Herbal drugs as per WHO guidelines.

2. (a) What is Adulteration? Write about different types of Adulteration with suitable examples.
   (b) Explain the procedure involved in determination of foreign matter pesticide residue in Herbal drugs.

3. (a) Discuss on Adulterant screening using advanced Analytical Techniques.
   (b) Give the protocol for Stability Testing of natural products.

4. (a) Explain bio-drug drug interactions with suitable examples.
   (b) Write notes on challenges in monitoring the safety of Herbal Medicines.

5. Write the procedure involved in determination of
   (a) Acid value
   (b) Moisture Content

6. Write short notes on
   (a) Validation of Herbal Therapies.
   (b) Global Marketing Management of Herbal Drugs

7. (a) Compare the monographs of Herbal Dugs mentioned in different Pharmacopoeia.
   (b) Explain the determination of Saponification Value.

8. (a) Explain the general methods of analysis of raw materials used in cosmetics manufacturing as per BIS.
   (b) Brief out the testing of baby care products.

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Code No: E-12450/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Computer Aided Drug Delivery System

Time: 3 Hours **Max.Marks:75**

Note: Answer any five questions. All questions carry equal marks.

1. Write history and role of computers in pharmaceutical research and development.

2. Write a note on following
   (i) Quality-by-Design (QbD) in pharmaceutical product development.
   (ii) ICH Q8 guidelines

3. What is active transport? Write about following transporters.
   (i) P-gp transporters (**ii)** OATP (**iii)** hPEPT1 (**iv)** BBB- Choline transporter

4. What is the objective of optimization? Write optimization parameters for formulation development. Explain development of emulsions and microemulsions as drug carriers.

5. Write a note on
   (i) Legal protection of innovative uses of computers in pharmaceutical R&D.
   (ii) Statistical modeling in pharmaceutical research and development.

6. Write a note on the following
   (i) Gastrointestinal absorption simulation
   (ii) *Invitro* dissolution & *invitro-invivo* correlation
   (ii) Biowaiver considerations

7. Write the role of computers in clinical data collection and management for clinical development.

8. Write a note on
   (i) Artificial intelligence and robotics in pharmaceutical automation
   (ii) Pharmaceutical applications, advantages and challenges of robotics in pharmaceutical product development

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Code No: E- 12451/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Cosmetics and Cosmeceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Explain Indian regulatory requirements for labeling of cosmetics. [9]
   (b) Explain the following terms. (i) Misbranded and spurious cosmetics
   (ii) Loan license. [6]

2. (a) Explain the common problems associated with oral cavity. [8]
   (b) Write a note on cleaning and care needs for eyelids and lips. [7]

3. (a) Describe the structure & growth cycle of hair with a neat diagram. [7]
   (b) Discuss about building blocks for formulation of a shampoo. [8]

4. Explain various controversies on use of parabens, formaldehyde liberators and dioxane in cosmetic products. [15]

5. (a) Explain design of cosmeceuticals product to address pigmentation problem. [7]
   (b) Describe cosmeceutical products for body odour and dandruff. [8]

6. (a) Discuss about the guidelines for herbal cosmetics by COSMOS [7]
   (b) Write a note on challenges in formulating herbal cosmetics. [8]

7. Explain the significance, classification and applications of rheological additives and surfactants used in cosmetics with examples. [15]

8. Write short notes on [7.5]
   (a) Soaps and syndetbars
   (b) Manufacturing process for perfumes [7.5]

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Code No: E-12448/PCI

FACULTY OF PHARMACY

M. Pharmacy II-Semester (PCI) (Pharmaceutics) (Main & Backlog) Examination, November 2023

Subject: Molecular Pharmaceutics (Nano Tech. & Targeted DDS)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) What are the events and biological process involved in drug targeting? [8]
   (b) What do you mean by ligand mediated targeting? [7]

2. (a) Explain the blood brain barrier? What are the factors affecting transport across The blood brain barrier? [8]
   (b) What are the ideal properties of carrier? [7]

3. (a) Discuss the methods for the preparation of phytosomes. [8]
   (b) Describe in detail about various methods of preparation of microspheres. [7]

4. Write about methods of preparation and evaluation of aerosols. [15]

5. (a) Explain the factors influencing intranasal drug delivery. [8]
   (b) Explain the nebulizers with suitable diagrams. [7]

6. (a) Explain about bone marrow transplantation in ex-vivo gene therapy. [8]
   (b) Discuss in detail about dry powder inhaler. [7]

7. Explain the methods of preparation and evaluation of nanoparticles. [15]

8. (a) Explain about liposomal gene delivery system. [8]
   (b) What are the factors influencing pulmonary drug delivery? [7]

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Code No: E-12449/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II –Semester (PCI) (Main & Backlog) Examination, October 2023

Subject: Advanced Bio Pharmaceutics & Pharmacokinetics

Time: 3 Hours **Max. Marks: 75M**

Note: Answer any five questions. All questions carry equal marks

1. (a) Explain the theories of dissolution?
   (b) Discuss the methods for enhancement of aqueous solubility of drugs? [5+10]

2. Explain compendial and alternative methods of in vitro drug dissolution? [15]

3. (a) A 60 kg patient received a single 25 mg oral dose of an antibiotic that is completely absorbed after oral administration. Serial samples were drawn, and drug plasma concentrations were determined using a sensitive analytical method. The plasma concentrations were as follows:

Time (hr)	0.0	0.2	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	12.0	14.0
Conc(ng/ml)	0.00	88.5	184.9	276.9	321.6	292.8	246.1	161.0	102.2	64.5	40.66	25.61

   Calculate all possible pharmacokinetic parameters? [15]

4. (a) Write about the experimental designs for bioequivalence studies? [6+9]
   (b) Discuss the *in vitro, in situ, in silico* methods of absorption and permeability of drugs?

5. (a) Discuss the PKPD drug interactions? [7+8]
   (b) Discuss pharmacokinetics of proteins and peptides?

6. (a) Explain physicochemical properties influencing drug absorption? [10+5]
   (b) Write a note on protein binding kinetics?

7. The equation that best describes the pharmacokinetics of a drug after oral administration of 500 mg dose is: $C = 1.18 (e^{-0.24t} - e^{-1.6t})$. Calculate all possible pharmacokinetic parameters? [15]

8. Explain ADME by non-linear drug kinetics? [15]

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Code No: E-12233/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Backlog) Examination, April / May 2023

Subject: Advanced Bio Pharmaceutics & Pharmacokinetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks

1. (a) Explain the dissolution theories [5]
   (b) Explain physicochemical properties influencing drug absorption [10]

2. (a) Explain compendial methods of in vitro drug dissolution [10]
   (b) Write a note on IVIVC [5]

3. (a) What is compartmental analysis [5]
   (b) Derive the equation of IV Bolus one compartment model with estimation of all the parameters? [10]

4. (a) Describe experimental designs for bioequivalence studies [7]
   (b) Discuss about the invitro, insitu, insilico methods of absorption and permeability of drugs [8]

5. (a) Discuss the pharmacodynamics and pharmacokinetic drug interactions [7]
   (b) Add a note on pharmacokinetics of proteins, peptides and monoclonal antibodies [8]

6. (a) Describe the methods for enhancement of aqueous solubility and dissolution of drugs [10]
   (b) Explain plasma protein binding of drugs [5]

7. (a) A patient received a single 5 mg oral dose of a bronchodilator that is completely absorbed after oral administration. The following plasma concentration time data were obtained:

Time (hr)	0.0	0.2	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	14.0
Conc(ng/ml)	0.00	10.0	21.5	33.4	40.7	37.6	31.1	18.6	10.2	5.44	1.47

i) Calculate all possible pharmacokinetic parameters [15]

8. (a) Explain the ADME by non-linear drug kinetics using equations [10]
   (b) Describe the dosage regimen calculations in multiple dosing [5]

Code No: E-12235/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Backlog) Examination, May 2023

Subject: Cosmetics and Cosmeceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal Marks

1. (a) Explain Regulatory provisions for sale and manufacturing of cosmetics.
   (b) Define Cosmetics, Misbranded cosmetics and spurious cosmetics.

2. (a) Describe the common problems associated with oral cavity.
   (b) Write a note on cleansing and care needs for hands.

3. (a)What are the building blocks for formulation of a moisturizing cream?
   (b) Describe factors affecting microbial preservative efficacy.

4. (a) Discuss about cosmeceutical products for dry skin and pigmentation.
   (b) Describe cosmeceutical products for body odour and dandruff.

5. (a) Discuss about the guidelines for herbal cosmetics by COSMOS.
   (b) Write a note on guidelines for preservatives in herbal cosmetics.

6. Write a note on (a) herbal ingredients used in hair care.
   (b) Cosmeceutical products for dental cavities.

7. Write a note on (a) offences and penalties.
   (b) surfactants-classification and applications.

8. (a) Write a note on challenges in formulating herbal cosmetics.
   (b) Write a note on perfumes listed as allergens in Europe Union regulations.

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Code No: E-12234/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Backlog) Examination,
April / May 2023
Subject: Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All Questions carry Equal Marks.

1. Write history and role of computers in pharmaceutical research and development.

2. Write a note on following
   i) Quality-by-Design (QbD) in pharmaceutical product development.
   ii) Write a note on ICH Q8 guidelines for good quality product.

3. What is active transport? Write about following transporters.
   i) P-gp transporters ii) OATP iii) BBB- Choline transporter

4. i) What is the objective of optimization? Write optimization parameters for formulation development.
   ii) Write the usage of computers in market analysis.

5. Write a note on the following
   i) *Invitro* dissolution & *invitro-invivo* correlation
   ii) Biowaiver considerations

6. Write a note on computer simulations in pharmacokinetics and pharmacodynamics.

7. Write the role of computers in clinical data collection and management for clinical development.

8. Write a note on the following
   i) Artificial intelligence and robotics in pharmaceutical automation
   ii) Pharmaceutical applications, advantages and challenges of robotics in pharmaceutical product development

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Code No: E-12232/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Backlog) Examination, April/May-2023

Subject: Molecular Pharmaceutics (Nano tech. Targeted DDS)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

(5 x 15 = 75 Marks)

1. (a) Explain the concepts, events and biological processes involved in drug targeting.
   (b) Explain blood brain barrier. What are the factors affecting drug transport across the BBB?

2. Write the methods for the preparation and applications of
   (a) Phytosomes
   (b) Electrosomes.

3. Explain the methods of preparation and evaluation of liposomes.

4. (a) Explain the methods of preparation and evaluation of nano particles.
   (b) Explain the applications of monoclonal antibodies.

5. (a) What are aerosols? Explain various propellants used in the manufacturing of Aerosols.
   (b) Explain intranasal insitu gels.

6. (a) Explain about liposomal gene drug delivery.
   (b) Write various diseases treated using gene therapy.

7. Define microspheres. Write in detail preparation and evaluation methods of microspheres.

8. (a) Explain about therapeutic antisense molecules.
   (b) Write about aquasomes.

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Code No: E-12126/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, December 2022

Subject: Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. Write about history of computers in pharmaceutical research and development.
2. Write the application of Quality-by-Design (QbD) in pharmaceutical development. Explain QbD approach for formulation development.
3. Discuss the importance and applications of statistical modeling in pharmaceutical research and development.
4. Write a note on computational modeling techniques for drug absorption, drug distribution and drug excretion.
5. Write a note on following i) P-gp transporters ii) hPEPT1 iii) BBB- Choline transporter
6. Describe briefly factorial design for optimization and screening of pharmaceutical formulation in formulation development with example.
7. Write briefly about
   i) Computer aided biopharmaceutical characterization for GI absorption simulation.
   ii) Write about *invitro* dissolution & *invitro-invivo* correlation
8. Write about application of artificial intelligence & robotics in pharmaceutical automation. Write advantages, disadvantages and challenges of robotics in pharmacy automation.

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Code No: E-12127/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, December 2022

Subject: Cosmetics and Cosmeceuticals

Time: 3 Hours **Max Marks: 75**

Note: Answer any five questions. All questions carry equal mark.

1. (a) Define the terms Cosmetics, Misbranded cosmetics, Spurious cosmetics. Write a note on Offences and Penalties with regard to manufacture and sale of cosmetics.
   (b) Write a note on conditions for obtaining licence for manufacture and sale of cosmetics.

2. (a) Discuss the problems relating to skin.
   (b) Discuss about the cleansing and care needs for body.

3. (a) Write a note on regulatory provisions relating to labeling of cosmetics
   (b) Write a note on structure of hair and hair growth cycle.

4. (a) Discuss about the building blocks for formulation of tooth paste.
   (b) Write a note on emollients and rheological additives.

5. (a) Describe cosmeceutical products for acne and sun-protection.
   (b) Write a note on cosmeceuticals for sensitive teeth.

6. Describe the COSMOS guidelines for herbal cosmetics.

7. (a) What are the challenges in formulating herbal cosmetics.
   (b) List the herbal ingredients used in Hair care.

8. (a) Write a note on formulation of soaps and syndet bars.
   (b) Write a note on sunscreens.

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Code No: E-12125/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) (Pharmaceutics) II – Semester (Main & Backlog) Examination, December 2022

Subject: Advanced Bio Pharmaceutics & Pharmacokinetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Describe the various methods for enhancement of aqueous solubility and dissolution rates. [9]
   (b) Describe the pH-partition hypothesis with limitations. [6]

2. (a) Explain various alternative in-vitro drug dissolution models? [7]
   (b) Write a note on IVIVC and Biowaivers? [8]

3. (a) Derive the equation for one compartment model by IV bolus drug administration. Add a note on the estimation of parameters. [10]
   (b) Determination of the following pharmacokinetics parameters with equations? (i) Cl_T (ii) Ka (iii) V_d (iv) K_E (v) T_{max} [5]

4. (a) Describe the experimental designs for bioequivalence studies. [10]
   (b) Describe relative and absolution bioavailability with equations. [5]

5. (a) Discuss the pharmacodynamics and pharmacokinetic drug interactions. [7]
   (b) Add a note on pharmacokinetics of proteins, peptides and monoclonal antibodies. [8]

6. A 60 kg patient received a single 25 mg oral dose of an antibiotic that is completely absorbed after oral administration. Serial samples were drawn, and drug plasma concentrations were determined using a sensitive analytical method. The plasma concentrations were as follows:
   (i) Calculate all possible pharmacokinetic parameters? [15]

Time (hr)	0.0	0.2	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	12.0	14.0
Conc(ng/ml)	0.00	88.5	184.9	276.9	321.6	292.8	246.1	161.0	102.2	64.5	40.66	25.61

7. (a) Explain plasma protein binding of drugs. [7]
   (b) Explain dosage form factors influencing drug absorption. [8]

8. (a) Explain the non-linear drug kinetics using equations. [10]
   (b) Describe the dosage regimen calculations in multiple dosing. [5]

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Code No. E-12124/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (Main & Backlog) Examination, December 2022

Subject: Molecular Pharmaceutics (Nano Tech and Targeted DDS)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Define drug targeting. Explain different types of drug targeting in detail.
(b) Write a note on tumor targeting.

2 (a) Describe hybridoma technology for production of monoclonal antibodies.
(b) How will you characterize monoclonal antibodies?

3 What are niosomes? Describe in detail methods of preparation and characterization of niosomes.

4 (a) Explain the cell biology and anatomy of blood brain barrier.
(b) Describe in detail invasive methods to brain targeting.

5 (a) What are aerosols? Explain various propellants used in the manufacturing of aerosols.
(b) Describe in detail evaluation methods of nasal drug delivery system.

6 (a) Explain detail about aquasomes.
(b) Give a brief account on phytosomes.

7 (a) Define gene therapy. Explain viral and non viral gene transfer methods.
(b) Explain aptamers as drugs of future.

8 Explain the methods for the preparation and evaluation of microspheres.

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Code No. D-8287/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Supply) Examination, May 2022

Subject: Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 Write a note on:
(a) History of computers in pharmaceutical research and development.
(b) Importance and applications of statistical modeling in pharmaceutical research and development.

2 (a) Write about Quality-by-Design (QbD) in pharmaceutical development.
(b) Explain QTTP and CQA in QbD.

3 (a) Write in brief on computational modeling techniques for drug ADMET.
(b) What is Active transport? Give the list of transporters useful in computational modeling of drug disposition. Explain P-gp transporter in detail.

4 (a) What is the concept of optimization in formulation development?
(b) Write about factorial design for optimization and screening in formulation development.

5 (a) Write the importance of computer aided biopharmaceutical characterization for GI absorption simulation.
(b) Write a note on in-vivo dissolution and IVIVC.

6 Write about computer simulations in pharmacokinetics and pharmacodynamic studies for whole organism and isolated tissues.

7 Write about computers in clinical development as clinical data collection and management.

8 (a) Discuss about artificial intelligence and robotics in pharmaceutical automation and write their application, advantages and disadvantages.
(b) Write current challenges and future directions of AI.

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Code No. D-8286/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Supply) Examination, May 2022

Subject: Advanced Bio Pharmaceutics and Pharmacokinetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Discuss about the factors influencing the drug absorption.
(b) Add note on pH partition hypothesis.

2 (a) Discuss the Compendia and Alternative methods of dissolution.
(b) Write a note on *in vitro- in vivo* correlation.

3 A 60 kg patient received a single 25mg oral dose of an antibiotic that is completely absorbed after oral administration. Serial samples were drawn and drug plasma concentrations were determined using a sensitive analytical method. The plasma concentrations were as follows:

Time (hr)	0.2	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	12.0	14.0
Conc(ng/ml)	88.5	184.9	276.9	321.6	292.8	246.1	161.0	102.2	64.5	40.66	25.61

4 After administration of a single IV dose of 75 mg of a drug to a healthy volunteer. The pharmacokinetics of this drug followed a two compartment model. The pharmacokinetics of this drug followed a two compartment model. The following parameters were obtained:

A=4.62 mg/L	B=0.64 mg/L
α=8.94 hr^{-1}	β=0.19 hr^{-1}

Calculate all possible pharmacokinetic parameters.

5 (a) Define clearance and explain the parameters with the equation.
(b) Write a note on dose adjustment in renal failure patients.

6 Discuss the pharmacokinetic of novel drug delivery systems.

7 Write in detail about the bioequivalence protocol.

8 Describe the causes of non-linearity and explain the non-linear kinetics.

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Code No. D8053/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main & Backlog) Examination, December 2021

Subject: Computer Aided Drug Delivery System

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.

(3 x 25 = 75 Marks)

1 Write history and applications of computers in pharmaceutical research and development.

2 Write about descriptive statistics and statistical parameters of statistical modeling in pharmaceutical research and development.

3 (a) Write the application and importance of QbD in pharmaceutical product development.
(b) Write a note on ICH Q8 guidelines.

4 What is active transport? Write about following transportaters.
(a) P-gp (b) hPEPTI (c) BBB-Choline transporter

5 (a) What is the objective of optimization? Explain in detail about Factorial design.
(b) Write the ethics of computing in pharmaceutical research.

6 (a) Write the importance of computer aided biopharmaceutical characterization for GI absorption simulation.
(b) Write a note on IVIVC and biowaiver considerations.

7 (a) Write role of computers in clinical data collection, management.
(b) Write about the Computer simulations in PK & PD for whole organism.

8 Discuss about application of artificial intelligence and robotics in pharmaceutical automation. Write their advantages and disadvantages.

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Code No. D8052/ PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, November 2021

Subject: Advanced Bio Pharmaceutics and Pharmacokinetics

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three of the following questions. (3 x 25 = 75 Marks)

1 Discuss in detail about the factors influencing the drug absorption.

2 (a) Write a note on *in vitro- in vivo* correlation.

(b) Explain the different dissolution theories.

3 The equation that best fits the plasma level time curve of drug after an IV bolus dose of 2000 mg is: C=143 e-0.87t

(a) What is Vd, $t^{1/2}$, (b) Plasma concentration after 6 hours, (c) How much of drug left in body after 6 hours, (d) when the next dose should be given if the drug becomes ineffective when the plasma level falls below 50 μ g.ml (e) How long will the plasma level lie in the therapeutic window if the above dose is given as IV bolus?

4 Write in detail about the bioequivalence protocol.

5 Discuss the pharmacokinetic of novel drug delivery systems using examples.

6 After administration of a single IV dose of 75 mg of a drug to a healthy volunteer. The pharmacokinetics of this drug followed a two compartment model. The following parameters were obtained:

A=4.62 mg/L	B=0.64 mg/L
α=8.94 hr^{-1}	β=0.19 hr^{-1}

Calculate all possible pharmacokinetic parameters.

7 Discuss the causes of non-linearity and explain the non-linear kinetics.

8 (a) Explain Noyes-Whitney equation and the parameters for dissolution of drugs.

(b) Write a note on dose adjustment in renal failure patients.

Code No. D8051/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main & Backlog) Examination, December 2021

Subject: Molecular Pharmaceutics (Nanotechnology & Targeted DDS)

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.
(3 x 25 = 75 Marks)

1 (a) What are the different types of targeting? Explain first order and second order targeting.
(b) What do you mean by ligand mediated targeting?

2 (a) Classify different methods of preparation of nanoparticles?
(b) Explain in detail different types of preparation of polymeric nanoparticles.

3 Describe in detail different methods of tumour targeting?

4 Describe in detail preparation of monoclonal antibodies. Mention few marketed preparations.

5 (a) What are niosomes ? What are the differences between niosomes and liposomes.
(b) Explain any five methods of preparation of niosomes.

6 (a) What are aerosols. What are the different types of containers used for aerosols?
(b) Explain the various evaluation methods to evaluate aerosols.

7 (a) Mention the advantages of intra nasal drug delivery system.
(b) Explain in detail different types of intra nasal formulation and how to evaluate the same?

8 Write a note on:
(a) Aptamers
(b) Liposomal gene drug delivery system.

* * *

Code No. D8054/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main & Backlog) Examination, December 2021

Subject: Cosmetics and Cosmeceuticals

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.

(3 x 25 = 75 Marks)

1 (a) Explain Regulatory provisions for manufacturing of cosmetics.
(b) Discuss regulatory requirements for labeling of cosmetics.

2 Discuss about the problems relating to skin and cosmeceutical product available for the skin problems.

3 Write a note on classification of perfumes and perfume ingredients listed as allergens in Europe Union regulations.

4 (a) What are the building blocks for formulation of a tooth paste?
(b) Write a note on antimicrobials as preservatives.

5 (a) Write a note on cleaning and care needs for scalp.
(b) Write a note on Loan license and conditions for obtaining license.

6 (a) Describe cosmeceutical products for dental cavities.
(b) Describe cosmeceutical products for body odour and dandruff.

7 (a) Write a note on challenges in formulating herbal cosmetics.
(b) Write a note on guidelines for preservatives in herbal cosmetics.

8 (a) Write a note on herbal ingredients used in Skin care.
(b) Write a note on surfactants.

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Code No: 12119/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.)

Examination, August 2021

Subject: Molecular Pharm. (Nano tech & targeted DDS)

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three Questions. **(3 x 25 = 75 Marks)**

1. Explain different types of drug targeting? Write in detail third order targeting with examples?

2. What are various methods to target brain? Explain.

3. What are liposomes? Describe various methods of preparation of liposomes. Give two examples of marketed liposomes.

4. a) What are monoclonal antibodies.
   b) Describe in detail Hybridoma technology to prepare Monoclonal antibodies.

5. a) Explain various propellants and containers used in the manufacture of aerosols.
   b) Write a note on intranasal insitu gels?

6. Explain in detail liposomal gene drug delivery system?

7. a) What are aptamers? explain.
   b) Write a note on anti sense molecules.

8. Explain in detail various diseases treated using gene therapy.

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Code No: 12120/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II - Semester (PCI) (Suppl.)

Examination, July 2021

Subject: Advanced Biopharmaceutics and Pharmacokinetics

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three Questions. **(3 x 25 = 75 Marks)**

1. After an IV injection of 500 mg of a new drug to a patient, the following data were obtained?

Collection interval (hr)	0-2	2-4	4-8	8-12	12-18	18-24
Urine volume (ml)	119	81	160	220	284	212
Urine conc.(mg/ml)	0.60	0.70	0.50	0.23	0.15	0.10
Plasma conc.(mg/ml)	22.3	17.7	12.5	7.88	4.42	2.21

   i) Estimate the biological half-life
   ii) Estimate the renal clearance?
   iii) Calculate the fraction of the administered dose excreted unchanged in the urine?

2. a) Write a note on *in vitro- in vivo* correlation?
   b) Discuss the different methods of dissolution testing?

3. Discuss the factors affecting dissolution rate?

4. a) Define the following?
      i) Compartment ii) Elimination half-life iii) Absolute bioavailability
   b) A drug that follows a two compartment pharmacokinetic model was given as a single IV bolus dose of 5.6 mg/kg. The equation is **$C\ (mg/L) = 18\ e^{-2.8t} + 6\ e^{-0.11t}$.** Calculate all possible pharmacokinetic parameters?

5. Describe the dose dependent kinetics? Explain the Michaelis - Menten equation?

6. a) Explain the study designs in bioequivalence studies?
   b) Write about BCS classification?

7. a) Write in detail about the pharmacokinetics of modified dosage forms?
   b) Write a note on Biologics

8. a) Discuss the pharmacokinetic drug interactions with suitable examples?
   b) Explain the various methods for permeability studies?

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Code No: 12121/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.)

Examination, July 2021

Subject : Computer Aided Drug Delivery System

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three Questions. **(3 x 25 = 75 Marks)**

1. Describe brief history of computers in pharmaceutical research and development properly mention the time lines of the development in the early stages

2. What is the need for computational modeling in drug disposition? What are the techniques of drug disposition?.

3. a) What is the concept of optimization in computer aided formulation development
   b) What are the various optimization parameters write about optimization technology

4. a) Mention and explain the various applications of Artificial intelligence in pharmaceutical automation.
   b) Write brief notes o Robotics in Pharmacy

5. Discuss computer simulations in PIC and PD for whole organism

6. What are the differences between non clinical, preclinical and clinical studies write short notes on clinical data collection

7. What do you mean by Invitro Invivo correlation where do you apply biowaiver considerations?

8. What do you mean by Design space? Write detail notes on various statistical design used in formulation development

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Code No: 12122 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester. (PCI) (Suppl.)

Examination, July 2021

Subject: Cosmetics and Cosmeceuticals

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three Questions. **(3 x 25 = 75 Marks)**

1. Explain Regulatory provisions for manufacturing of cosmetics.

2. Discuss about the problems relating to skin and cosmeceutical products available for the skin problems.

3. Describe the structure & growth cycle of hair with a neat diagram and add a note on cleansing and care needs for scalp.

4. (a) What are the building blocks for formulation of a tooth paste?
   (b) Write a note on antimicrobials as preservatives.

5. Write a note on classification of perfumes and perfume ingredients listed as allergens in Europe Union regulations.

6. (a) Describe cosmeceutical products for dental cavities.
   (b) Describe cosmeceutical products for body odour and dandruff.

7. (a) Write a note on challenges in formulating herbal cosmetics.
   (b) Write a note on guidelines for preservatives in herbal cosmetics.

8. (a) Write a note on herbal ingredients used in hair care.
   (b) Write a note on surfactants.

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Code No: 6334/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester.(PCI) (Main & Backlog)

Examination, October 2020

Subject: Advanced Biopharmaceutics & Pharmacokinetics

Time: 2 Hours **Max. Marks: 75**

Note : Answer any Three questions **(3 x 25=75 Marks)**

1. a) Explain the different theories of dissolution?
   b) Discuss in detail about the factors influencing the drug absorption?

2. a) A single IV dose of 75 mg of a drug was administered to a healthy volunteer. The following parameters were obtained

A=4.62 mg/L	B=0.64 mg/L
α=8.94 hr^{-1}	β=0.19 hr^{-1}

   Calculate all possible pharmacokinetic parameters?
   What will be the amount of drug remaining in the body after 8 hrs?

3. a) Write a note on *in vitro- in vivo* correlation?
   b) Discuss the alternative methods of dissolution testing?

4. a) Explain the study designs in bioequivalence studies?
   b) Write about BCS classification?

5. Describe the dose dependent kinetics? Explain the Michaelis - Menten equation?

6. A 60 kg patient received a single 25 mg oral dose of an antibiotic that is completely absorbed after oral administration. The plasma concentrations were as follows:

Time (hr)	0.2	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	12.0	14.0
Conc(ng/ml)	88.5	184.9	276.9	321.6	292.8	246.1	161.0	102.2	64.5	40.66	25.61

   Calculate all possible pharmacokinetic parameters?

7. a) Write in detail about the pharmacokinetics of modified dosage forms?
   b) Define the following
   I) Bioequivalence II) Absolute Bioavailability III) Volume of Distribution

8. a) Discuss the pharmacokinetic drug interactions with suitable examples?
   b) Explain the various methods for permeability studies?

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Code No: 6333/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main & Backlog)

Examination, October 2020

Subject: Molecular Pharmaceutics. (Nano tech & targeted DDS)

Time: 2 Hours **Max. Marks: 75**

Note : Answer any Three questions **(3 x 25=75 Marks)**

1. Explain various methods of tumour targeting?

2. a. Mention different types of targeting?
   b. Explain various methods of preparations of polymeric nanoparticles?

3. a. Describe various types of preparation of mircrospheres?
   b. How will you evaluate microsperes?

4. a. What are niosomes?
   b. Describe various method of preparation ofniosomes.

5. a. Describe applications of Monoclonal antibodies.
   b. What are aquasomes?

6. a. What are aerosols?
   b. Explain preparation and evaluation of aerosols.

7. a. What do you mean by gene therapy? What are all the diseases treated using this therapy?
   b. Explain in detail in vivo gene therapy?

8. Explain in detail therapeutic applications of antisense molecules and aptamers?

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Code No: 6335/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main & Backlog)

Examination, October 2020

Subject : Computer Aided Drug Delivery System

Time: 2 Hours **Max. Marks: 75**

Note : Answer any Three questions **(3 x 25=75 Marks)**

1. Write about quality by design in pharmaceutical development Mention various scientifically based QBDS.

2. Discuss computational modeling of drug disposition.

3. What is the impact of fasted and fed stater on oral drug development in computational modeling?

4. Write short notes on data collection and various methods of date a collection? Give detailed description about the process before, during and after data collection.

5. a) What do you mean by population modeling in pharmaceutical research?
   b) Write short notes on Descriptive versus mechanistic modeling

6. Write about active transport and explain in detail about five transporters in computational modeling

7. Write about four types of ethical issues associated with computer ethics

8. Discuss about the future of computers in pharmaceutical industry and also mention the various challenges faced by the pharmaceutical industry currently what can be done to overcome these challenges?

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Code. No: 6108/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Supply.) Examination, January 2020

Subject : Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. Describe a brief history of computers in pharmaceutical research and development. Mention the time line of the development in early stages. 15

2. Write notes on 15
   1. Sensitivity analysis
   2. Optimal design
   3. Population modeling

3. (a) Write about quality by design in pharmaceutical product development 8
   (b) What do you mean by QTPP 7

4. Discuss about the modeling techniques related to computational modeling of drug disposition with respect to ADMET 15

5. How the computer is used in optimizing the various parameters in pharmaceutical product development

6. Describe in detail about philosophy and ethics of computing in pharmaceutical research 15

7. What is computational fluid dynamics and how it is applicable to the pharmaceutical industry 15

8. Discuss about the future of computers in pharmaceutical industry. What are the current challenges faced by pharmaceutical industry? What can be done to overcome these challenges? 15

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Code. No: 6106/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.) Examination, January 2020

Subject: Molecular Pharmaceutics
(Nano Technology and Targeted Drug Delivery Systems)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1	(a) Define drug targeting? What are the ideal characteristics of a carrier?	6
	(b) Explain different types of drug targeting in detail?	9
2	Explain different types of tumour targeting methods in detail?	15
3	(a) Explain various transport mechanisms across Blood brain barrier?	5
	(b) Describe in detail invasive and non-invasive brain targeting methods?	10
4	(a) Describe hybridoma technology of Mab preparation?	8
	(b) How will you characterize monoclonal antibodies?	7
5	(a) What are liposomes? Explain the role of cholesterol in the preparation of liposomes?	5
	(b) Explain any five (5) methods of preparation of liposomes? Add a note on fate of liposomes?	10
6	What are aquasomes? Describe in detail method of preparation and characterization of aquasomes?	15
7	(a) What are aerosols? Explain various propellants used in the manufacturing of aerosols	7
	(b) Describe in detail evaluation methods of nasal drug delivery system?	8
8	(a) What are gene drug delivery systems? Explain in detail viral and non viral gene transfer methods?	9
	(b) Write a note on liposomal gene drug delivery system?	6

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Code No: 6109/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II- Semester (PCI) Supplementary Examination, January 2020

Subject: Cosmetics and Cosmeceuticals

Time: 3 Hours **Max Marks: 75**

Note: Answer Any Five Questions. ALL Questions carry Equal Marks.

1	a)	Define Cosmetics. Explain regulatory provisions relating to manufacture of cosmetics, conditions for obtaining license and loan license.	10
	b)	Write a note on Indian regulatory requirements for labeling of cosmetics.	5
2	a)	Describe the structure of skin and problems of skin.	10
	b)	Discuss about the cleansing and care needs for face.	5
3	a)	What are the building blocks for formulation of a shampoo?	10
	b)	Write a note on perfumes and classification of perfumes.	5
4	a)	Describe cosmeceutical products for dental cavities.	7
	b)	Describe cosmeceutical products for sun-protection and acne.	8
5	a)	Discuss about the guidelines for herbal cosmetics by COSMOS.	10
	b)	Write a note on guidelines for preservatives in herbal cosmetics.	5
6		Write a note on	
	a)	Herbal ingredients used in skin care	7
	b)	Cosmeceutical products for dandruff.	8
7		Write a note on	
	a)	Perfume ingredients.	6
	b)	Rheological additives-classification and applications.	9
8	a)	Write a note on challenges in formulating herbal cosmetics.	8
	b)	Write a note on controversial ingredients in cosmetics.	7

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Code. No: 6107/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.) Examination, January 2020

Subject : Advanced Biopharmaceutics and Pharmacokinetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. (a) Discuss about the theories proposed for the dissolution process and the factors affecting dissolution. 10
   (b) What is *in-vitro-in-vivo* correlations (IVIVC) and explain in brief 5

2. (a) Write in details about factor affecting dosage forms in drug absorption 10
   (b) State and Explain the Noyes-Whitney equation 5

3. Write notes on
   (a) p^H-partition hypothesis and its limitations 8
   (b) Explain the biopharmaceutical factor affecting drug bioavailability 7

4. (a) Explain the pharmacokinetic parameters of a drug which follows one compartment open model when given by intravenous bolus with relevant mathematical equations. 8
   (b) Explain the various methods for assessment of bioavailability. 7

5. (a) Define Non-Linear pharmacokinetics. How do you estimate the pharmacokinetics parameters (K_{max} and V_{max}) by using Michaelis - Menten equation 10
   (b) Explain the biopharmaceutical classification system (BCS) with examples and what are its application. 5

6. (a) Write a note on various study designs used for bioequivalence studies 8
   (b) Write the application of pharmacokinetics in monoclonal antibodies and gene therapies 7

7. (a) Explain the various methods for determining absorption of drugs *in-vitro, in-situ* and *in-vivo* and their their correlation with examples. 10
   (b) Following a 650 mg I.V.bolus dose of a drug to a 65kg subject, the plasma drug concentration was found to decline biexponentially. The equation, that best described the drug kinetic was; $C=76^{e-14t} + 33^{e-3t}$. Calculate the following parameters Vc, Vp, Vd.ss, Vd. area and K_E etc. 5

8. A dose of cirprofloxaction 250 mg I.V. bolus was administered to a patient and the plasma concentration vs time data is obtained. Assume the drug follows two compartment open model. Calculate all possible pharmacokinetic parameters. 15

Time (hrs)	0.25	0.5	0.75	1.5	2	2.5	3	5	6	7
Plasma Conc. (μ g/ml)	5.38	4.33	3.5	2.99	2.12	1.70	1.43	1.05	0.80	0.70

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Code. No: 13319/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2019

Subject : Molecular Pharmaceutics (Nano Tech. and Targeted DDS)

Time: 3 Hours **7**

M 5

ax. Marks:

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1.	(a) Discuss about the various approaches for drug delivery to brain.	10
	(b) Explain the concepts behind targeted drug delivery system.	5
2.	Explain the methods of preparation and evaluation of liposomes	15
3.	(a) Explain the methods of preparation and evaluation of electrosomes.	8
	(b) Explain the methods of preparation of aquasomes, and their applications.	7
4.	(a) Write about method of preparation of pharmaceutical aerosols.	8
	(b) Explain the factors influencing intranasal drug delivery system.	7
5.	(a) Explain about therapeutic antisense molecules	10
	(b) Write about metered dose inhaler	5
6.	(a) Write a short note on monoclonal antibodies	8
	(b) Give a brief account of exvivo gene therapy	7
7.	(a) Explain detail about targeting of drugs to tumor cells	8
	(b) Give a brief account on aptamers	7
8.	Give an account of the methods for the preparation of nanoparticles. Add a note onthe evaluation of nanoparticles.	15

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Code. No: 13322/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2019

Subject : Cosmetics and Cosmeceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. Write a note on Regulatory provisions relating to manufacture of cosmetics 15

2. Write a note on Indian regulatory requirements for labeling of cosmetics 15

3. Discuss in detail about skin related problems 15

4. (a) Write a note on structure of skin and its functions 10
   (b) Explain about cleansing and care of body and under arms. 5

5. (a) Give detailed account of various building blocks for formulation of body creams 10
   (b) Write a note on factors affecting microbial preservative efficacy. 5

6. Write a note on classification and EU regulations of perfumes 15

7. Explain about the design of skin protectants 15

8. (a) What are the challenges in formulating herbal cosmetics 8
   (b) Write a note on herbal ingredients used in skin care products. 7

Code. No: 13321/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2019

Subject : Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. Write role of computers in pharmaceutical research and development.

2. Write about application of descriptive statistics in pharmaceutical research and Development.

3. (a) Discuss quality –by-Design (QbD) in pharmaceutical product development 8
   (b) Write a note on ICH Q8 guidelines for good quality product 7

4. What is active transport? Write about following transporters
   (a) P-gp
   (b) BBB-Choline transporter

5. (a) What is the objective of optimization? Write optimization parameters for formulation development 10
   (b) Write application of computers in market analysis 5

6. (a) Write about *invitro* dissolution & *invitro-invivo* correlation. 10
   (b) Write a note on Biowaiver considerations 5

6. Write role of computers in clinical data collection and management for clinical development

8. Discuss about artificial intelligence and robotics in pharmaceutical automation and write their application, advantages and disadvantages.

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Code. No: 13320/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2019

Subject : Advanced Biopharmaceutics and Pharmacokinetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. (a) Explain in detail various factors affecting dissolution. 10
   (b) Write a note on Biopharmaceutics classification system 5

2. (a) Explain various causes of nonlinearity. Write Michaels Menten equation and explain the terms there in 8
   (b) Write important characteristics of carrier mediated transport Compare facilitated diffusion and active transports 7

3. Write in detail about
   (a) Clearance 5
   (b) Physiological model 5
   (c) Absolute & relative bioavailability 5

4. (a) List compendia methods of dissolution Explain alterative methods of dissolution testing 8
   (b) Write in detail about in vitro in vivo correlation 7

5. (a) Write the significance of absorption rate constant. How do you determine Ka by Wagner nelson method, 8
   (b) Explain various methods to study drug permeability 7

6. (a) Oral bolus dose: 10mg Drug follows one compartment model, assume that drug is 80% absorbed Following is blood data.

Time (hrs)	0.25	0.5	0.75	1.00	2	4	6	10	14	20
Concentration (ng/ml)	2.83	5.43	7.75	9.84	16.2	22.15	23.01	19.09	13.9	7.97

   Determine elimination constant, Ka, t1/2 t_{max}, C_{max}, V_d and Clearance 15

7. (a) Explain pharmacokinetic drug interactions with examples 8
   (b) Write a note on biosimilars 7

8. (a) Discuss briefly the influence of pharmaceutical excipients on drug bioavailability 7
   (b) Explain the application of pharmacokinetic in design of modified release dosage forms 8

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Code No. 13166/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Cosmetics and Cosmeceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. Write a note on Indian regulatory requirements for labelling of cosmetics. (15)

2. Write a note on Regulatory provisions relating to manufacture of cosmetics. (15)

3. (a) Write a note on structure of hair and hair growth. (10)
   (b) Write a note on common problems associated with oral cavity. (5)

4. Discuss in detail about skin related problems. (15)

5. (a) Give detailed account of various building blocks for formulation of body creams. (10)
   (b) Classify and write the applications of surfactants. (5)

6. Write a note on classification and EU regulations of perfumes. (15)

7. Explain about the design of skin protectants. (15)

8. (a) What are the challenges in formulating herbal cosmetics. (8)
   (b) Write a note on herbal ingredients used in hair care products. (7)

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Code No. 13165/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 Write history of computers in pharmaceutical research and development.

2 Discuss the importance and applications of statistical modeling in pharmaceutical research and development.

3 Write application of Quality-by-Design (QbD) in pharmaceutical development. Explain QbD approach for formulation development with example.

4 (a) Write in brief on computational modeling techniques for drug absorption, drug distribution and drug excretion.
(b) Write a note on P-gp transporters.

5 Describe briefly factorial design for optimization and screening of pharmaceutical formulation in formulation development with example.

6 (a) Write briefly about computer aided biopharmaceutical characterization for GI absorption simulation.
(b) Discuss Computer simulations in PK & PD for whole organism.

7 Write the applications of computers in clinical data collection and management.

8 a) Write about application of artificial intelligence & robotics in pharmaceutical automation. Write advantages and disadvantages of robotics in pharmacy automation.
b) Write current challenges and future directions of pharmacy automation.

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Code No. 13163/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Molecular Pharmaceutics
(Nano Technology and Targeted Drug Delivery Systems)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. a. What are the ideal properties of a carrier? (5)
   b. Explain different types of drug targeting with examples? (10)

2 a. What are the limitations of drug targeting to tumour? Explain EPR targeting? (7)
   b. What are the active targeting methods to target tumour? (8)

3 a. Explain blood brain barrier? What the factors affecting drug transport across the BBB? (6)
   b. Explain various non-invasive targeting methods to brain? (9)

4 a. Describe in detail various methods of preparation of microspheres? (10)
   b. Explain the drug release mechanism from microspheres? (5)

5 a. Explain in detail nasal drug delivery system? (10)
   b. Write a note on preparation of Monoclonal antibodies? (5)

6 a. What are aerosols? Explain various propellants used in the manufacturing of Aerosols. (7)
   b. Explain different methods to characterize aerosols? (8)

7 a. Define gene therapy? Explain few diseases targeted for treatment using gene drug delivery system. (9)
   b. Explain aptamers role in targeted cancer therapy? (6)

8 Write a note on following
   a. Stealth liposomes
   b. Phytosomes
   c. Aquasomes (15)

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Code No. 13164/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Suppl.) Examination, February 2019

Subject: Advance Biopharmaceutics & Pharmacokinetics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write in detail about mechanism of drug absorption with suitable diagrams.(10)
   (b) State and Explain the Noyes-Whitney equation. (5)

2. Write notes on
   (a) pH-Partition hypothesis and its limitations (8)
   (b) Explain the pharmacokinetic and pharmacodynamic drug-drug interaction. (7)

3. (a) Discuss about the theories proposed for the dissolution process and the factors affecting dissolution. (10)
   (b) What is *in-vitro-in-vivo* correlations (IVIVC) and explain in brief. (5)

4. (a) How do you calculate absorption rate constant from plasma-concentration data following an oral dose using Wagner Nelson method. (8)
   (b) Explain the various methods for assessment of bioavailability. (7)

5. (a) Define Non-Linear pharmacokinetics. How do you estimate the pharmacokinetic parameters (K_{max} and V_{max}) by using Michaelis-Menten equation. (10)
   (b) Explain the biopharmaceutical classification systems (BCS) with examples and what are its application (5)

6. (a) Describe the experimental protocol and analysis of data for bioequivalence studies for conventional dosage form. (10)
   (b) Write the application of pharmacokinetics in targeted drug delivery system. (5)

7. (a) Explain the various methods for determining absorption of drugs *in-vitro,in-situ* and *in- vivo* and their correlation with examples. (10)
   (b) Pharmacokinetics of 500 mg paracetamol after oral administration is best described by the equation $C=1.18(e^{-0.24t} - e^{-1.6t})$.Calculate the C_{max}, t_{max} and $t_{1/2}$ of the drug. (5)

8. A dose of ciprofloxacin 250 mg I.V.bolus was administered to a patient and the plasma concentration vs time data is obtained. Assume the drug follows two compartment open model. Calculate all possible pharmacokinetic parameters. (15)

Time(hrs)	0.25	0.5	0.75	1.5	2	2.5	3	5	6	7
Plasma conc. (µg/ml)	5.38	4.33	3.5	2.99	2.12	1.70	1.43	1.05	0.80	0.70

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Code No. 1209/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2018

Subject: Molecular Pharmaceutics
(Nano Technology and Targeted Drug Delivery Systems)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 a) Explain the concepts, events and biological processes involved in drug targeting. (8)
b) Explain in detail about targeting of drugs to tumor cells. (7)

2. Explain the methods of preparation and evaluation of nanoparticles. (15)

3 a) Explain the methods of preparation and evaluation of microspheres. (10)
b) Explain the methods of preparation of aquasomes. (5)

4 a) Write about containers, propellants and evaluation tests for pharmaceutical aerosols. (10)
b) Explain about intranasal drug delivery system. (5)

5 a) Explain about bone marrow transplantation in exvivo gene therapy. (10)
b) Give a brief note on invivo gene therapy (5)

6 a) Discuss in detail gene expression systems (both viral and nonviral gene transfer). (10)
b) Give an account of liposomal gene delivery system. (5)

7. Give a brief account of i) aptamers; ii) Therapeutic antisense molecules. (8+7)

8. Explain the methods of preparation and evaluation of liposomes. (15)

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Code No. 1210/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2018

Subject: Advance Biopharmace. & Pharmacokinetics

Time: 3 Hours **Max. Marks : 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Derive expressions for c_{max} and t_{max} for one compartment open model, extra vascular administration. (8)

(b) Explain with examples cytochrome p450 based drug interactions. (7)

2 (a) What are the different methods for assessment of bioavailability? (8)
(b) What are the special concerns in bioavailability and bioequivalence studies. (7)

3 (a) Write the significance of different volumes of distribution in two compatment model. (5)
(b) Write a note on volume of distribution and clearance. (10)

4 (a) Explain various methods to study drug permeability. (7)
(b) Write about IVIVC. (8)

5 (a) Derive Michaelis-Menten equation. How do you estimate K_m and V_m. (10)
(b) How do you compare dissolution profiles? (5)

6 (a) Explain the applications of pharmacokinestic principles in controlled release dosage forms. (8)
(b) Write a note on micro climate intracellular pH and tight junction complex. (7)

7 (a) Enumerate physicochemical factors of the drug affecting dissolution. (7)
(b) Explain the kinetics of IV infusion for one compartment model. (8)

8 (a) Explain various cross over designs in bioequivalence studies. (7)
(b) Write in detail about compartment models. (8)

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Code No. 1212/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2018

Subject: Cosmetics and Cosmeceuticals

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Explain Regulatory provisions for sale and manufacturing of cosmetics. (10)
(b) Define Cosmetics, Misbranded cosmetics and spurious cosmetics. (5)

2 (a) Describe the structure & growth cycle of hair with a neat diagram. (8)
(b) Discuss about the cleansing and care needs for scalp. (7)

3 (a) What are the building blocks for formulation of a tooth paste? (8)
(b) Write a note on antimicrobials as preservatives. (7)

4 (a) Describe cosmeceutical products for acne and sun-protection. (7)
(b) Describe cosmeceutical products for body odour and dandruff. (8)

5 (a) Discuss about the guidelines for herbal cosmetics by COSMOS. (10)
(b) Write a note on guidelines for preservatives in herbal cosmetics. (5)

6 Write a note on
(a) herbal ingredients used in hair care. (7)
(b) Cosmeceutical products for dental cavities. (8)

7 Write a note on
(a) offences and penalties. (6)
(b) surfactants-classification and applications. (9)

8. (a) Write a note on challenges in formulating herbal cosmetics. (8)
(b) Write a note on perfumes listed as allergens in Europe Union regulations. (7)

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Code No. 1211/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2018

Subject: Computer Aided Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Write short note on "Statistical Modeling". 3x5
(b) Descriptive versus mechanistic modeling.
(c) Population modeling

2 Write about ICH Q8 guide lines. What are the regulatory and industrial views on quality by design? 15

3 Write about active transport and explain any three of the following : 3x5
(a) h PEPTI
(b) ASBT
(c) OCT
(d) OATP
(e) BBB – choline transporter

4 (a) How to screen various parameters in pharmaceutical product development by using computers? 7 ½
(b) What do you mean by factorial designs in optimization technology? 7 ½

5 Discuss in detail about computer simulation in pharmacokinetic and pharmacodynamic studies. 15

6 Write short notes on clinical data collection. Give detail description about the process before, during and after data collection. 15

7 (a) Explain various applications of artificial intelligence. 7 ½
(b) Write notes on pharmaceutical automation. 7 ½

8 (a) What do you mean by "Biowavier consideration" and where do you apply these biowavier studies? 7 ½
(b) Write detail notes on Invitro, Invivo correlation. 7 ½

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Code No. 1209/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II-Semester (PCI) (Main) Examination, August 2018

Subject: Molecular Pharmaceutics
(Nano Technology and Targeted Drug Delivery Systems)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 a) Explain the concepts, events and biological processes involved in drug targeting. (8)
b) Explain in detail about targeting of drugs to tumor cells. (7)

2. Explain the methods of preparation and evaluation of nanoparticles. (15)

3 a) Explain the methods of preparation and evaluation of microspheres. (10)
b) Explain the methods of preparation of aquasomes. (5)

4 a) Write about containers, propellants and evaluation tests for pharmaceutical aerosols. (10)
b) Explain about intranasal drug delivery system. (5)

5 a) Explain about bone marrow transplantation in exvivo gene therapy. (10)
b) Give a brief note on invivo gene therapy (5)

6 a) Discuss in detail gene expression systems (both viral and nonviral gene transfer). (10)
b) Give an account of liposomal gene delivery system. (5)

7. Give a brief account of i) aptamers; ii) Therapeutic antisense molecules. (8+7)

8. Explain the methods of preparation and evaluation of liposomes. (15)

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