Code No. D-8258/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, August 2022

Subject: Industrial Pharmacy

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

Note: Answer all questions PART – A, any two questions from PART – B and any seven question from PART – C.

PART – A (10 x 2 = 20 Marks)

1 Write a note on SUPAC.
2 What is validation?
3 Write a note on DQ, IQ, OQ and PQ.
4 What is QRM?
5 Define API and excipient.
6 What are various phases of clinical trials?
7 What is the aim of NDA?
8 Define Bioavailability and Bioequivalence.
9 Write a note on CDSCO.
10 What is RDTL and its functions?

PART – B (2 x 10 = 20 Marks)

11 (a) Write the General considerations for pilot plant and scale up.
(b) Write a note on platform technology.

12 (a) Write a note on six sigma concept.
(b) Write a note on ISO 14000.

13 (a) Discuss Regulatory requirements and approval procedures for New Drugs.
(b) Write the responsibilities of State Licensing authorities.

PART – C (7 x 5 = 35 Marks)

14 Explain the procedure for pilot plat scale-up for semisolid dosage forms.
15 What is technology transfer? Write general principles of Technology Transfer.
16 Write the role and responsibility of regulatory affairs professionals.
17 Write a note on technology transfer agencies in India.
18 Write briefly on Investigational New Drug (IND) Application.
19 Write about QbD and its applications.
20 Write about the Certificate of Pharmaceutical Product (COPP).
21 Write a note on the principle and process of QRM.
22 Write NDA Review process.

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Code No. D-8257/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, August 2022

Subject: Instrumental Methods of Analysis

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

Note: Answer all questions PART – A, any two questions from PART – B and any seven question from PART – C.

PART – A (10 x 2 = 20 Marks)

1. Define auxochrome and chromophore with example.
2. What is Quenching and types of quenching?
3. Write the interferences in Flame photometry and types of interference.
4. Name the Infra-Red radiation source.
5. Define the term chromatography and the general principle involved in it.
6. Mention the factors affecting Electrophoretic Mobility.
7. Write about the temperature program in Gas chromatography.
8. Explain different types of pumps used in HPLC and their brief working principle.
9. Explain the principle involved in Ion Exchange Chromatography.
10. Write the theory involved in Gel Chromatography.

PART – B (2 x 10 = 20 Marks)

11. (a) Explain in detail about the construction and working principle of detectors used in UV-Vis spectroscopy.
    (b) Write about the Methodology involved in Paper Chromatography.
12. (a) Describe the sources and sampling techniques in IR spectroscopy.
    (b) Explain the factors affecting in exchange methodology in ion exchange chromatography.
13. (a) Explain the applications of HPLC with examples.
    (b) Write about the Instrumentation of Affinity chromatography.

PART – C (7 x 5 = 35 Marks)

14. Explain the technique of Capillary Electrophoresis.
15. Write about electronic transitions and solvent effect on absorption spectra.
16. Describe the theory involved in fluorimetric technique.
17. Explain the instrumentation of Nephelotubiodmetry.
18. Write the factors affecting vibration in IR spectroscopy.
19. Differentiate between single and multi-component analysis in UV-Vis spectroscopy with examples.
20. Explain the principle and Interference in Atomic Absorption spectroscopy.
21. (a) Write the principle involved in column chromatography.
    (b) Explain the working principle of Thermocouple Detector.
22. Write about the Detectors used in HPLC.

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Code No. D-8260/PCI

FACULTY OF PHARMACY

B. Pharmacy VII - Semester (PCI) (Backlog) Examination, September 2022

Subject: Novel Drug Delivery Systems

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

PART – A

Note: Answer all questions. **(10 x 2 = 20 Marks)**

1. Define terms sustained, controlled and targeted release dosage forms.
2. Write ideal characters suitable for selection of drug for controlled drug delivery system.
3. Explain about inflatable systems.
4. Explain the Nasal and Pulmonary routes of drug delivery.
5. Write the advantages and disadvantages of gastroretentive drug delivery system.
6. Explain various coating materials used in microencapsulation.
7. Write a note on transmucosal permeability.
8. What is floating time and floating lag time.
9. Write the applications of monoclonal antibodies.
10. Compare and contrast liposomes and niosomes.

PART – B

Note: Answer any two questions. **(2 x 10 = 20 Marks)**

11. Explain in detail physiochemical and biological factors affecting controlled release formulations.
12. Explain in detail coacervation phase separation method with suitable examples.
13. Discuss about advantages and disadvantages and development of intra uterine devices and applications.

PART – C

Note: Answer any seven questions. **(7 x 5 = 35 Marks)**

14. Discuss the classification and applications of polymers used in controlled drug delivery system.
15. Explain the theories of mucoadhesion.
16. Explain about factors affecting permeation in transdermal drug delivery system.
17. Discuss the approaches used in development of gastroretentive drug delivery system.
18. Explain about nasal sprays and nebulizers.
19. Explain about osmotic pump.
20. Discuss the ocusert with neat sketch.
21. Explain the preparation methods of nanoparticles.
22. Explain dry powder and metered dose inhalers.

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Code No. D-8259/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, September 2022

Subject: Pharmacy Practice

Time: 3 hours **Max Marks: 75**

PART - A

Note: Answer all the questions. **(10 x 2 = 20 Marks)**

1. Define Primary, Secondary and Tertiary hospital.
2. Mention the functions of hospital pharmacy
3. Mention the classification of ADR
4. Define idiosyncrasy.
5. Mention few examples of pharmacokinetic drug interactions
6. Mention few drugs which require TDM
7. Define patient counselling.
8. Define lead time.
9. Define investigational drug.
10. Give a general patient counselling information for NSAIDs

PART - B

Note: Answer any two questions **(2 x 10 = 20 Marks)**

11. Describe different types of drug interactions. Add a note on reporting and management of ADR
12. Describe organisation, structure, type and design of wholesale and community pharmacy outlet
13. Explain different types of drug distribution system in a hospital. What do you mean by satellite pharmacy?

PART - C

Note: Answer any seven questions **(7 x 5 = 35 Marks)**

14. Define hospital formulary. What are the contents of hospital formulary? What is the difference between hospital formulary and essential drugs list?
15. Explain the role of pharmacist in improving medication adherence and highlight few counselling barriers.
16. Describe schedule N of drugs and cosmetics act rules 1945.
17. Describe the policies of pharmacy and therapeutic committee.
18. Explain the systematic approach of handling a drug information query.
19. Explain the role of a pharmacist in training and education.
20. Explain hospital budget preparation and implementation.
21. Define OTC drugs. What is the role of pharmacist in implementing rational use OTC drugs.
22. Classify investigational drugs. Explain haematological tests and its significance.

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Code No. D-8182/PCI

FACULTY OF PHARMACY

B. Pharmacy VII - Semester (PCI) (Main & Backlog) Examination,
February / March 2022

Subject: Instrumental Methods of Analysis

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

PART - A

Note: Answer all questions: **(10 x 2 = 20 Marks)**

1. State and explain Beer-Lambert equation.
2. What is fluorescence quenching? Give examples.
3. Write the principles of Flame photometry technique.
4. Write the applications of Nephelometry and turbidometry techniques.
5. Write different types of stationary phase column packing materials used in HPLC.
6. Write Van Deempter equation.
7. What are the different types of Ion exchange resins used in Ion-exchange chromatography?
8. Define theoretical plate and give formula for calculating theoretical plates.
9. What is an electronic transition and types?
10. Write the principle involved in affinity chromatography.

PART - B

Note: Answer any two questions: **(2 x 10 = 20 Marks)**

11. Describe different components of IR spectrophotometer.
12. Explain the principles and experimental details of paper chromatography for Quantitative analysis.
13. Explain the principles and instrumentation of Gas chromatography technique.

PART - C

Note: Answer any seven questions: **(7 x 5 = 35 Marks)**

14. Explain in brief about Paper electrophoresis technique.
15. Describe different methods for quantitative analysis of single component samples by UV spectrophotometry.
16. Explain the principles, advantages and disadvantages and applications of thin layer chromatography.
17. Write about Gel Permeation chromatography.
18. Write the principles and applications of Atomic absorption spectroscopy.
19. Explain different sample handling techniques used in IR spectroscopy.
20. Explain the principles of fluorescence and Phosphorescence with help of Joblonski diagram.
21. Explain the principles and applications of partition and adsorption chromatography.
22. Write the different factors affecting electrophoretic mobility of ions in electrophoresis separations.

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Code No. D-8183/PCI

FACULTY OF PHARMACY

B. Pharmacy VII - Semester (PCI) (Main & Backlog) Examination,
February / March 2022

Subject: Industrial Pharmacy – II

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

PART - A

Note: Answer all questions: **(10 x 2 = 20 Marks)**

1 What is the need of pilot plant studies in pharmaceutical industries?
2 Write the level of changes expected under SUPAC.
3 Explain the quality risk management to technology transfer.
4 Describe the role of project team in the technology transfer.
5 Enlist at least four names of regulatory authorities functioning all around the world.
6 Enumerate the categories and type of INDs.
7 What are the benefits of NABL accreditation?
8 Mention the difference between corrective actions and preventive actions in quality system.
9 Write the functions of state regulatory authority.
10 What are the regulatory requirements for new drug approval?

PART - B

Note: Answer any two questions: **(2 x 10 = 20 Marks)**

11 Explain the steps involved in scale-up technology.
12 Define TQM and explain its key elements.
13 Discuss IND approval process in detail with help of flow diagram.

PART - C

Note: Answer any seven questions: **(7 x 5 = 35 Marks)**

14 Discuss the scale-up considerations for liquid oral pharmaceuticals.
15 Define the following: (a) Quality (b) QC (c) QA (d) Technology transfer (e) QbD
16 Discuss business process benchmarking as a tool of quality management.
17 What are the roles of regulatory affairs personnel in pharmaceutical industry?
18 Describe different models for the statistical design of clinical trials.
19 Discuss transfer of technology between R & D and manufacturing unit.
20 Differentiate between GMP and GLP.
21 Discuss importance of non-clinical drug development.
22 Describe the terms “QTPP” and “CQA” concerning QbD.

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Code No. D-8184/PCI

FACULTY OF PHARMACY

B. Pharmacy VII - Semester (PCI) (Main & Backlog) Examination,
February / March 2022

Subject: Pharmacy Practice

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

PART - A

Note: Answer all questions: **(10 x 2 = 20 Marks)**

1. What are the roles of clinical pharmacist in ward rounds?
2. Write the classification of drug related problems.
3. Mention the requisites & objectives for management of materials in hospital pharmacy.
4. Describe the significance of Drug Information Center.
5. Explain the important considerations for Therapeutic Drug Monitoring.
6. Give a brief note on the factors affecting drug variability.
7. Write a short note on material requirement for community pharmacy.
8. Give definition of drug integrations and classify them accordingly.
9. Enumerate the types of drug ADRs with examples.
10. Write a note on rational use of drugs.

PART - B

Note: Answer any two questions: **(2 x 10 = 20 Marks)**

11. Define P & T Committee and write its objectives, organization and various functions.
12. Define Hospital and enumerate the organization and functions of hospital.
13. What is meant by clinical pharmacy? Explain functions and responsibility of clinical pharmacy.

PART - C

Note: Answer any seven questions: **(7 x 5 = 35 Marks)**

14. Give a comprehensive note on factors affecting Therapeutic Drug Monitoring.
15. Explain the roles and responsibility of hospital pharmacist.
16. Describe the procurement or purchasing procedure for pharmaceuticals in detail.
17. Explain various hematologic tests and their significance.
18. Explain the steps involved in the preparation of hospital formulary.
19. Elaborate the requirements for establishment of Drug Information Center.
20. Provide the detailed role of pharmacist in medication adherence.
21. Write all the inclusive steps involved in patient counseling.
22. Define Inventory Control. Specify the methods of Inventory Control.

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Code No. D-8185/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Main & Backlog) Examination,
February / March 2022

Subject: Novel Drug Delivery Systems

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

PART - A

Note: Answer all questions: **(10 x 2 = 20 Marks)**

1. Define terms sustained, controlled and targeted release dosage forms.
2. Enlist ideal characters suitable for selection of drug for controlled drug delivery system.
3. Define microencapsulation, write its applications.
4. What are implantable drug delivery system with examples?
5. Write the advantages and disadvantages of mucoadhesive drug delivery system.
6. Explain various coating materials used in microencapsulation.
7. Write a note on permeation enhancers with examples.
8. What is floating time and floating lag time?
9. Write the applications of monoclonal antibodies.
10. Write the methods of evaluation of liposomes.

PART - B

Note: Answer any two questions: **(2 x 10 = 20 Marks)**

11. Explain in detail physicochemical and biological factors affecting controlled release formulations.
12. Explain the methods of microencapsulation.
13. Discuss the basic components, formulation approaches for development of transdermal drug delivery system.

PART - C

Note: Answer any seven questions: **(7 x 5 = 35 Marks)**

14. Discuss the classification and applications of polymers used in controlled drug delivery system.
15. Explain the theories of mucoadhesion.
16. Write a note on osmotic pump.
17. Discuss the approaches used in development of gastroretentive drug delivery system.
18. Explain about nasal sprays and nebulizers.
19. Write a note on niosomers.
20. Discuss the ocuserts with neat sketch.
21. Explain the applications of intrauterine devices.
22. Explain the formulation considerations of buccal drug delivery system.

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Code No. 12332/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, September 2021

Subject: Instrumental Method of Analysis

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

PART – A

Note: Answer any seven questions. **(7 X 3 = 21 Marks)**

1. Explain the principle involved in Silicon photodiode detector in UV-Vis spectroscopy?
2. What are Singlet, Doublet and Triplet electronic states in Fluorimetry?
3. Define the term Retention time and Resolution in HPLC?
4. Explain the principle involved in Bolometer Detector?
5. Define the term Rf value.
6. Write the principles involved in Gel electrophoresis?
7. Mention different types of columns used in Gas chromatography?
8. Write different detectors compatible to HPLC?
9. Classify the Ion exchange chromatography?
10. Write about the deviations of Beer-Lamberts Law?

PART – B

Note: Answer any one questions. **(1 X 14 = 14 Marks)**

11. (a)Explain Theory and Instrumentation of Affinity Chromatography?
    (b) Derive Beer-Lamberts Law?
12. Explain in detail the Instrumentation and Derivatization technique in Gas Chromatography?
13. (a) Write about the Spectrophotometric titrations with examples?
    (b) Explain the Internal and External conversions in fluorimetry?

PART – C

Note: Answer any five questions. **(5 X 8 = 40 Marks)**

14. Write about the fundamental modes of Vibrations in polyatomic molecules?
15. Explain the Applications of Atomic Absorption spectroscopy with example?
16. Write in detail about the factors affecting Electrophoretic Mobility?
17. Describe the methodology of Adsorption Column Chromatography?
18. Write about the Interferences and their types in Flame Photometry?
19. Write a note on Wavelength selectors and sources of IR spectroscopy?
20. Describe the Principle involved in different sources of radiation of UV-Vis spectroscopy?
21. Write the methodology and application of Thin Layer Chromatography?
22. What is Quenching and explain the types of Quenching with examples?

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Code No.12333/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, September 2021

Subject: Industrial Pharmacy - II

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

PART – A

Note: Answer any seven questions. **(7 X 3 = 21 Marks)**

1. What is Pilot Plant?
2. Write a note on SUPAC.
3. What is Technology Transfer?
4. Name few approved regulatory bodies and Technology Transfer agencies in India.
5. What is the role of regulatory affairs?
6. What are various phases of clinical trials?
7. What is Quality Assurance?
8. Write a note on GLP.
9. Write a note on Indian regulatory.
10. What is the role of Drug control laboratory?

PART – B

Note: Answer any one questions. **(1 X 14 = 14 Marks)**

11. What is Pilot plant and scale-up? Explain in detail about the scale up techniques for Solid dosage forms (Tablets/Capsules).
12. (a) Write a note on Indian Regulatory. Write C D S C O functions.
    (b) Write short note on State Licensing authorities.
13. (a) Write the principles of TQM.
    (b) Explain the principles of QBD.

PART – C

Note: Answer any five questions. **(5 X 8 = 40 Marks)**

14. Explain the procedure for pilot plant scale-up for liquid dosage form.
15. What is technology transfer? Write general principles of Technology Transfer.
16. Write the role of regulatory affairs department in drug approval.
17. What is QRM? Describe the principle and process of QRM.
18. Write briefly on Master Formula Record and its importance.
19. Write a note on ICH guidelines.
20. Explain about Central Drugs Laboratory and its function.
21. Write brief note on (i) IND (ii) NDA.
22. Write protocol for technology transfer.

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Code No.12334/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, September 2021

Subject: Pharmacy Practice

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

PART – A

Note: Answer any seven questions. (7 X 3 = 21 Marks)

1. Define Hospital. Classify it based on clinical ground.
2. What is Idiosyncrasy? Give examples.
3. Differentiate hospital formulary and drug list.
4. Enlist the types of drug distribution systems.
5. Mention the specific objectives of health education.
6. Discuss the interpretation of the prescription.
7. Define Budget. Mention the approaches involved in the budget preparation.
8. Explain the significance of OTC drugs.
9. Classify drug store based on design.
10. Mention the role of hospital pharmacist in the investigational use of drugs.

PART – B

Note: Answer any one questions. (1 X 14 = 14 Marks)

11. Define Therapeutic Drug Monitoring (TDM). Mention its objectives and explain the process involved in TDM.
12. (a) Explain in detail the objectives of Pharmacy and Therapeutic Committee (PTC).
    (b) Discuss the role of PTC in adverse drug monitoring.
13. Define Clinical Pharmacy. Explain in detail the functions and responsibilities of clinical pharmacist.

PART – C

Note: Answer any five questions. (5 X 8 = 40 Marks)

14. Discuss in detail the functions of hospital pharmacy.
15. Explain the role and responsibilities of community pharmacist.
16. Mention the role of Pharmacist in the medication adherence.
17. Describe the various systems involved in the dispensing of drugs to inpatients.
18. Illustrate the criteria for addition or deletion of drugs from hospital formulary.
19. Define patient counseling. Enlist the steps involved in patient counseling.
20. Discuss the role of Pharmacist in the interdepartmental communication and community health education.
21. Describe in brief the rational use of common over the counter medications.
22. Mention the various laboratory blood tests. Explain their significance.

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Code No.12335/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Backlog) Examination, September 2021

Subject: Novel Drug Delivery Systems

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

PART – A

Note: Answer any seven questions. (7 X 3 = 21 Marks)

1. Define the following dosage forms?
   (a) Controlled drug delivery systems (b) Targeted drug delivery system.
2. Differentiate between matrix and reservoir systems?
3. List out the methods used for microencapsulation?
4. Define the following: (a) Implants (b) Transdermal drug delivery system.
5. Types of permeation enhancers used in TDDS with examples?
6. Define the following: (a) Liposomes (b) Niosomes
7. Differentiate between Zero Order and First Order release kinetic?
8. List out the different types of nanoparticles?
9. Enumerate the applications of monoclonal antibodies?
10. Write the advantages of Ocuserts?

PART – B

Note: Answer any one questions. (1 X 14 = 14 Marks)

11. Discuss the formulation of Transdermal drug delivery systems with the components and examples? Add a note on factors affecting permeation?
12. Write in detail about the coacervation phase separation technique with examples?
13. Write in detail about the following:
    (a) Explain about the Alzet osmotic pump?
    (b) Mucoadhesive drug delivery system?

PART – C

Note: Answer any five questions. (5 X 8 = 40 Marks)

14. Discuss about the factors influencing formulation of controlled drug delivery system?
15. Write the polymerization techniques?
16. Explain the Wuster process for microencapsulation with an example?
17. Explain the different theories of mucoadhesion?
18. Describe the formulation of floating drug delivery systems?
19. Discuss about the metered dose inhalers?
20. Write a note on intraocular barriers? Describe the methods to overcome the problem?
21. Write about the different types and applications of Intra-uterine devices?
22. Write about the elementary osmotic pump?

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Code No. 12224/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Main) Examination, March 2021

Subject: Instrumental Methods of Analysis

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

PART – A

Note: Answer any seven questions. **(7 X 3 = 21 Marks)**

1. Define chromophore and Auxochrome and give examples.
2. Explain the phenomenon of Fluorescence and Phosphorescence.
3. What are the different types of fundamental modes of vibration in molecules after absorption of IR radiations?
4. Write the principles of partition and adsorption chromatography.
5. Write the different fuel gases and oxidants used in flame photometry technique.
6. Write the applications of gel permeation chromatography.
7. Write the ion exchange mechanism of ion exchange chromatogramphy.
8. Define retardation factor.
9. What is Bathochromic and Hypsochromic shift?
10. Write the principle involved in affinity chromatography.

PART – B

Note: Answer any one questions. **(1 X 14 = 14 Marks)**

11. Describe different components of UV spectrophotometer with a labeled diagram.
12. Explain the principles and experimental detail of thin layer chromatography for Quantitative analysis.
13. Explain the principles and instrumentation of HPLC technique.

PART – C

Note: Answer any five questions. **(5 X 8 = 40 Marks)**

14. Discuss the factors influencing intensity of fluorescence and applications of Fluorimetry technique.
15. Explain about gel electrophoresis.
16. Explain different sample handling techniques used in IR spectroscopy.
17. Write the theory and principle involved in flame photometry technique.
18. Write short notes on nepheloturbidometry.
19. Describe the different types of detectors used in Gas Chromatography.
20. Explain the different techniques used in paper chromatography.
21. Write the principles and applications of Atomic absorption spectroscopy.
22. Write the different factors affecting electrophoretic mobility of ions in electrophoresis separations.

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Code No.12227/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Main) Examination, March 2021

Subject: Novel Drug Delivery Systems

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

PART – A

Note: Answer any seven questions. **(7 X 3 = 21 Marks)**

1. Write the advantages and disadvantages of controlled release dosage forms.
2. Explain various pharmacokinetic properties for selection of drug for controlled drug delivery system.
3. What are niosomes, write its structural components.
4. What are transdermal drug delivery system. Write its applications.
5. Write the advantages and disadvantages of mucoadhesive drug delivery system.
6. Define microspheres and microcapsules.
7. Write note on permeation enhancers with examples.
8. What is floating time and floating lag time.
9. Write the applications of targeted drug delivery system.
10. Write about classification of liposomes.

PART – B

Note: Answer any one question. **(1 X 14 = 14 Marks)**

11. Explain the approaches used in development of gastro retentive drug delivery systems.
12. Explain in detail coacervation phase separation with suitable examples.
13. Discuss classification, properties and applications of polymers used in controlled drug delivery system.

PART – C

Note: Answer any five questions. **(5 X 8 = 40 Marks)**

14. Discuss the physicochemical factors affecting controlled drug delivery system.
15. Explain the principles of mucoadhesion.
16. Write a note on metered dose inhaler.
17. Discuss the basis used in development of transdermal drug delivery system.
18. Explain about intra-uterine devices.
19. Write about production of monoclonal antibodies.
20. Discuss the ocular barriers, methods to overcome barriers.
21. Explain the approaches used in development of controlled drug delivery systems.
22. Explain the formulation considerations of buccal drug delivery system.

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Code No. 12226/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Main) Examination, March 2021

Subject: Pharmacy Practice

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

PART – A

Note: Answer any seven questions. **(7 X 3 = 21 Marks)**

1. Describe the role of clinical pharmacist in health care setting?
2. Enumerate the types of drug related problems.
3. Mention the requisite Objectives for management of materials in hospital pharmacy.
4. Indicate the advantages and disadvantages of Unit Dose Distribution System.
5. Provide four examples of TDM drugs with their therapeutic range.
6. Give a brief note on Factors which influence drug variability?
7. Write a short note on the Material requirement for community pharmacy.
8. Define ADR and classify.
9. Explain types of drug interactions with example.
10. Write a note on rational use of drugs.

PART – B

Note: Answer any one question. **(1 X 14 = 14 Marks)**

11. Define hospital formulary and elaborate the stepwise procedure involved in the preparation of hospital formulary.
12. What is clinical pharmacy? Elucidate functions and responsibility of clinical pharmacy.
13. Give a detailed account on the factors affecting Therapeutic Drug Monitoring.

PART – C

Note: Answer any five questions. **(5 X 8 = 40 Marks)**

14. Explain the roles and responsibility of hospital pharmacist.
15. Write down the legal requirements for establishment and maintenance of drug store.
16. Enumerate the organization and functions of hospital.
17. Explain in detail about the role of pharmacist in medication adherence.
18. Define Pharmacy and Therapeutic Committee & explain the objectives, organization and functions.
19. Give comprehensive note on the steps involved in patient counseling.
20. Define Inventory Control. Specify the methods involved in Inventory Control.
21. Describe the procurement or purchasing procedure for pharmacists in detail.
22. Explain the various hematologic tests and their significance.

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Code No. 12225/PCI

FACULTY OF PHARMACY

B. Pharmacy VII-Semester (PCI) (Main) Examination, March 2021

Subject: Industrial Pharmacy - II

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

PART – A

Note: Answer any seven questions. **(7 X 3 = 21 Marks)**

1. What is platform technology?
2. Define: (a) Pilot Plant (b) Scale-up.
3. 'Technology transfer means physical transfer of goods'. True or false, explain.
4. Write the roles of regulatory affairs department.
5. Explain the term "Technology transfer".
6. Differentiate between IND and NDA.
7. Write the applications of Quality by Design.
8. What is OOS? How does OOS apply only to finished products?
9. Enlist functions of regulatory authorities.
10. Write the vision and mission of CDSCO.

PART – B

Note: Answer any one question. **(1 X 14 = 14 Marks)**

11. Explain the process of Change control with the help of flow-chart.
12. Discuss the NDA approval process in detail, illustrate with the help of flow diagram.
13. Explain the features of finished product technology transfer as per WHO guidelines.

PART – C

Note: Answer any five questions. **(5 X 8 = 40 Marks)**

14. Discuss the stages of pharmaceutical product life-cycle.
15. Explain the principles of Good Laboratory Practice (GLP).
16. Describe in detail the barriers to technology transfer.
17. What is Investigator's Brochure (IB)? Comment on the content of IB.
18. Discuss the objectives of pilot plant.
19. Explain SUPAC guidelines.
20. Write about ISO 9000 series.
21. Describe the phases of clinical trials.
22. Enlist the key elements of TQM and explain any one of them.

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