Code No: E-12398/PCI

FACULTY OF PHARMACY

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

Subject: Pathophysiology

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

PART - A

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

1. Define the following terms
   (a) Hypertrophy (b) Acidosis
2. What are the causes of hepatitis B?
3. Define gout and write its symptoms.
4. What is diabetes? How it is caused?
5. Distinguish between exocrine and endocrine gland.
6. Mention the types of anaemia.
7. Differentiate Atherosclerosis & Arteriosclerosis.
8. Explain alcoholic liver disease.
9. Define osteoporosis and osteoarthritis.
10. Differentiate between myocarditis and cardiomyopathy.

PART-B

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

11. Write briefly about the principle of wound healing in the skin.
12. Describe pathogenesis of depression in detail.
13. Explain in detail various cellular events of inflammation.

PART-C

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

14. What is Alzheimer disease? Enumerate its signs and symptoms.
15. Explain the pathogenesis of asthma.
16. What is ischemic heart disease? Explain its types.
17. Describe the pathophysiology of meningitis.
18. What are peptic ulcers? Discuss pathophysiology.
19. Mention aetiology and symptoms of inflammatory bowel disease.
20. Describe the causes and symptoms of AIDS.
21. Define homeostasis. Write various components of feedback system.
22. Explain the aetiology and pathogenesis of acute renal failure.

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Code No: E-12420/PCI

FACULTY OF PHARMACY

B. Pharm VI-Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Quality Assurance

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

PART-A

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

1. Write any three parameters each for GMP and TQM.
2. Define the term quality control.
3. Mention different personal records.
4. What is the importance of a specification for any activity?
5. List different secondary packing materials.
6. What is GLP?
7. Mention different methods to give complaint to an industry.
8. What is SOP?
9. Define the term calibration.
10. Write the scope of validation.

PART-B

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

11. Discuss the details of QbD.
12. Explain the various aspects of premises of a pharmaceutical industry.
13. Write the calibration procedure of a P^H meter.

PART-C

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

14. Write short notes on ICH guidelines.
15. Give informative notes on ISO9000 series.
16. Write about maintenance of stores for raw materials.
17. Explain quality control tests for rubber closures.
18. What are the general provisions for GLP?
19. Write about recalling and waste disposal procedures.
20. Explain the contents of master formula record.
21. Discuss on general principles of analytical method validation.
22. Explain good warehousing practice of a Pharmaceutical industry.

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Code No: E-12421/PCI

FACULTY OF PHARMACY

M.Pharmacy I-Semester (PCI) (Common to all) (Backlog) Examination, November-2023

Subject: Modern Pharmaceutical Analytical Techniques

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

Note: Answer any Five Questions. All Questions carry Equal marks.

1. a) Explain the electronic transitions with suitable examples
   b) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. (6+9)

2. a) Explain the sampling techniques in IR spectroscopy.
   b) What are the applications of IR spectroscopy (9+6)

3. a) What is the principles of flame photometrty? Explain the instrumentation.
   b) What are the factors affecting fluorescence? (9+6)

4. a) Explain chemical shift and the factors affecting chemical shift ?
   b) Draw a schematic NMR spectrum and explain splitting α signal intensity. (10+5)

5. With a neat labelled diagram, explain MS instrumentation. Draw MS spectrum for any two compounds α explain its peaks.

6. a) Classify the ionization techniques in MS. Explain any three methods in detail.
   b) Explain the fragmentation rules in MS. (9+6)

7. a) Explain HPLC instrumentation with a labelled diagram.
   b) Explain the factors affecting resolution & peak symmetry. (8+7)

8. a) Explain the principle and applications of capillary electrophoresis
   b) Classify the types of crystals and add a note on the applications of X-ray diffraction. (8+7)

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Code No: E-12437/PCI

FACULTY OF PHARMACY

M.Pharmacy (Pharmacy Practice) I-Semester (PCI) (Backlog) Examination, November-2023

Subject: Clinical Pharmacy Practice

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

Note: Answer any Five Questions. All Questions carry Equal marks.

1. (a) Discuss the evolution of clinical pharmacy practice and its scenario in the modern world.
   (b) Discuss different types of pharmacist's interventions with suitable examples (6+9)

2. (a) Explain the DUE cycle in detail.
   (b) Add a note on the role of clinical pharmacist in medicine use evaluation. (10+5)

3. (a) Define and explain the methods of Pharmacovigilance.
   (b) Give an account of Materiovigilance programme of India (10+5)

4. (a) Discuss the communication skills required for efficient patient counseling.
   (b) Add a note on strategies to overcome the barriers during counseling. (10+5)

5. (a) Explain all the haematological tests included in complete blood picture with their appropriate interpretations. (10+5)
   (b) Explain the reference ranges and significance of Serum Creatinine and BUN.

6. (a) Discuss the prerequisites for the establishment of Drug Information Centre.
   (b) Explain the preparation of written responses while answering a drug information request. (8+7)

7. (a) Compare and contrast tertiary and primary drug information resources. (7+8)
   (b) Discuss Liver Function Tests in detail.

8. (a) Describe pharmaceutical care concept.
   (b) Define and discuss the role of clinical pharmacist in patient Medication History Interview. (7+8)

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Code No: E-12441/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Semester (PCI) (Backlog) Examination, November-2023

Subject: Good Regulatory Practices

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

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

1. (a) Write a note on Global Harmonization Task Force (GHTF) guidance documents. [8]
   (b) Write a note on WHO cGMP guidelines. [7]

2. (a) Explain the types of Audits and Audit tools. [10]
   (b) What are the goals of laboratory Quality Audit? [5]

3. (a) Explain the CFR Part 210. [5]
   (b) Describe USFDA GLP Regulations. [10]

4. (a) Describe the general check list of 21 CFR Part 11. [8]
   (b) Describe principles and SOPs of GALP. [7]

5. (a) Write about Principles and Documentation in Good Distribution Practices. [8]
   (b) Write a note on USP GDP. [7]

6. (a) Describe Six Sigma concept. [5]
   (b) Explain Quality by Design tool for Quality Management. [10]

7. (a) Write a note on Types of Validation. [7]
   (b) Explain about ICH guidelines. [8]

8. (a) Describe ISO and QCI standards for GALP. [8]
   (b) Explain about HVAC validation. [7]

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Code No: E-12388/PCI

FACULTY OF PHARMACY

B. Pharmacy I Semester (PCI) (Backlog) Examination, November 2023

Subject: Human anatomy and Physiology-I

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

PART - A

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

1. Define Homeostasis and Hemopoiesis?
2. Define Signal transduction in cell communication?
3. List the bones in appendicular skeleton?
4. Write the functions of synovial joints?
5. Write the functions of platelets?
6. Explain the terms vasodilation and vasoconstriction?
7. Write the functions of X^{th} cranial nerve?
8. List different types of taste buds?
9. Explain the terms End systolic volume and End diastolic volume?
10. Write the structure and functions of endoplasmic reticulum?

PART - B

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

11. Define blood pressure and explain its regulation mechanisms?
12. Describe the structure of eye? Explain the physiology of vision?
13. Classify tissues? Explain in detail about different types of epithelial tissues?

PART - C

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

14. Describe the structure and functions of hyaline and elastic cartilage?
15. Draw a neat labelled diagram of skin?
16. Explain the structure and function of following bones. (i) Sternum (ii) Lumbar vertebra.
17. Define ECG and correlate ECG with the events of cardiac cycle.
18. Explain the physiology of balance?
19. Explain the composition and functions of blood?
20. Explain the structure and functions of lymph nodes with a neat labelled diagram?
21. Explain in detail about the structure and functions of plasma membrane with a neat labelled diagram?
22. List out cranial nerves and write their functions?

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Code No: E-12410/PCI

FACULTY OF PHARMACY

B. Pharmacy V Semester (PCI) (Backlog) Examination, November 2023

Subject: Medicinal Chemistry - II

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

PART-A

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

1. Write the structures and uses of Triprolidine hydrochloride.
2. Write the MOA of Spironolactone.
3. Write the synthesis of Isosorbide dinitrite.
4. Explain the antithyroid drug with examples.
5. Write the uses and mechanism of action of Thiazolidinedione's.
6. Write the structure of Cortisone and Hydrocortisone.
7. Explain Anti-hyperlipidemic agents with examples.
8. What are proton pump inhibitors.
9. Write the structure and uses of nitro-glycerine, chlorthiazide.
10. Write the mechanism of action of Dibucaine.

PART-B

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

11. (a) Write short notes on drugs for erectile dysfunction.
    (b) Write the synthesis and uses of Tolbutamide.
12. Write the classification with one structure from each category of Diuretics. Explain the mechanism of action of each class.
13. Write a short notes on oral contraceptives.

PART-C

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

14. Explain Antineoplastic agents with examples. Write the mechanism of action of Antimetabolite.
15. Write the MOA, uses and synthesis of metformin.
16. Write the classification of calcium channel blockers with structures.
17. Write the MOA and synthesis of Nitroglycerin.
18. Write a short notes on Anti-arrhythmic Drugs.
19. Write the SAR of local anaesthetic agents.
20. Explain the Nomenclature and Stereochemistry of steroids.
21. Write a short note on the alkylating agents.
22. Write the structure, uses and MOA of Omeprazole.

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Code No: E-12454/PCI

FACULTY OF PHARMACY

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

Subject: Computer Aided Drug Design

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

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

1. (a) What is QSAR? Describe the physicochemical parameters used in QSAR. [8+7]
   (b) Explain how QSAR helps in drug design or analogue design.

2. (a) Discuss, how Contour map analysis is used in 3D QSAR drug design? [8+7]
   (b) Write the applications and limitations of Hansch analysis.

3. (a) What is quantum mechanics? Describe the use of quantum mechanics in Drug design. [8+7]
   (b) What is molecular docking? Discuss the steps involved in molecular docking?

4. (a) Describe the steps involved in Homology modeling of a protein. [8+7]
   (b) Discuss the concept of predicting ADMET properties and its importance in drug design.

5. (a) Explain about various docking methods and write their advantages. [8+7]
   (b) Discuss about Knowledge based and Consensus scoring techniques in docking.

6. (a) Write a short note on : (a) Drug likeness screening [8+7]
   (b) Write about structure based *in silico* virtual screening.

7. (a) Explain about rigid docking, Flexible docking and extra-precision docking. [8+7]
   (b) Explain, how molecular docking is useful in rational design of new drugs?

8. Write a short note on: [8+7]
   (a) Fragment based drug design
   (b) Statistical methods used in QSAR

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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-12462/PCI

FACULTY OF PHARMACY

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

Subject: Indian System of Medicine

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

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

1. Define traditional medicine and herbal medicine. List the various classes of traditional medicine. Discuss the principles and concepts of Siddha and Unani systems of medicines.

2. (a) Write the treatment modalities in Naturopathy and Aromatherapy.
   (b) Discuss the importance of Yoga and give a note on Relaxation techniques.

3. Write the history and concepts of Homeopathy system of medicine. Explain the principles of homeopathy system.

4. Write about
   (i) Ayurvedic pharmacopoeia.
   (ii) Shodhana process.
   (iii) Carrier oils in aromatherapy.

5. Discuss the importance of stability studies. Explain the methods of stability studies.

6. What is evaluation? Discuss the problems in standardization. Write the WHO guidelines for standardization of herbal medicines.

7. List the various Ayurvedic formulations and describe the preparation and importance of any four formulations.

8. Write the objectives, functions and achievements of CCRAS, CCRS and CCRH.

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Code Number: E-12458/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II Semester (PCI) (Main & Backlog) Examinations, November 2023

Subject: Principles of Drug Discovery

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

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

1. Explain Target and lead with examples. Write about various methods of target identification in drug discovery process. [15]

2. (a) Write a note on combinatorial chemistry. [8+7]
   (b) Describe about role of zinc finger proteins in target identification and validation.

3. (a) Explain in brief about cell based high throughput screening. [8+7]
   (b) Explain in detail about virtual screening techniques.

4. (a) Describe in brief about Hansch analysis and free Wilson analysis. [8+7]
   (b) Write a note on CoMSIA.

5. (a) Describe in detail about types of protein structure. [8+7]
   (b) Explain about HTS and its importance.

6. (a) What is the role of nucleic acid and protein micro array in target discovery and validation. [8+7]
   (b) Write a note on protein structure prediction and molecular modelling.

7. (a) Describe the application of X-Ray crystallography in protein structure prediction. [8+7]
   (b) Write a note on economy of drug discovery.

8. (a) Write the importance of enzyme assays in drug discovery. [8+7]
   (b) Write a note on role of transgenic animals in target validation.

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Code No: E-12466/PCI

FACULTY OF PHARMACY

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

Subject: Quality Control and Quality Assurance

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

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

1. (a) Write in detail about ICH Q series guidelines. [8]
   (b) Explain about Quality control and Quality assurance. [7]

2. Write about the following
   (a) Organization and personnel responsibilities. [5]
   (b) Maintenance of sterile areas. [5]
   (c) Personal records and environmental control. [5]

3. Define IPQC. Write in detail about different IPQC tests for tablets and parenterals. [15]

4. (a) What is SOP? Write about different techniques to write SOP. [8]
   (b) Write a note on Quality audit plan. [7]

5. (a) Write about mix-up and cross contamination. [8]
   (b) Explain about Expiry date calculation and calculation of yields. [7]

6. Explain various quality control tests for Glass as a packaging material. [15]

7. (a) Write a note on Production record review. [7]
   (b) Aspectic process control. [8]

8. Discuss Good laboratory practices for quality control laboratory in detail. [15]

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Code No: E-12469/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacotherapeutics - II

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

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

1. Explain pain pathways. Discuss the management of acute pain with the help of an algorithm. What are the commonly reported triggers and diagnostic criteria for migraine headache?

2. Describe the clinical presentation and general approach to management of early to advanced Parkinson's disease. What are the modifiable risk factors of Ischemic Stroke?

3. Explain the non-pharmacological therapy and pharmacotherapy for cognitive symptoms of Alzheimer's disease. Write a short note on treatment of Obstructive sleep apnea.

4. Discuss the renal disorders induced by drugs in detail.
   Explain the management of tuberculosis.

5. Give an outline of management of HIV infection.
   Briefly discuss the treatment of Meningitis.

6. Explain the pharmacotherapy of Dengue fever and Helminthiasis. What are the pathogens involved in etiopathogenesis of gastroenteritis.

7. Briefly explain the management of Lung cancer. Write a short note on chemotherapy induced nausea and vomiting.

8. What are the general principles of cancer chemotherapy? Explain the treatment strategies and management of Acute Leukemias with the help of an algorithm.

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Code No: E-12477/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Regulatory Aspects of Herbal & Biologicals

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

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

1. (a) Describe the content and format of labeling for human prescription drug and biological products in US. [9+6]
   (b) Differentiate the Biologics and Biosimilars.

2. (a) What is Reference product, interchangeable product? Write the potential benefits of biosimilars and advantages of biosimilars. [9+6]
   (b) Differentiate the generics and biosimilars.

3. Give an informative note on
   (a) International society of blood transfusion (ISBT) [8+7]
   (b) International Haemovigilence network (HIN)

4. (a) Describe the regulations of blood and blood products in India. [8+7]
   (b) Write about development and approval of biosimilars in the EU.

5. Write about [8+7]
   (a) Data requirement for clinical trial application in India.
   (b) Post market data for similar biologics.

6. Discuss in detail about the good manufacturing practices in India. [15]

7. Describe the safety and legislations about the herbal drugs in India and USA. [15]

8. (a) Describe the data requirement for preclinical studies of biologicals in India. [7+8]
   (b) Write about development and approval of biosimilars products in US.

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Code No: E-12473/PCI

FACULTY OF PHARMACY

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

Subject: Pharmaceutical Validation

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

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

1. Define qualification. Explain different phases of qualification process of analytical equipment. [15]

2. Write a short note on
   (a) Factory Acceptance Test [8]
   (b) Qualification of Friability test apparatus. [7]

3. Write a short note on
   (a) Advantages of Validation [5]
   (b) Validation master plan [5]
   (c) Calibration of FTIR [5]

4. (a) What are the different parameters in HVAC to be examined? [7]
   (b) Write about validation of compressed air and nitrogen. [8]

5. Describe the method validation parameters for a new analytical method as per ICH guidelines. [15]

6. Define process validation. Explain the process validation of capsules. [15]

7. Write a short note on
   (a) GAMP [8]
   (b) Cleaning of facilities. [7]

8. Write a short note on
   (a) Rights and responsibilities of patentee. [8]
   (b) Significance of Transfer of Technology. [7]

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Code No: E-12402/PCI

FACULTY OF PHARMACY

B. Pharmacy III Semester (PCI) (Backlog) Examination, November 2023

Subject: Physical Pharmaceutics-I

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

PART-A

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

1. Write the solubility expressions.
2. Write the diffusion principles in biologic systems.
3. Write a note on liquid crystals and applications.
4. What are eutectic mixtures?
5. Write a note on detergency.
6. Write uses of surfactants.
7. Write the classification of complexes.
8. Write a note on complexation and drug action.
9. Define Isotonic solutions and Hypotonic solutions.
10. Write applications of buffers.

PART-B

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

11. (a) Write a note on quantitative approach to the factors influencing solubility of drugs.
    (b) Write a note on mechanisms of solute - solvent interactions.
12. Write a note on Refractive index, optical rotation, dielectric constant and dissociation constant.
13. (a) Explain various methods for determination of surface tension.
    (b) What is protein binding. Write the importance of protein binding.

PART-C

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

14. Write a note on Raoult's law and real solutions.
15. What is critical solution temperature? Write its applications.
16. Write a note on crystalline state and amorphous.
17. What is Polymorphism. Write its applications.
18. Write a note on HLB scale and its applications.
19. Write the applications of complexation in pharmacy.
20. Write a note on buffer capacity and maximum buffer capacity. Write Vanslyke's equation.
21. Write about pH scale. Write methods for determination of pH.
22. Write a note on buffers and its importance in pharmaceutical and biological systems.

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Code No: E-12425/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Chemistry) I Semester (PCI) (Backlog) Examination, November 2023

Subject: -Advanced Organic Chemistry-I

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

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

1. (a) Write the mechanism and stereochemistry of E1 and E2 eliminations.
   (b) Enlist the types of rearrangement reactions and discuss the mechanisms of any two. [8+7]

2. (a) Give a method of preparation, mechanism and applications of
   (i) Aluminiumisopropoxide (ii) Witting reagent
   (b) Discuss the method of formation, structure, stability and synthetic applications of free Radicals. [8+7]

3. Discuss the mechanism and applications of following named reactions. [15]
   (a) Brook rearrangement (b) Sandmeyer Reaction (c) Vilsmeyer-Haack Reaction

4. (a) Discuss the mechanism and applications of Doebner-Miller Reaction and Baeyer-Villiger oxidation.
   (b) Give an account of synthetic applications of Mannich reaction & Michael addition reaction. [8+7]

5. (a) Discuss the synthetic importance of protecting reactive functional groups in organic synthesis.
   (b) Give an account on protection of Amine and Carboxyl groups and their synthetic importance. [8+7]

6. Write a note on: [15]
   (a) Combes Quinoline synthesis (b) Traube purine synthesis
   (c) Pinner pyrimidine Synthesis

7. Outline the synthesis of following: [15]
   (a) Celecoxib (b) Chlorpromazine (c) Mercaptopurine

8 (a) Discuss c-x disconnections in alcohols and carbonyl compounds.
   (b) Discuss the retro synthetic strategies for Four and Five membered ring systems. [8+7]

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Code No. E-12422/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Drug Delivery System

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

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

1. a) What do you mean by personalised drug delivery system?
   b) Write a note on 3D printing of pharmaceuticals and telepharmacy

2. a) Describe the various principles involved in rate controlled drug delivery system.
   b) Write a note on pH & enzyme activated system.

3. a) What are the advantages and disadvantages of buccal drug delivery system. How buccal formulations are evaluated?
   b) Describe in detail any two theories of mucoadhesion.

4. a) What are the barriers and explain various methods to overcome the barriers of ocular drug delivery system.
   b) With a neat sketch draw the structure of the skin. What are the barriers of skin? What are the techniques to overcome the skin barriers?

5. a) Explain in detail mucosal delivery of vaccines.
   b) Write a note on single shot vaccines.

6. a) Explain matrix and reservoir type of transdermal drug delivery system.
   b) Explain any five evaluation methods of transdermal formulations?

7. a) Explain strategies to formulate a stable protein and peptide drug formulations.
   b) Describe physical and chemical stability of proteins.

8. a) What are biodegradable polymers? Explain various mechanism of polymer degradation from a drug delivery system.
   b) What are the applications of polymers in controlled drug delivery system.

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Code No: E-12431/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacognosy) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Advanced Pharmacognosy- I

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

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

1. (a) Write the importance of Pharmacognosy in herbal drug industry. [5]
   (b) Discuss about current good cultivation and collection practices of medicinal Plants. [10]

2. (a) Explain recent advances in marine drugs research. [10]
   (b) Write notes on marine toxins. [5]

3. Give biological source, marker compounds, medicinal uses and health benefits of
   (a) Soya bean [7.5]
   (b) Garlic. [7.5]

4. What are Phytopharmaceuticals? Write informative notes on [3+6+6]
   (a) Flavonoids (b) Vitamins

5. (a) WHO guidelines for safety monitoring of natural medicines . [7]
   (b) Write notes on bio-drug drug interactions with suitable examples. [8]

6. Write notes on
   (a) In-situ conservation of medicinal plants. [7.5]
   (b) Formulation of neutraceuticals [7.5]

7. Write notes on
   (a) Dietary fibres [7.5]
   (b) FSSAI guidelines [7.5]

8. Write notes on occurrence and characteristic features of
   (a) Withanolides [7.5]
   (b) Taxol. [7.5]

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Code No: E-12428/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Advanced Pharmacology – I

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

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

1. a) Write a note on drug absorption process. [7]
   b) Describe in detail about G-Proteins. [8]

2. a) Discuss the pharmacology of dopamine. [8]
   b) Explain in brief about role of histamine transmission in CNS. [7]

3. a) Classify cholinergic agents. Write the pharmacology of acetylcholine. [8]
   b) Write a note on NANC. [7]

4. a) Classify antipsychotics. Write the pharmacology of haloperidol. [8]
   b) Write a note on local anesthetics. [7]

5. a) Write a note on digoxin and nitroglycerine. [10]
   b) Write a note on heparine. [5]

6. a) Explain in brief about significance of protein binding. [6]
   b) Write the physiological role of nuclear receptors. [9]

7. a) Describe the pharmacology of adrenaline. [10]
   b) Write a note on diazepam. [5]

8. a) Explain about the anti-platelet drugs. [10]
   b) Write a note on opioid receptors. [5]

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Code No: E-12434/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Analysis) I – Semester (PCI) (Backlog) Examination, November 2023

Subject: Advanced Pharmaceutical analysis

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

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

1. (a) Define Impurity and give the classification of impurities in new drug substances. [5]
   (b) Explain the guidelines for reporting and control of elemental impurities in new drug products. [10]

2. (a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. [10]
   (b) Write a short note on the qualification of degradation products. [5]

3. (a) Explain the factors affecting the stability of drug substances and drug products. [10]
   (b) How do you perform photostability of formulations? [5]

4. (a) Write about different analytical techniques used in the characterization of degradants. [10]
   (b) What is impurity profiling and give its importance in the testing of pharmaceutical products? [5]

5. (a) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals. [10]
   (b) What are accelerated stability studies and how do you calculate the shelf life of drug products? [5]

6. Write about the following
   (a) Radio immunoassay [8]
   (b) Optical Immunoassay [7]

7. (a) Describe the principle and procedure involved in the biological assay of oxytocin. [8]
   (b) What are antitoxins? Give biological assay of Diptheria antitoxin. [7]

8. (a) Discuss the different polymerase chain reaction studies for gene expression. [8]
   (b) Explain the different steps involved in the production of antibodies. [7]

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Code: E-12438/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacy Practice) I – Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmacotherapeutics-I

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

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

1. (a) Discuss about types and etiopathogenesis of hyperlipidemias. [8]
   (b) Define and write the management of arrhythmias. [7]

2. (a) Discuss about types and etiopathogenesis of angina. [8]
   (b) Write the management of hypertension. [7]

3. (a) Discuss about types and etiopathogenesis of asthma. [8]
   (b) Write the pathogenesis and management of hyperthyroidism. [7]

4. Discuss about types, etiopathogenesis and management of diabetes mellitus. [15]

5. (a) Discuss about types and etiopathogenesis of peptic ulcer disease. [8]
   (b) Discuss about pharmacotherapy of inflammatory bowel diseases. [7]

6. (a) Discuss about etiopathogenesis and management of diarrhoea. [10]
   (b) Write short notes on liver cirrhosis. [5]

7. (a) Classify different types of anaemia and explain the pathophysiology and Management of Iron deficiency anaemia. [8]
   (b) Write short notes on drug induced skin disorders. [7]

8. (a) Discuss about etiopathogenesis of rheumatoid arthritis. [7]
   (b) Discuss about types and management of glaucoma. [8]

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Code No: E-12442/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Documentation and Regulatory Writing

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

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

1. (a) Explain the importance of EPDB for drug substance and drug products. [7]

   (b) Explain the batch formula records in detail. [8]

2. (a) Describe the contents of Site Master File. [10]

   (b) What is product development report (PDR)? Discuss the significance of PDR. [5]

3. (a) Describe the modules of ICH-CTD format with granularity. [10]

   (b) Define and compare paper CTD and electronic CTD. [5]

4. (a) Describe the aim , requirement and organization of ASEAN Common Technical Dossier (ACTD). [9]

   (b) Write a note on Electronic Submission gateways. [6]

5. (a) Discuss the internal and external Audits in detail. [8]

   (b) Explain the purpose of Global Harmonization Task Force (GHTF) study group 4 guiding document. [7]

6. (a) Write a detailed note on Pre-approval Inspections. [7.5]

   (b) Outline FDA inspection process for drug distribution channels. [7.5]

7. (a) Discuss the Post Approval Changes (SUPAC) process for an approved drug product. [10]

   (b) Write a note on Prior approval supplement. [5]

8. Write short notes on

   (a) Importance and steps involved in root cause analysis. [7.5]

   (b) CBE 30. [7.5]

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Code No: E-12445/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Quality Management Systems

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

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

1. (a) Define quality and write a note on quality policy. [8]
   (b) Write the importance of vision and mission in the quality policy. [7]

2. (a) Write in detail about perception of quality with respect to customer, how Customer complaints are handled. [8]
   (b) Write a note on cost of quality, how can we optimize costs. [7]

3. (a) Write a detailed note on principles of TQM. [8]
   (b) Write a in detail about ISO 9001: 2015. [7]

4. (a) What is OOS & OOT's? Explain in detail. [7]
   (b) Write a note on complaints and product recall. [8]

5. (a) Write in detail about IPQC and line clearance. [8]
   (b) Write a note on ICH guidelines on stability testing of pharmaceutical substances. [7]

6. (a) What is statistical process control, write in detail about statistical control charts. [8]
   (b) Write in detail about NABL accreditation and certification. [7]

7. (a) Write a note on Quality risk management. [8]
   (b) Write in detail about self-inspection. [7]

8. (a) Write a detailed note on Quality by design as per ICH. [8]
   (b) Define benchmarking, what are the reasons for bench marking. [7]

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Code No: E- 12389/PCI

FACULTY OF PHARMACY

B. Pharmacy I Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmaceutical Analysis

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

PART - A

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

1. Define volumetric analysis and list out the types of Volumetric analysis.
2. What is Pharmacopoeia? Mention different pharmacopeias
3. What is neutralization titration? Give one example.
4. List out the types of redox titrations.
5. Mention different electrodes used in potentiometry
6. What are metal indicators and mention any three metal indicators.
7. Define limit test and write its significance
8. Write the applications of polarography.
9. Define molarity and Normality
10. Differentiate Iodimetry and Iodometry.

PART - B

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

11. Write the theories of acid-base indicators.
12. Discuss the principle and steps involved in gravimetric analysis with example.
13. Write the Principle, method and applications of Counductometry.

PART - C

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

14. Write briefly about different types of errors.
15. Write a note on Buffer solutions and their applications in Pharmaceutical Analysis.
16. Write properties of primary standard and secondary standard substances and give the examples.
17. How do you prepare and standardize 1N sodium hydroxide solution?
18. Write in detail any one method of precipitation titrations.
19. Define limit test and explain the limit test for iron.
20. Discuss the principle and write the applications of diazotization titrations.
21. Write the construction and working of standard hydrogen electrode.
22. Explain the principle and applications of precipitation titrations with example.

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Code. No: E-12411/PCI

FACULTY OF PHARMACY

B. Pharmacy V Semester (PCI) (Backlog) Examination, November 2023
Subject: Industrial pharmacy I

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

PART-A

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

1. What is BCS classification of drugs? Write example of each class.
2. Enlist the methods to study particle size and shape of solids.
3. What is the use of glidant, lubricant and anti-adherent in tablet manufacturing?
4. Write the methods for pharmaceutical emulsion manufacturing.
5. Enlist the quality control tests for hard gelatin and soft gelatin capsules.
6. Give significance of pelletization.
7. Describe sterility test for eye ointments.
8. What are the different routes of administration for parenteral products?
9. Define and classify cosmetics.
10. Discuss the role of packaging in pharmaceuticals.

PART-B

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

11. (a) Explain IPQC for uncoated tablets.
    (b) Write the significance of tablet coating. Describe the process of sugar coating.
12. (a) Explain official and non-official QC tests for glass as packaging material.
    (b) Discuss evaluation tests for pellets.
13. Discuss the components of aerosol with neat and labelled diagram. Add a note on types of propellant.

PART-C

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

14. Describe the methods to study solid forms.
15. Explain racemization and polymerization of API with examples.
16. Write a note on manufacturing of pharmaceutical suspensions.
17. Discuss tablet manufacturing defects and techniques to overcome them.
18. Describe steps involved in extrusion-spheronization.
19. Explain manufacturing of SGC.
20. Discuss the method of pyrogen testing for injections.
21. Describe manufacturing and evaluation of shampoo.
22. Explain the formulation and labelling requirements for ophthalmic products.

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Code No: E-12455/PCI

FACULTY OF PHARMACY

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

Subject: Pharmaceutical. Process Chemistry

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

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

1. (a) Explain the strategy and stages of scale up process.
   (b) Explain in detail validation of Large scale Process. [7+8]

2. (a) Discuss the factors affecting Crystallization.
   (b) Explain the Theory of filtration and its limitations. [7+8]

3. (a) Write the types of oxidation reactions and liquid phase oxidation reaction.
   (b) Write the kinetics and Mechanism of aromatic nitration. [8+7]

4. (a) Explain about aerobic and anaerobic fermentation with examples.
   (b) Write a note on streamlining reaction steps and route of selection in reaction progress kinetic analysis. [7+8]

5. (a) Write a detail note on MSDS.
   (b) Write about fire hazards and types of fire and fire extinguishers. [8+7]

6. (a) Write the case study on Industrial reduction process.
   (b) Write about hazard labels of chemicals and personal protection equipment. [8+7]

7. (a) Explain about azeotropic distillation.
   (b) Write a note on kinetics and different types halogenation reactions. [8+7]

8. (a) Write about OHSAS-1800.
   (b) Write the types of impurities in API and their sources. [8+7]

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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-12463/PCI

FACULTY OF PHARMACY

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

Subject: Herbal Cosmetics

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

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

1. Describe the various classes of cosmetics. Discuss the regulatory requirements for manufacturing and sale of herbal cosmetics.

2. Write the physiology and structure of skin. List the various classes of skin cosmetics and describe the preparation of any two types of face packs.

3. What are the dentifrices and mouth washes. Describe the preparation standardization of Mouth washes.

4. Give importance of various hair preparations. Write the preparation and standardizations of two shampoos and conditioners.

5. Write about
   (a) Moisturizing creams
   (b) Herb and chemical interactions.
   (c) Scope of herbal cosmetics industry.

6. List various raw materials used in preparations of cosmetics and give their importance with examples. Give an informative note on design of herbal cosmetic formulations.

7. Discuss in detail about toxicity studies and standardization methods of herbal cosmetics.

8. Write a note on
   (a) Anti-sunburn preparations.
   (b) Import and export of herbal cosmetics.
   (c) Compatibility studies of herbal cosmetics.

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Code No: E-12459/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research & Pharmacovigilance

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

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

1. (a) Describe the schedule Y guidelines for biomedical research. [8]
   (b) Explain the ethical principles governing informed consent process. [7]
2. (a) Write the role of investigator and sponsor in clinical trials. [7]
   (b) List the differences between randomized and non-randomized CT. [8]
3. What are the guidelines followed for the preparation of investigational brochure and report forms. [15]
4. Define Pharmacovigilance. Add a note on history and PV programs in India. [15]
5. Explain in detail about Argus, Aris G Pharmacovigilance and Vigiflow. [15]
6. (a) Write a note on Pharmacoeconomics. [8]
   (b) Write the importance of safety pharmacology. [7]
7. Write about WHO international drug monitoring programme. [15]
8. Define ADR. Explain the detection and reporting methods of ADRs. [15]

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Code No: E-12467/PCI

FACULTY OF PHARMACY

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

Subject: Herbal & Cosmetic Analysis

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

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

1. (a) Discuss the standardization of herbal drugs according to WHO guidelines. [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) Write a note on Global marketing management? [7]

3. (a) Discuss adulterant screening of herbal drugs using HPLC? [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-food 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 skin creams as per BIS. [7]

6. Write notes on
   (a) Global marketing management. [6]
   (b) Determination of Acid value of cosmetic products. [4]
   (c) Analysis of dental preparations. [5]

7. Write about Indian 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: E-12470/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Pharmacokinetics and Therapeutic Drug Monitoring

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

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

1. Explain the importance of tabulations in designing dosage regimen. Add a note on compartment models.
   Discuss various methods used for conversion of intravenous dosing to oral dosing.

2. Give an account of the relationship between pharmacogenetics and PK considerations. Discuss the drug interactions related to pharmacokinetics of a drug. What is the role of a pharmacist in managing such drug interactions.

3. Discuss the analysis of population pharmacokinetic data.
   Explain the genetic polymorphism in drug targets.

4. Briefly explain the following
   (a) Modeling covariate relationships
   (b) Precision of the parameter estimates and confidence interval

5. Explain the following
   (a) Drug dosing in geriatrics.
   (b) General approach for dosage adjustment in renal failure

6. Explain the components of the protocol for therapeutic drug monitoring.
   Describe the procedure of therapeutic drug monitoring for Sodium valproate and Gentamicin.

7. Discuss the advantages and disadvantages of hemodialysis and peritoneal dialysis. What are the pharmacokinetic changes that occur in patients with obesity?

8. Discuss the effects of genetic polymorphism in Cytochrome P-450 isoenzymes on drug response. Write a short note on adaptive method of dosing.

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Code No: E-12478/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) II Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Regulatory Aspects of Medical Devices

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

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

1. (a) Define Medical Device. Describe in detail about the risk based classification of Medical Devices. [8]
   (b) Write a note on history of Medical Device Regulation. [7]

2. (a) Write Quality Principles and essential principles of Medical Devices & IVDs. [9]
   (b) Write about Quality System Regulations of Medical Devices: ISO 13485. [6]

3. (a) Write a note on Quality Risk Management of Medical Devices: ISO 14971. [8]
   (b) Write a note on clinical investigation of Medical Devices. [7]

4. (a) Write the regulatory approval process for Medical Devices (510k). [8]
   (b) Write about Investigational Device Exemption (IDE). [7]

5. (a) Write about the Labelling requirements 21 CFR Part 801. [8]
   (b) Write the Classification of Medical Devices & IVD as per US FDA & EU & ASEAN. [7]

6. (a) Write the regulatory approval process for In vitro Diagnostics (In Vitro Diagnostics Directive). [8]
   (b) Write a note on CE Certification process. [7]

7. (a) Write the Quality System requirements and clinical evaluation and investigation for Medical Devices for ASEAN. [15]

8. (a) Write a note on IMDRF Study groups. [7]
   (b) Describe the Quality System Requirements 21 CFR Part 820. [8]

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Code No: E-12474/PCI

FACULTY OF PHARMACY

M. Pharmacy II Semester (PCI) (Pharm. Quality Assurance) (Main & Backlog) Examination, November 2023

Subject: Audits & Regulatory Compliance

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

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

1. (a) Describe different types of audit and explain the responsibilities of auditor. [10]
   (b) What do you mean by management of Audit? [5]

2. (a) Explain various categories of deficiencies that may be identified during the external audit of the pharma companies? [10]
   (b) Give a brief note on "quality systems approach". [5]

3. (a) Discuss cGMP regulations related to resources and manufacturing operations. [10]
   (b) How do you address nonconformities during quality control activities? [5]

4. (a) Give an overview of auditing procedure of a vendor of API. [7]
   (b) Explain how granulation procedures are audited in tablet manufacturing. [8]

5. (a) Write a note on the quality assurance in manufacturing of Water for Injection. [8]
   (b) Write a note on the quality audit of building of a microbiological laborator. [7]

6. (a) “Conduct of internal audits is essential in pharma industry”. Justify the Statement. [7]
   (b) Give a brief note on the auditing of HVAC components. [8]

7. (a) Give a brief note on audit checklist of effluent treatment process. [7]
   (b) Explain on the audit of pharmaceutical packaging material. [8]

8. What are the checklist items in a GMP audit of a finished product manufacturing Facility? [15]

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Code No: E-12403/PCI

FACULTY OF PHARMACY

B. Pharmacy III Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmaceutical Microbiology

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

PART – A

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

1. Write Koch's Postulates.
2. Explain the contribution of Joseph Lister in the field of microbiology
3. Explain principle involved in Simple staining technique
4. Explain how ethylene oxide used for sterilization with mechanism of action.
5. Explain lysogeny in virus.
6. Define Antiseptic, Disinfectant, inhibition and Bactericide.
7. Write about clean area classification.
8. Write about media used in animal cell culture.
9. What are primary, established and transformed cell cultures?
10. What is HEPA?

PART – B

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

11. Explain different methods of evaluation of disinfectants.
12. Explain the ultra structure of Bacteria with neat labelled diagram.
13. Explain about assessment of new antibiotic.

PART – C

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

14. Write about Redial-Walker test.
15. Explain about preservation of pure cultures.
16. Explain Acid fast staining.
17. Write the applications of Animal cell culture.
18. Explain the reproduction in Bacteriophages.
19. Explain about Indole production test.
20. Explain morphology of viruses.
21. Write about Dark field microscopy.
22. Write about different sources of contamination in aseptic area.

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Code No: E-12426/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Chemistry) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Advanced Medical Chemistry

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

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

1. (a) What are leads? Discuss the concept of lead discovery.
   (b) Discuss the criteria for the identification of target and its validation in drug discovery. [8+7]

2. (a) Define prodrug and discuss the applications of prodrugs with suitable examples.
   (b) Discuss the strategies to overcome the drug resistance to antibiotics. [9+6]

3. (a) Give the classification of Antihypertensive agents with examples and write The synthesis of Captopril.
   (b) Explain how the chirality of a drug is important for its pharmacological activity of chiral drugs. [9+6]

4. (a) Give the classification of enzyme inhibitors with suitable examples.
   (b) Discuss the rational design of reversible enzyme inhibitors [10+5]

5. (a) Define and differentiate peptide drugs and peptidomimetics with examples and discuss the concept of peptidomimetic drug design.
   (b) Discuss the chemistry of prostaglandin. [8+7]

6. (a) Give the classification of antineoplastic drugs with suitable examples.
   (b) Write a note on AchE inhibitors [9+6]

7. Write a note on:
   (a) Lead optimization
   (b) Molecular modifications in analogue design. [7+8]

8. (a) Discuss about receptor theories to describe the terms Partial agonist, antagonist and Inverse agonist.
   (b) Classify antiviral agents with suitable examples and discuss the mechanisms of action of Acyclovir. [8+7]

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Code No: E-12423/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Modern Pharmaceutics

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

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

1. List out the methods used for drug- excipient interactions and discuss any three methods in detail with examples? [15]

2. (a) Discuss the ICH guidelines for calibration and validation of equipment with an example? [10]
   (b) Write about validation and it's types? [5]

3. (a) Write a note on inventory management and production control management? [10]
   (b) Describe the layout of buildings, services according to GMP? [5]

4. Discuss the methods for enhancement of aqueous solubility of drugs? [15]

5. (a) Discuss ANOVA?
   (b) Describe the comparison of dissolution profiles using f1 and f2 factors?

6. (a) Discuss about the factorial designs for optimization of formulation? [8]
   (b) Explain the terms DQ, IQ, OQ and PQ? [7]

7. (a) Explain the phases of compaction profile? [7]
   (b) Write a note on Total quality management? [8]

8. (a) Discuss about SMEDDS and their method of preparation? [8]
   (b) Write about the variance and standard deviation and their application in pharmaceutical formulations? [7]

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Code No: E-12435/PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar. Analysis) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmaceutical Validation

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

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

1. (a) Explain the terms qualification and validation. Write in detail about steps involved in qualification of analytical instruments. [10]
   (b) Explain the calibration of Electronic balances used in analytical work. [5]

2. (a) How do you qualify UV spectrophotometers? Explain. [10]
   (b) Write about FAT and SAT. [5]

3. Write short notes on
   (a) HAVC system validation [8]
   (b) Pharmaceutical water system validation [7]

4. Describe method validation parameters as per ICH guidelines for validation of new analytical procedures. [15]
5. (a) What is an intellectual property right? Explain about different types of IPR. [8]
   (b) Explain the criteria of the patentability of an invention and the steps in the patent application. [7]

6. (a) Explain the procedure involved in the qualification and calibration of HPLC. [10]
   (b) Write about the cleaning of facilities. [5]

7. (a) Explain the steps involved in the preparation of the validation Master Plan (VMP). [10]
   (b) Write a short note on the Digital significance of 21 CFR part II. [5]

8. (a) Write about the international patenting requirement procedure. [8]
   (b) Write about PCT and WIPO. [7]

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Code No: E-12446/PI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Quality Control and Quality Assurance

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

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

1. Differentiate Quality Control and Quality Assurance. Describe the concept and evolution of Quality Control and Quality Assurance. [15]

2. Define Good Laboratory Practice and write the protocol for conduct of non-clinical testing. [15]

3. Explain the various CPCSEA guidelines for laboratory animal facility. [15]

4. Write a short note on
   (a) Standard Operating Procedure [8]
   (b) Batch Manufacturing Record [7]

5. Write in detail about in-process quality control (IPQC) tests for
   (a) Capsules [7]
   (b) Parenterals [8]

6. (a) Describe the overview of ICH guidelines with Q series [8]
   (b) Write a short note on Calculation of yields. [7]

7. (a) Write a short note on good documentation practice guidelines. [8]
   (b) What are the different types of audits? Explain in detail audit methods and techniques involved in it. [7]

8. Write a short note on
   (a) Change Control [8]
   (b) Copyright and trade mark. [7]

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Code No: E-12432/PCI

FACULTY OF PHARMACY
M. Pharmacy (Pharmacognosy) I – Semester (PCI) (Backlog) Examination, November 2023
Subject: Phytochemistry

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

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

1. a) Discuss the importance of drug discovery process and methods of drug discovery techniques. [7+8]
   b) Write the role of plants in drug discovery process using suitable examples.

2. Write the chemistry, isolation and biosynthesis of Sennosides and Digitoxin [15]

3. Describe the biological source, chemistry and isolation of [5+5+5]
   a) Ephedrine b) Piperine c) Quercitin

4. Discuss the principle and applications of LC/MS and GC/MS in elucidation of phytoconstituents. [15]

5. Elucidate the structure of following compounds using spectroscopic techniques
   a) Carvone b) Citral c) Menthol [5+5+5]

4. Define and classify the extractions techniques. Write the principle, merits and Demerits any four extraction techniques. [15]

7. Define and classify the chromatography techniques. Give the principle, Instrumentation and applications of HPLC. [15]

8. a) Write about protocol design of lead molecule [8+7]
   b) Flash chromatography

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Code No: E-12429/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmacological and Toxicological Screening Methods - I

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

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

1. a) Describe in detail about regulations for laboratory animal care as per CPCSEA guidelines. [10]
   b) Discuss the principle and applications of bioassay [5]

2. List out and explain in detail any two screening methods of following classes of drugs:
   a) Anxiolytics [7]
   b) Drugs for Alzheimer's disease [8]

3. Describe the screening methods used to evaluate a compound for
   a) Anti-inflammatory activity [8]
   b) Anti-asthmatic activity [7]

4. Define diabetes. List out the methods available to induce diabetes experimentally and describe streptozotocin induced method. [15]

5. Define immunoassay. Outline principles of immunoassay and describe different types of immunoassay. [15]

6. Write short notes on:
   a) Alternate animal experiments [7]
   b) Immunoassay of digoxin [8]

7. Define Parkinsonism. Enlist the models available to screen drugs for Parkinsonism and describe any two methods. [15]

8. Describe the preclinical screening procedures for the following:
   a) Hepatoprotective agents [9]
   b) Antifertility agents [6]

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Code No: E-12439/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacy Practice) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Hospital & Community Pharmacy

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

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

1. (a) What are the infrastructural requirements for hospital pharmacy? [8]
   (b) Write the composition and responsibilities of infection control committee. [7]

2. (a) Write different types of hospital budgeting procedures and mention their advantages and limitations. [7]
   (b) Explain the purchase and Inventory control management in hospital pharmacy. [8]

3. (a) Write about training and continual education programs for pharmacists. [8]
   (b) Describe the organization of a hospital and the role of hospital pharmacist. [7]

4. (a) Write about NABH guidelines for the management of medicines. [8]
   (b) Describe the community pharmacy financial and staff management. [7]

5. (a) Define OTC Medications. Describe in detail counselling of any three category of OTC medications [8]
   (b) Discuss about different software's and databases used in community pharmacies? [7]

6. (a) Describe the role of community pharmacist in control of malaria. [8]
   (b) What is the role of pharmacist in promoting rational use of drugs in the community? [7]

7. (a) What are the legal requirements of a prescribed medication order? [8]
   (b) How Health promotion activities are carried out by a community pharmacist for pregnant and breast feeding women? [7]

8. (a) Discuss the objectives and methods of home medicines review program. [7]
   (b) Describe the rational use of analgesics and anti-diarrheal preparations. [8]

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Code No: E-12443/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Clinical Research Regulations

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

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

1. (a) Write a note on Phase I and Phase III clinical trials. [6]
   (b) Write a note on Clinical Trial protocol. [9]

2. (a) Describe the Historical perspectives that resulted in ethics to be followed in clinical research. [10]
   (b) Describe the Informed consent process. [5]

3. (a) Write a note on clinical research regulations in Europe Union (EMA) [9]
   (b) Describe guidelines for Medical Devices in India. [6]

4. (a) Explain the ICH E6 guidelines with regard to Good Clinical Practice. [9]
   (b) Describe ICMR ethical guidelines for biomedical research. [6]

5. (a) Write a note on CFR 21 Part 50 with regard to protection of human subjects. [9]
   (b) Explain ISO 14155. [6]

6. Discuss about
   (a) ANDA 505(j) of the FD&C Act. [5]
   (b) Responsibilities of sponsor, CRO and investigator in ethical conduct of clinical research. [10]

7. Write a note on
   (a) Europe union Eudralex volume 3 guidelines. [10]
   (b) ICH E9 with regard to general biostatics principle applied in clinical research. [5]

8. Write a note on
   (a) Randomized clinical trials. [8]
   (b) Instituitonal review board. [7]

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Code No: E-12390/PCI

FACULTY OF PHARMACY

B. Pharmacy I – Semester (PCI) (Backlog) Examination, November 2023
Subject: Pharmaceutics

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

PART - A

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

1. Define creams and pastes.
2. Explain the preparation of any one effervescent powder.
3. What are gelling agents, give two examples?
4. What is displacement value? Write its importance.
5. Define chemical incompatibility. Give two examples.
6. Differentiate gargles and mouthwashes.
7. Find the strength of 75% v/v alcohol in terms of Proof spirit.
8. Define and classify powders with examples.
9. Write the formula for cold cream.
10. Define syrups and elixirs.

PART - B

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

11. Explain the methods of preparation of ointments.
12. Define and classify incompatibility. Explain physical incompatibility and methods to overcome physical incompatibility with examples.
13. What are Suppositories? Write a note on different bases used in preparation of Suppositories?

PART - C

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

14. Define prescription. Explain various parts of prescription.
15. Explain therapeutic incompatibility.
16. Discuss about formulation of liquid dosage forms with examples.
17. Explain in brief about any six factors affecting posology.
18. What are the salient features of Indian Pharmacopoeia?
19. Explain the preparation of vanishing cream.
20. Explain the tests for identification of type of emulsions.
21. Prepare 900ml of 60% v/v alcohol from 90% v/v alcohol and 30% v/v alcohol.
22. Explain various methods to adjust isotonicity.

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Code No: E-12412/PCI

FACULTY OF PHARMACY

B. Pharmacy V-Semester (PCI) (Backlog) Examination, November 2023
Subject: Pharmacology – II

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

PART-A

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

1. What is arrhythmia? Mention two drugs used in its treatment.
2. Discuss the mechanism of antianginal effect of Glyceryl trinitrate.
3. What are fibrinolytics? Mention two examples.
4. Classify antidiuretics.
5. Describe the triple response of histamine.
6. What are the different uses of antihistaminics.
7. What are the adverse effects of Corticosteroids?
8. What are the therapeutic uses of T_3 & T_4?
9. Mention the uses of oral contraceptives.
10. Define bioassay. List out the types of bioassays.

PART-B

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

11. Explain the various methods of bioassay of oxytocin and d-tubocurarine.
12. (a) Classify the non-steroidal anti-inflammatory agents with examples.
    (b) Explain the mechanism of action, uses and adverse effects of salicylates.
13. (a) What is congestive heart failure? Classify the drugs used for its treatment.
    (b) Explain the mechanism of action, adverse drug reactions and uses of digoxin.

PART-C

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

14. Write short notes on oral anticoagulants.
15. Write the pharmacological actions and uses of prostaglandins.
16. Explain the pharmacology of Sodium nitroprusside.
17. Write the mechanism of action, adverse drug reactions and therapeutic uses of ACE inhibitors.
18. Explain the pharmacology and uses of vasopressin.
19. Write the pharmacology of allopurinol.
20. Write the mechanism of action, adverse drug reactions and uses of metformin.
21. What are the methods of bioassay of insulin? Discuss any one method in detail.
22. Write a brief note on oral contraceptives.

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Code No: E-12452/PCI

FACULTY OF PHARMACY

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

Subject: Advanced Spectral Analysis

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

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

1. (a) How do you interpret the presence of different functional groups in IR spectra. Indicate the wave number regions for different functional groups.
   (b) Explain woodward fieser rules with examples.

2. Discuss NOESY, COSY and inadequate techniques.

3. (a) Discuss the fragmentation patterns of important functional groups in mass spectroscopy.
   (b) Explain Mc Lafferty rearrangement with examples.

4. Discuss the principle, instrumentation and and applications of
   (a) GCMS
   (b) Flash chromatography

5. Discuss the principle, instrumentation and and applications of
   (a) HPTLC
   (b) LC-NMR

6. Give brief account on the principle and applications of
   (a) DSC
   (b) Raman spectroscopy

7. Write a note on
   (a) Bioassays
   (b) RIA of Digitalis

8. Give a brief note on
   (a) TGA
   (b) CE-MS

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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-12460/PCI

FACULTY OF PHARMACY

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

Subject: Medicinal Plant Biotechnology

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

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

1. (a) Discuss genetic and molecular biology as applied to Pharmacognosy. [8]
   (b) Write informative notes on genetic code and gene expression. [7]

2. (a) What is tissue culture? Explain embryogenesis and its applications. [8]
   (b) Explain sterilization methods used in tissue culture. [7]

3. Explain immobilization technique of plant cell in detail. Give its advantages, disadvantages and applications. [15]

4. What is biotransformation? Discuss about bioreactors for large scale production of secondary metabolites using suitable examples. [15]

5. (a) Explain production of ergot alkaloids in detail. [10]
   (b) Give informative notes on enzymes of Pharmaceutical interest. [5]

6. Write short notes on
   (a) Applications of plant biotechnology. [5]
   (b) Protoplast fusion technique. [5]
   (c) Precursors for production of secondary metabolites. [5]

7. (a) Write notes on Transgenic plants. [7]
   (b) Give informative notes on PCR in plant genome analysis. [8]

8. Write notes on
   (a) DNA recombinant technology. [5]
   (b) Hairy root culture [5]
   (c) Single cell protein. [5]

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Code No: E-12456/PCI

FACULTY OF PHARMACY

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

Subject: Advanced Pharmacology - II

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

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

1. (a) How are thyroid hormones synthesized and classify antithyroid drugs?
   (b) Write short notes on sex hormones [10+5]

2. (a) Explain the mechanism of resistance of antimicrobial agents.
   (b) Classify antiviral drugs. Discuss the pharmacology of Nucleoside reverse transcriptase inhibitors. [7+8]

3. (a) Discuss about insulin preparations.
   (b) Write the pharmacology of glucocorticoids. [5+10]

4. (a) What are β -lactam antibiotics? Explain the mechanism of action, therapeutic Uses and adverse effects. [8+7]
   (b) Classify antifungal drugs. Discuss the pharmacology of amphotericin B.

5. (a) Discuss about cellular and biochemical mediators involved in allergy and inflammation.
   (b) Write in brief about NSAID's. [10+5]

6. (a) Write short notes on immunosuppressants. [7+8]
   (b) Classify antiulcer drugs and explain about H2 receptor antagonists.

7. (a) What is chronotherapy? Discuss about the chronotherapy of diabetes.
   (b) Discuss about the treatment for diarrhoea. [8+7]

8. (a) Explain in detail about the generation of free radicals. [8+7]
   (b) Discuss about the protective activity of certain important antioxidants.

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Code No: E-12464/PCI

FACULTY OF PHARMACY

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

Subject: Advanced Instrumental Analysis

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

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

1. (a) Explain about various parameters in HPLC.
   (i) Peak shape (ii) Capacity factor
   (iii) Plate number and plate height (iv) Resolution.

   (b) Write about Preparative HPLC.

2. (a) Discuss about Size-Exclusion Chromatography and Affinity chromatography?
   (b) Explain about head space sampling in Gas chromatography

3. (a) Write the instrumentation and applications of SFC.
   (b) Explain about Crown ethers and buffer additives in capillary electrophoresis?

4. Explain about Electron impact, CI, FAB, ESI Ionization techniques in mass spectrometry?

5. (a) What do you mean by chemical shift? Explain the various factors influencing it?
   (b) Write about 2DNMR?

6. (a) Write about Chiral Chromatography?
   (b) Discuss the derivatization methods of Gas chromatography?

7. (a) Explain about columns and column problems in HPLC?
   (b) Discuss about NOESY.

8. (a) Explain about LC-MS analysis?
   (b) Write about (i) coupling constant (ii) LC-NMR?

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Code No: E-12471/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacoepidemiology & Pharmacoeconomics

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

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

1. (a) Write the scope and applications of pharmacoepidemiology. [6]
   (b) Describe in detail about drug use measures. [9]

2. (a) Write the importance of case reports and case series. [7]
   (b) Write a note on cross sectional study and case control study. [8]

3. (a) Explain the significance of pharmacoeconomic studies in health care system. [7]
   (b) Write a note on cross sectional study and case control study. [8]

4. (a) Describe the advantages of cost minimization analysis. [5]
   (b) Write the significance of cost benefit analysis and cost effective analysis. [10]

5. (a) Write the applications of pharmacoeconomics. [7]
   (b) Write a note on sensitivity analysis and markov modeling. [8]

6. (a) Explain the software used in pharmacoeconomic analysis. [8]
   (b) Write the concept health related quality of life. [7]

7. (a) Describe the concept of incidence and prevalence. [8]
   (b) Write a note on medications adherence measurements. [7]

8. (a) Explain about the meta analysis. [8]
   (b) Write a note on history of pharmacoeconomics. [7]

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Code No: E-12479/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Food & Nutraceuticals

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

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

1. (a) What are Functional and Medical Foods? Write a detailed note on the importance, scope and role of Functional and Medical Foods. [9]
   (b) Write about the Scope and Opportunities in Nutraceutical Market. [6]

2. (a) Discuss about the NSF Standards for Food and Dietary Supplements. [8]
   (b) Write briefly about GMP for nutraceuticals. . [7]

3. (a) Describe the organization and functions of food safety and standards authority of India. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in India. [7]

4. Summarize the USFDA Food Safety and Modernization Act regulations with respect to dietary supplements and ingredients. [15]

5. (a) Discuss European Regulation on Novel Foods and Novel Food Ingredients. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in Europe. [7]

6. Give an overview of the WHO guidelines on daily iron and folic acid supplementation in pregnant women. [15]

7. Explain the salient features of Food Safety and Standard Act 2006. [15]

8. Write short notes on
   (a) Recommended Dietary Allowances (RDA) in USA [7.5]
   (b) History of Food and Nutraceutical Regulations [7.5]

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Code No: E-12475/PCI

FACULTY OF PHARMACY

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

Subject: Pharmaceutical Manufacturing Technology

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

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

1. Describe the factors influencing plant layout and special provisions of plant layout.
2. Discuss about area planning & environmental control, wall and floor treatment, utilities in advanced sterile product manufacturing.
3. Discuss about in process quality control tests of ointments and suspensions.
4. Discuss about in process Quality control tests for Tablets.
5. Describe process automation in small volume parenteral and large volume parenteral.
6. Describe about quality control tests for packaging materials and filling equipment.
7. Elaborate Process analytical technology.
8. Discuss about different types of closures and closure liners.

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Code No: E-12404/PCI

FACULTY OF PHARMACY

B. Pharmacy III Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmaceutical Engineering

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

PART-A

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

1. What is Reynolds number? Expand terms applicable to it.
2. Mention the official standards of sieves.
3. List the critical parameters in working of ball mill
4. Define black body and gray body.
5. Write the mechanisms of heat transfer.
6. Differentiate between distillation and evaporation.
7. What is equilibrium moisture content and mentions its significance.
8. Draw the diagram of ribbon blender.
9. What is filter aid and filter media?
10. Write merits and demerits of inorganic materials for plant construction.

PART-B

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

11. Describe the size separation principles, construction, working, merits and demerits of sieve shaker.

12. Write the construction, working principle, merits and demerits plate and frame filter press with washing facility.

13. Write the theories of corrosion and explain the methods to prevent corrosion.

PART-C

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

14. Explain the factors influencing the size reduction.
15. Write construction and working of pilot tube.
16. Describe fourier's law and stefan boltzmann law for heat transfer along with their significance.
17. What is Mean free path and mention its significance in construction and working of molecular distillation unit.
18. Write the characteristics and working of propellers, turbines and paddles
19. Explain the multiple effect evaporator and its economy.
20. Explain the equipment parts and their functioning in a fluid bed dryer.
21. Describe super centrifuge with the help of a diagram and mention its applications.
22. Write basic equipment applicable to material handling systems.

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Code No: E-12440/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacy practice) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Clinical Research

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

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

1. (a) Explain drug development process in detail. [9]
   (b) Write a note on principles of ethic in bio medical research. [6]

2. (a) Explain different randomization techniques. [6]
   (b) Explain the types of research designs based on controlling methods and time Sequences. [9]

3. Write a note on preparation of guidelines for
   (a) Protocol [5]
   (b) Contracts and agreements [5]
   (c) Informed Consent Form [5]

4. (a) Write a note on procurement and storage of investigational product. [7]
   (b) Write in detail about filing procedures [8]

5. (a) Explain in detail clinical trial data management in detail. [7]
   (b) Explain about quality assurance and quality control in clinical trials. [8]

6. (a) Write in detail on sampling methods and health outcome measures with examples. [10]
   (b) Write a note on challenges in implementation of ethical guidelines. [5]

7. What are the roles and responsibilities of
   (a) Contract research organization. [5]
   (b) Study Coordinator. [5]
   (c) Monitor. [5]

8. (a) Write a note on planning and execution of Clinical trials. [5]
   (b) Write about bio equivalence and bio availability studies. [5]
   (c) Discuss various phases of clinical trials. [5]

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Code No: E-12447/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Product Development and Technology Transfer

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

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

1. (a) What is ANDA, what information must be provided for filing ANDA. [5]
   (b) Write a note on drug development process. [10]

2. (a) Write in detail about physico-chemical properties, solubility enhancement techniques considered during product development. [8]
   (b) Write a note on CDSCO product registration guidelines. [7]

3. (a) What are the major technical aspects to be considered during pilot plant scaleup for semi solid dosage forms. [10]
   (b) Write a note on benefits and difficulties in pilot plant scaleup. [5]

4. (a) Write a note on aseptic and medical device packing. [7]
   (b) Write in detail about Quality control tests for containers, closures, and secondary Packing materials. [8]

5. (a) Write a detailed note on development and technology transfer from R & D to Production. [8]
   (b) Write a note on documentation of technology transfer. [7]

6. (a) Write in detail about the techniques for study of crystal properties. [8]
   (b) Write in detail about stability testing during product development. [7]

7. (a) Write a note on requirements of enteral packing and aseptic packing. [8]
   (b) Write a detailed note on guidelines for post marketing surveillance. [7]

8. (a) Write a note on qualitative and quantitative technology transfer models. [8]
   (b) Write a note on SUPAC. [7]

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Code No: E-12433/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacognosy) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Industrial Pharmacognostical Technology

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

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

1. Describe the location; layout, infrastructure and regulatory requirements for establishing herbal drug industry. [15]

2. Discuss about Exim and Trips policy with reference to herbal drugs. [15]

3. Write in detail about good laboratory practice in Herbal Industry. [15]

4. Write a note on [5+5+5]
   (a) Ayurvedic Pharmacopoeia
   (b) British Herbal Pharmacopoeia
   (c) Siddha Pharmacopoeia.

5. Define the term evaluation of crude drugs. Describe in detail about WHO guidelines in standardization of Herbal drugs. [15]

6. Describe the monographs of following drugs. [5+5+5]
   (a) Withania (b) Digitalis (c) Artemisia

7. Write the importance of stability studies. Describe the various methods of stability testing. [15]

8. Write about [5+5+5]
   (a) Geographical indication
   (b) Copy rights
   (c) Patent filling.

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Code No: E-12427/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Chemistry) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Chemistry of Natural Products

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

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

1. Write how the natural products acts as a leads in the following classes of drugs
   (a) Antimalarial drugs
   (b) Beta lactam antibiotics.

2. (a) Write the general methods for the structural elucidation of flavanoids.
   (b) Write the structural elucidation of quercetin.

3. (a) Write a note on Sapogenins and cardiac glycosides.
   (b) Discuss chemistry of contraceptive agents.

4. (a) Give classification, isoprene and special isoprene rules of Terpenoids.
   (b) Discuss in brief the structural elucidation of Citral and Retinol.

5. (a) Write a note on chemistry and physiological significance of following vitamins
   (i) Vitamin E (ii) Niacin (iii) Vitamin C
   (b) Write in detail about Hybridoma technology.

6. Discuss the active constituents & their uses in the following crude drugs.
   (i) Curcuma longa (ii) Pterocarpus marsupium (iii) Gymnema sylvestre
   (iv) Phyllanthus niruri (v) Swertia chirata

7. Write the structural characterization of functional groups in the following compounds using IR, ^{1}H NMR, ^{13}C NMR and Mass spectral data (Write approximate values)
   (i) Quercetin (ii) Vitamin D (iii) Digoxin (iv) Camphor (v) Pencillin G

8. (a) Explain the principles of RNA & DNA estimation and its applications.
   (b) Write a note on Adrenocorticoids.

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Code No: E-12424/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Regulatory Affairs

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

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

1. a) Explain Hatch-Waxmann Act and its Amendments. [9]
   b) Write a note on Master formula record. [6]

2. a) Explain the regulatory requirements for approval of API. [8]
   b) What is the impact of outsourcing Bioavailability and Bioequivalence studies to Contract Research Organisations (CRO) [7]

3. a) Explain ANDA approval process. [8]
   b) Explain the regulatory requirements for approval of NDA for novel therapies. [7]

4. a) Write a note on chemistry, manufacture and control in pharmaceutical industry. [9]
   b) Write a note on Regulations for Medical devices. [6]

5. a) Explain the regulatory requirements of Europe Union. [9]
   b) Write a note on Investigation medicinal products dossier. [6]

6. a) Write a note on global submission of NDA. [8]
   b) Write a note on Investigator Brochure. [7]

7. Discuss about (a) Health Insurance Portability and Accountability Act. [9]
   b) Institutional Review Board. [6]

8. a) Write a note on Pharmacovigilance and safety monitoring in clinical trials. [9]
   b) Write a note on CTD format. [6]

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Code No: E-12430/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Cellular and Molecular Pharmacology

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

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

1. (a) Discuss about tissue necrosis and autophagy.
   (b) Explain how cell cycle will be regulated.

2. (a) Write a descriptive note on G protein coupled receptors.
   (b) Write a brief note on Cyclic AMP signaling pathway.

3. (a) Write a note on JAK and STAT signaling pathway.
   (b) Enlist various gene transfer techniques with its applications.

4. (a) Write a note on principle and applications of genomic tools.
   (b) Explain in detail principle and applications of recombinant DNA technology.

5. (a) Discuss the principle and applications of PCR and DNA electrophoresis.
   (b) Give the applications of metabolomics and nutrigenomics.

6. Write a descriptive note on immunotherapeutic with its significance in clinical practice.

7. (a) Write a note on glucose uptake and calcium influx assay.
   (b) Write a note on various types of cell culture techniques.

8. (a) Explain principle and applications of flow cytometry.
   (b) Write a note on biosimiliars and cryopreservation.

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Code No: E-12436/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Food Analysis

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

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

1. a) Define and classify Proteins [5]
   b) Explain various methods for determination of proteins. [10]

2. a) Explain various methods for determination of oil and fats. [7]
   b) Define vitamins explain any two methods for determination of Vitamin A [8]

3. Write about the following
   a) Analysis of preservatives [5]
   b) Flavor and flavor enhancers [5]
   c) Analysis of stabilizers [5]

4. a) Explain the Gerber method for determination of fat in milk [7]
   b) Define milk. Enlist and write identification tests for the different adulterants in milk. [8]

5. a) Explain BIS and AGMARK [8]
   b) Define Pesticides and how do you analyse organochloro pesticides. [7]

6. Define carbohydrates? Explain various methods for determination of carbohydrates. [15]

7. a) Explain the determination of Ethyl alcohol content in Beer. [8]
   b) Determination of salt content in butter by Volhard's method. [7]

8. a) Explain the changes in food carbohydrates during digestion, absorption and metabolism [10]
   b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C. [5]

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Code No: E-12444/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Regulations and Legislation for Drugs and Cosmetics, Medical Devices, Biologicals and Herbal and Food and Nutraceuticals in India and Intellectual Property Rights

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

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

1. a) What are Medical Devices? Describe the regulations and guidelines for approval of Medical devices.
   b) Describe the content and format for preparation of clinical trial dossier. [9+6]

2. Describe the objective of DPCO and NPPA. Explain the methods of price fixation of bulk drugs, formulations and new drugs. [15]

3. a) Define the terms Advertisement, Magic remedies, Nutraceuticals, Cosmetics and formulations.
   b) Describe the organization, functions and responsibilities of state pharmacy council. [7+8]

4. a) What is patent? Write about the objectives, rights of patentee.
   b) Define Intellectual Property Rights. Narrate the types of IPRs. [6+9]

5. What are the objectives of?
   a) Pharmacy act; b) Narcotic drugs and Psychotropic substances act;
   c) CPCSEA; d) CDSCO e) Medicinal and Toilet preparation act. [15]

6. a) Explain the constitution and functions of Pharmacy council of India. [7+8]
   b) Give an informative note on Copyrights.

7. a) Differentiate between bonded and non bonded laboratory. Describe the construction of bonded laboratory. [8+7]
   b) Give an informative note on CPCSEA guidelines on animal experimentation.

8 a) Describe the regulatory requirement for conducting BA and BE studies [8+7]
   b) Write an informative note on ICH guidelines for stability studies.

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Code No: E- 12391/PCI

FACULTY OF PHARMACY

B. Pharmacy I Semester (PCI) (Backlog) Examination, November 2023

Subject: Pharmaceutical Inorganic Chemistry

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

PART – A

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

1. Write about oral rehydration salts.
2. Give the physiological role of calcium.
3. What are dentifrices? Give some examples.
4. Write are antidotes. Mention the antidotes used in cyanide poisoning.
5. Write the composition of ringer's injection.
6. Define antacids and give with examples.
7. Write the category and importance of ferrous gluconate.
8. Define impurity and give three examples.
9. Give the difference between Antiseptic and Disinfectant.
10. What is radioactivity and its significances?

PART – B

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

11. Define isotonic solution. Explain the methods of adjusting tonicity.

12. (a) Write the significances of Antacids. Give the method of preparation, assay and uses of Sodium bicarbonate.
    (b) Give the method of preparation, assay and uses of Hydrogen peroxide.

13. Explain principle and procedure involved in the limit test for Iron and Chlorides.

PART – C

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

14. Write preparation, properties and uses of Potassium iodide and sodium nitrite.
15. Define Astringent. Write the method of preparation and uses of Zinc sulphate.
16. Explain the principle and procedure involved in the limit test for Lead.
17. Add a note on Emetics.
18. Discuss the Pharmaceutical applications of Radioactive substance.
19. Write a note on Physiological acid –base balance.
20. Write the preparation, assay and uses of Sodium thiosulphate.
21. What are Antimicrobial and give four examples. Explain mechanism of action.
22. List out the various classes of Cathartic agents with examples.

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Code No: E-12405/PCI

FACULTY OF PHARMACY

B.Pharmacy IV Semester (PCI) (Main & Backlog) Examination, October 2023

Subject: Pharmaceutical Organic Chemistry - III

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

PART – A

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

1. What are diastereomers? Give an example.
2. Discuss elements of symmetry with examples.
3. Define optical activity and meso compound.
4. Discuss any two synthetic methods of pyrrole.
5. Write any two reactions of Oxazole.
6. Explain why pyridine is more basic than pyrrole?
7. Give any two medicinally important compounds and uses of pyrimidine and isoquinoline.
8. Mention any two applications of Birch reduction.
9. Write any two reactions of thiophene.
10. Explain geometrical isomerism with examples.

PART – B

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

11. (a) Explain the sequence rules for R and S system of nomenclature of optical isomers.
    (b) Give a brief account on Asymmetric synthesis.

12. Write any two synthetic methods, three reactions and medicinal uses of
    (a) Furan (b) thiazole.

13. Describe the mechanism and applications of following reactions
    (a) Beckmann rearrangement (b) Claisen-schimdt condensation.

PART – C

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

14. Define racemic mixture. Explain the various methods of resolution of racemic mixture.
15. Write about different conformations of cyclohexane.
16. Mention the applications of Lithium Aluminium Hydride.
17. Describe the mechanism of clemmenson reduction and mention its applications?
18. Explain fischer indole synthesis.
19. Discuss the mechanism and applications of Sodium borohydride.
20. Explain Skraups synthesis of Quinoline.
21. Explain stereospecific or stereoselective reactions with examples
22. Give the structures and specific uses of drugs containing (i) pyridine (ii) purine.

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Code No: E-12395/PCI

FACULTY OF PHARMACY

B. Pharmacy II Semester (PCI) (Main & Backlog) Examination, October 2023

Subject: Human Anatomy and Physiology-II

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

PART – A

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

1. Enlist the function of Urinary system.
2. Draw the neat labelled diagram of neuron.
3. What is the role of pancreas and liver in GIT?
4. What does parturition mean?
5. List the disorders of GIT.
6. What are the functions of urinary system?
7. What is artificial respiration?
8. Write a note on sex hormones.
9. Write two functions of BMR.
10. Write the function of pineal gland.

PART – B

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

11. Write in detail about Anatomy of GI Tract. Add a note on phases involved in digestion.
12. Write in detail about the hormones released by anterior pituitary gland. Add a note on reflex activity.
13. Write a note on genetic pattern of inheritance.

PART – C

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

14. Write a note on generation of action potential.
15. Define neurotransmitter. Add a note on biogenic amines.
16. What are the various regulation centres of respiration?
17. Write a note on Formation and role of creatinine Phosphate.
18. Write a note on spermatogenesis.
19. Write a note on actions and production of thyroid hormones.
20. Briefly discuss about Anatomy of male and female reproductive system.
21. Define vital capacity and write about various volumes and capacities.
22. Write the steps involved in micturition process.

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