Code No: G-13038/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods – II

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

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

1. What is reproductive toxicity? Discuss the study design and importance of male and female reproductive toxicity studies. (15)

2. (a) Describe in detail the determination of LD_{50} in acute toxicity testing of drugs as per OECD. (10)
   (b) Define and classify toxicology. (5)

3. Define IND. Explain in detail the studies needed for IND submission. (15)

4. Write short notes on:
   (a) Dermal irritation studies (8)
   (b) Skin sensitization studies (7)

5. Elucidate in detail the alternatives to animal toxicity testing. (15)

6. (a) Explain in detail about schedule Y. (8)
   (b) Write a note on dermal toxicity testing. (7)

7. Define genotoxicity. Discuss in detail the *in vitro* and *in vivo* genotoxicity studies. (15)

8. (a) Explain the applications of toxicokinetics. (7)
   (b) Discuss the importance and principles of safety pharmacology studies. (8)

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Code No: G-13040/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research & Pharmacovigilance

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

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

1. (a) Discuss in detail about the ICH-GCP guidelines. (8)
   (b) Discuss the composition and responsibilities of IRB. (7)

2. Explain in detail about Randomised Controlled Trail (RCT) and Non Randomised Controlled Trail (Non RCT). (15)

3. Explain the methods of Safety Monitoring in clinical trials. (15)

4. (a) Define Pharmacovigilance. Add a note on its history and progress in India. (8)
   (b) What are the roles and responsibilities of Industry & National Programmes in Pharmacovigilance. (7)

5. (a) Define ADR. Classify ADR and write detection and reporting method. (8)
   (b) What are the guidelines followed for the preparation of investigational brochure? (7)

6. (a) Discuss about Pharmacoepidemiology and Safety Pharmacology. (8)
   (b) Add a note on Pharmacoeconomics. (7)

7. Describe the Schedule Y guidelines for biomedical research. (15)

8. What are the various statistical methods for evaluating medication safety data? (15)

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Code No: G-13037/PCI

FACULTY OF PHARMACY

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

Subject: Advanced. Pharmacology- II

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

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

1. (a) Explain the signalling pathway of insulin.
   (b) What is the replacement therapy of corticosteroid?
2. (a) Explain the mechanism of action and resistance of Ciprofloxacin.
   (b) Discuss about the Bedaquiline and Delamanid.
3. (a) Explain the mechanism of action and resistance of Streptomycin.
   (b) Explain in detail about Ibrexafungerp.
4. (a) Explain the uses and adverse effects of Mebendazole and Diethylcarbamazine.
   (b) What are the toxicities of drugs used in cancer chemotherapy?
5. (a) Explain in detail about Mammalian target of Rapamycin (mTOR).
   (b) How can you manage COPD?
6. (a) Discuss about the H_2 receptor antagonists.
   (b) How do prokinetic drugs stimulate gastrointestinal motility?
7. (a) How do 5-HT_3 receptor antagonist help with diarrhoea-dominant abdominal pain associated with IBS?
   (b) What is constipation? Write a note on osmotic purgatives.
8. (a) What are antioxidants? Briefly explain enzymatic antioxidants.
   (b) Discuss about recent advances in treatment of cancer.

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Code No: G-13039/PCI

FACULTY OF PHARMACY

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

Subject: Principles of Drug Discovery

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

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

1. (a) Write a note on importance of targets in drug discovery. (7)
   (b) Describe in detail about role of genomics in target discovery. (8)

2. (a) Write the importance of cell based assay in drug discovery process. (8)
   (b) Write the applications of NMR in protein structure prediction. (7)

3. (a) Write a note on concept of traditional drug design. (10)
   (b) Write a note on Pharmacophore de-novo drug design. (5)

4. (a) Describe brief about manual docking and flexible docking. (10)
   (b) Write a note on hammet constant. (5)

5. (a) Explain the concept of drug likeness screening. (8)
   (b) Write a note on advantages of prodrug design. (7)

6. (a) Explain in brief about significance of zinc finger proteins in drug discovery. (8)
   (b) Write the types resins used in solid phase synthesis. (7)

7. (a) Describe the application of X-Ray crystallography in protein structure prediction. (8)
   (b) Write a note on applications of transgenic animals in drug discovery. (7)

8. (a) Explain about the scintillation proximity assay. (7)
   (b) Write a note on statistical methods for QSAR. (8)

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Code Number: F-7217/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II Semester (PCI) (Backlog) Examinations, May 2024

Subject: Principles of Drug Discovery

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

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

1. (a) Write a note on importance and process of lead identification in drug discovery. [8+7]
   (b) Describe in detail about role of Nucleic acid microarray in target discovery.

2. (a) Write the importance of antisense technology in drug discovery process. [8+7]
   (b) Write the applications of X-ray crystallography in protein structure prediction.

3. (a) What is the difference between traditional drug design and rational drug design. [8+7]
   (b) Write a note on threading model of protein structure prediction.

4. (a) Describe briefly about High throughput screening. [8+7]
   (b) Write a note on hammet constant in QSAR.

5. (a) Explain the concept of pharmacophore-based drug designing. [8+7]
   (b) Write a note on concept of prodrug design in drug designing.

6. (a) Explain in brief about flexible docking in drug discovery. [8+7]
   (b) Write a descriptive note on De novo technique.

7. (a) Write a note on Free Wilson analysis in QSAR. [8+7]
   (b) Write a note on applications of transgenic animals in drug discovery.

8. (a) Explain about structure based rational drug design. [8+7]
   (b) Write a note on COMFA as 3D-QSAR approach.

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Code No: F-7216/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods - II

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

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

1. (a) Describe in detail the determination of LD_{50} in acute toxicity testing of drugs as per OECD. [10]
   (b) Define and classify toxicology. [5]

2. Write short notes on:
   (a) Skin sensitization studies [7]
   (b) Acute eye irritation studies [8]

3. What is reproductive toxicity? Discuss the study design and importance of male and female reproductive toxicity studies. [15]

4. Define IND. Explain in detail the studies needed for IND submission. [15]

5. Elucidate in detail the alternatives to animal toxicity testing. [15]

6. (a) Write about acute, sub-acute and chronic toxicity studies as per OECD guidelines. [8]
   (b) Write a note on dermal toxicity testing. [7]

7. Define genotoxicity. Discuss in detail the *in vitro* and *in vivo* genotoxicity studies. [15]

8. (a) Explain the applications of toxicokinetics. [7]
   (b) Discuss the importance and principles of safety pharmacology studies. [8]

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Code No: F-7215/PCI

FACULTY OF PHARMACY

M.Pharmacy (Pharmacology) II-Semester (PCI) (Backlog) Examination, May 2024

Subject: Advanced Pharmacology - II

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

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

1. (a) Explain the synthesis, storage and release of thyroid hormones.
   (b) Write short notes on oral contraceptives. [8+7]

2. (a) Classify oral hypoglycaemic agents and explain in detail about sulphonyl ureas.
   (b) Write short notes on drugs affecting calcium metabolism. [8+7]

3. (a) Discuss about the antimetabolites used in cancer chemotherapy.
   (b) Write short notes on antifungal drugs. [8+7]

4. (a) Discuss about the alkylating agents used in cancer chemotherapy.
   (b) Write short notes on macrolide antibiotics. [8+7]

5. (a) Explain the biochemical mediators of inflammation.
   (b) Write the Pharmacotherapy of asthma and COPD. [7+8]

6. (a) Write short notes on immunostimulants. [7+8]
   (b) What is peptic ulcer? Explain the different approaches for its treatment.

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

8. (a) Explain about the recent advancements in the treatment of Alzheimer's.
   (b) Discuss the role of free radicals in etiopathology of cancer. [8+7]

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Code No: F-7218/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research & Pharmacovigilance

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

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

1. (a) Discuss in detail about the ICH-GCP guidelines. [8]
   (b) Explain the structure and content of an Informed Consent Process. [7]

2. Explain in detail about Randomised Controlled Trail (RCT) and Non Randomised Controlled Trail (Non RCT). [15]

3. Explain the methods of Safety Monitoring in clinical trials. [15]

4. (a) Define Pharmacovigilance. Add a note on its history and progress in India. [8]
   (b) Discuss the roles and responsibilities in Pharmacovigilance. [7]

5. (a) Define ADR. Classify ADR and write detection and reporting method. [8]
   (b) Discuss the management of ADR's? [7]

6. (a) Discuss about Pharmacoepidemiology and Safety Pharmacology. [8]
   (b) Add a note on Pharmacoeconomics. [7]

7. What are the various statistical methods for evaluating medication safety data? [15]

8. Describe the ICMR guidelines for biomedical research. [15]

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Code No: E-12457/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods – II

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

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

1. Discuss in detail the OECD principles of Good Laboratory Practice (GCP) in drug development. [15]

2. Explain the regulatory requirements of ICH for the new drug safety assessment.

3. Write short notes on:
   (a) Genotoxicity studies [8]
   (b) Teratogenicity studies [7]

4. Define IND. Elucidate the importance and industry perspectives of IND enabling studies. [15]

5. Write notes on:
   (a) Principles of toxicokinetic studies [7]
   (b) Alternatives to animal toxicity testing [8]

6. Write short notes on:
   (a) Dermal irritation studies [8]
   (b) Skin sensitization studies [7]

7. What is carcinogenesis? Explain the methods of testing the compound for carcinogenicity? [15]

8. Define safety pharmacology. Describe in detail the Tier1and Tier2 safety pharmacology studies. [15]

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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-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 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-12241/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods - II

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

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

1. Write a detailed note on determination of LD_{50} as per OECD-425 guideline.

2. (a) Write about acute, sub-acute and chronic toxicity studies as per OECD guidelines.
   (b) Write a note on skin sensitization studies.

3. Write short notes on:
   (a) Female reproductive studies
   (b) Genotoxicity studies

4. Define IND. Elucidate the importance and industry perspectives of IND enabling studies.

5. Write notes on:
   (a) Alternatives to animal toxicity testing
   (b) Applications of toxicokinetic studies

6. Write short notes on:
   (a) Acute eye irritation studies
   (b) Dermal toxicity studies

7. Define safety pharmacology. Describe in detail the Tier1and Tier2 safety pharmacology studies.

8. What is carcinogenesis? Explain the methods of testing the compound for carcinogenicity?

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Code No: E-12243/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research and Pharmacovigilance

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

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

1. (a) Write a note on pharmacoeconomics.
   (b) Write the importance of safety pharmacology.

2. Define pharmacovigilance. Add a note on history, Write about Pv programs in India.

3. (a) Define clinical trials. Explain the different types of clinical trials
   (b) What are the various safety monitoring protocols in clinical trials?

4. (a) Explain the structure and content of an informed consent process.
   (b) Write a note on The Indian Council of Medical Research.

5. (a) What are the ethical guidelines for biomedical research.
   (b) Write about schedule Y.

6. (a) What are the roles and responsibilities of Investigator and sponsor in Clinical Trials?
   (b) What are various types and designs of clinical-trials?

7. (a) Write a note on active and passive surveillance.
   b) Enlist the international classification of diseases.

8. (a) Discuss about vaccine safety surveillance.
   (b) Explain in detail about - Aris G Pharmacovigilance and vigiflow.

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Code No: E-12242/PCI

FACULTY OF PHARMACY

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

Subject: Principles of Drug Discovery

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

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

1. a) Write the role protein microarrays in drug discovery. [8]
   b) Describe about the economics of drug discovery. [7]

2. a) Write the importance of enzyme assays in drug discovery . [8]
   b) Write note on homology modeling. [7]

3. a) Write a note on concept of virtual drug design. [10]
   b) Write a note on Pharmacophore based screening. [5]

4. a) Describe about the de-novo drug design. [7]
   b) Write the role of log-p value in QSAR. [8]

5. a) Explain the concept of free Wilson analysis [7]
   b) Write a note on type's prodrug design techniques. [8]

6. a) Explain in brief about significance of nucleic acid microarrays in drug discovery. [8]
   b) Write the concept of combinatorial synthesis and its advantages. [7]

7. a) Describe the application of NMR in protein structure prediction. [8]
   b) Write the role of stearic factors in QSAR. [7]

8. a) Explain about the high content screening techniques. [7]
   b) Write a note on site specific prodrug delivery techniques. [8]

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Code No: E-12240/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Backlog) Examination,
April / May 2023
Subject: Advanced Pharmacology - II

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

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

1. (a) How are thyroid hormones synthesized? Classify antithyroid drugs.
   (b) Write short notes on sex hormones.

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

3. (a) Discuss about various insulin preparations.
   (b) What are corticosteroids? Explain the pharmacology of glucocorticoids?

4. (a) Discuss about the alkylating agents used in cancer chemotherapy.
   (b) Write short notes on macrolide antibiotics.

5. (a) Classify allergic or hypersensitivity reactions.
   (b) Discuss about bronchodilators and drugs used in treatment of COPD.

6. (a) Write short notes on immunostimulants.
   (b) What is peptic ulcer? Explain different approaches in its treatment.

7. (a) What is chronotherapy? Explain the chronotherapy of diabetes.
   (b) Discuss about the treatment for constipation.

8. (a) Explain about the recent advancements in the treatment of Alzheimer's.
   (b) Discuss the role of free radicals in etiopathology of cancer.

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Code No: E-12133/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods - II

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

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

1. Discuss the ICH guidelines for toxicity studies in detail.

2. Write short notes on:
   (a) Acute eye irritation studies
   (b) Dermal toxicity studies

3. What is reproductive toxicity? Discuss the study design and importance of male and female reproductive toxicity studies.

4. (a) Write about various studies required for IND submission.
   (b) Write the role and responsibilities of
      (i) Sponsorer
      (ii) Investigator in clinical research

5. Elucidate in detail the alternatives to animal toxicity testing.

6. Explain the importance of OECD principles of Good Laboratory Practice (GLP) in drug development.

7. Define genotoxicity. Discuss in detail the *in vitro* and *in vivo* genotoxicity studies.

8. (a) Discuss the importance and principles of safety pharmacology studies.
   (b) Explain the principles of toxicokinetics.

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Code No: E-12135/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research and Pharmacovigilance

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

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

1. (a) Write a note on Pharmacoepidemiology.
   (b) Write the importance of safety pharmacology

2. Define pharmacovigilance. Add a note on role of pharmacovigilance in regulating adverse drug reaction.

3. (a) Define clinical trials. Explain the different types of clinical trials.
   (b) What are the various safety monitoring protocols in clinical trials?

4. (a) Discuss in detail about the ICH-GCP guidelines.
   (b) Discuss the composition and responsibilities of IRB.

5. (a) What are the ethical guidelines for biomedical research?
   (b) Write about schedule Y.

6. (a) Write in detail about the role of contract research organization and its management.
   (b) What are various types and designs of clinical trials?

7. (a) Write a note on active and passive surveillance.
   (b) Enlist the international classification of diseases.

8. (a) Discuss about vaccine safety surveillance.
   (b) Write a note on Statistical methods for evaluating medication safety data.

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Code No: E-12132/PCI

FACULTY OF PHARMACY

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

Subject: Advanced Pharmacology - II

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

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

1. (a) Explain the synthesis, storage and release of thyroid hormones.
   (b) Write short notes on oral contraceptives.
2. (a) Classify oral hypoglycaemic agents and explain in detail about sulphonyl ureas.
   (b) Write short notes on drugs affecting calcium metabolism.
3. (a) Discuss about the antimetabolites used in cancer chemotherapy.
   (b) Write short notes on antifungal drugs.
4. (a) Explain the mechanism of resistance of β-lactam agents.
   (b) Classify antifungal drugs. Discuss the pharmacology of nystatin.
5. (a) Explain the biochemical mediators of inflammation.
   (b) Write the Pharmacotherapy of asthma and COPD.
6. (a) Write short notes on immunosuppressants.
   (b) Classify antiulcer drugs and explain about H2 receptor antagonists.
7. (a) What is chronotherapy? Write the applications of chronotherapy.
   (b) Discuss about the treatment for emesis.
8. (a) Explain in detail about the generation of free radicals.
   (b) Discuss about the protective activity of certain important antioxidants.

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Code No: E-12134/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II Semester (PCI) (Main & Backlog) Examinations, December 2022

Subject: Principles of Drug Discovery

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

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

1. (a) Write a note on importance of targets validation in drug discovery.
   (b) Describe in detail about role of Protein microarray in target discovery.

2. (a) Write the importance of enzyme based assay in drug discovery process.
   (b) Write the applications of NMR in protein structure prediction.

3. (a) Write a note on concept of traditional drug design.
   (b) Write a note on Pharmacophore de-novo drug design.

4. (a) Describe briefly about manual docking and flexible docking.
   (b) Write a note on hammet constant.

5. (a) Explain the concept of drug likeness screening.
   (b) Write a note on advantages of prodrug design.

6. (a) Explain in brief about significance of zinc finger proteins in drug discovery.
   (b) Write the types of resins used in solid phase synthesis.

7. (a) Describe the application of X-Ray crystallography in protein structure prediction.
   (b) Write a note on applications of transgenic animals in drug discovery.

8. (a) Explain about the scintillation proximity assay.
   (b) Write a note on statistical methods for QSAR.

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Code No. D-8296/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research and Pharmacovigilance

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

Note: Answer any five of the following questions.

1 (a) Discuss the good clinical Practice (ICH-GCP) guideline.
(b) Write a note on Institutional review board.

2 (a) Define ADR. Classify ADR and write detection and reporting method.
(b) How do you manage ADR's?

3 Write in detail about informed consent process. Add a note on ICMR guideline for biomedical research.

4 (a) Write the role of clinical trial personnel in contract research organization (CRO).
(b) List the difference between randomized and non-randomized CT.

5 (a) Discuss about safety pharmacology and pharmacoepidemiology
(b) Define Pharmacoeconomics. Add a note on its importance in pharmacy.

6 What are the guideline followed for the preparation of investigational brochure and report forms?

7 (a) Define Pharmacovigilance. Add a note on its history and progress in India.
(b) Discuss the roles and responsibilities in Pharmacovigilance.

8 (a) Discuss the statistical method for evaluating medical safety data.
(b) Write the types and design of clinical trials.

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Code No. D-8293/PCI

FACULTY OF PHARMACY

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

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.

2 (a) Classify oral hypoglycaemic agents and explain in detail about sulphonyl ureas.
(b) Write short notes on drugs affecting calcium metabolism.

3 (a) Discuss about various insulin preparations.
(b) What are corticosteroids and explain the pharmacology of glucocorticoids?

4 (a) Explain the mechanism of resistance of β-lactam agents.
(b) Classify antifungal drugs. Discuss the pharmacology of nystatin.

5 (a) Classify allergic or hypersensitivity reactions.
(b) Discuss about bronchodilators and drugs used in treatment of COPD.

6 (a) Write short notes on immunosuppressants.
(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 constipation.

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

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Code No. D-8294/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods – II

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

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

1 Discuss in detail the OECD principles of Good Laboratory Practice (GCP) in drug development.

2 Write short notes on:
(a) Skin sensitization studies
(b) Dermal irritation studies

3 What is reproductive toxicity? Discuss the study design and importance of male and female reproductive toxicity studies.

4 Define IND. Explain in detail the studies needed for IND submission.

5 Elucidate in detail the alternative to animal toxicity testing.

6 Explain the regulatory requirements of ICH for the new drug safety assessment.

7 Define genotoxicity. Discuss in detail the *in vitro* and *in vivo* genotoxicity studies.

8 (a) Explain the principles of toxicokinetics.
(b) Discuss the importance and principles of safety pharmacology studies.

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Code No. D-8295/PCI

FACULTY OF PHARMACY

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

Subject: Principles of Drug Discovery

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

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

1 (a) Write a note on importance of targets in drug discovery.
(b) Describe in detail about role of SiRNA in target discovery.

2 (a) Write the importance of cell based assay in drug discovery process.
(b) Write the levels of protein structure with neat labeled diagram.

3 (a) Write a note on concept of rational drug design.
(b) Write a note on Pharmmacophore mapping.

4 (a) Describe the types of docking techniques.
(b) Write a note on hanch analysis.

5 (a) Explain the concept of 3D-QSAR.
(b) Write a note on advantages of prodrug design.

6 (a) Explain in brief about significance of zinc finger proteins in drug discovery.
(b) Write the types of resins used in solid phase synthesis.

7 (a) Describe the application of X-Ray crystallography in protein structure prediction.
(b) Write a note on applications of transgenic animals in drugs discovery.

8 (a) Explain about the High Thoughtful screening.
(b) Write a note on statistical methods of QSAR.

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Code No. D8061/PCI

FACULTY OF PHARMACY

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

Subject: Principles of Drug Discovery

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

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

(3 x 25 = 75 Marks)

1 (a) Write the role protein microarrays in drug discovery.
(b) Describe about the economics of drugs discovery.

2 (a) Write the importance of enzyme assays in drug discovery.
(b) Write note on homology modeling.

3 (a) Write a note on concept of virtual drug design.
(b) Write a note on PHarmacophore based screening.

4 (a) Describe about the de-novo drug design.
(b) Write the role of log-p value in QSAR.

5 (a) Explain the concept to free Wilson analysis.
(b) Write a note on types prodrug design techniques.

6 (a) Explain in brief about significance of nucleic acid micro arrays in drug discovery.
(b) Write the concept of combinatorial synthesis and its advantages.

7 (a) Describe the application of NMR in protein structure prediction.
(b) Write the role of stearic factors in QSAR.

8 (a) Explain about the high content screening techniques.
(b) Write a note on site specific prodrug delivery techniques.

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Code No. D8060/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods – II

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

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

(3 x 25 = 75 Marks)

1 (a) Describe in detail the determination of LD_{50} in acute oral toxicity testing of drugs as per OECD 425 guideline.
(b) Define and classify toxicology.

2 (a) Write about sub-acute and chronic toxicity studies as per OECD guidelines.
(b) Write a note on dermal toxicity testing.

3 Write short note on:
(a) Genotoxicity studies
(b) Teratogenicity studies

4 Define IND. Elucidate the importance and industry perspective of IND enabling studies.

5 Write short notes on:
(a) Applications of toxicokinetic studies
(b) Alternatives to animal toxicity testing

6 Write short notes on:
(a) Acute eye irritation studies
(b) Skin sensitization studies

7 What is carcinogenesis? Explain the methods of testing the compound carcinogenicity.

8 Define safety pharmacology. Describe in detail the Tier 1 and Tier 2 safety pharmacology studies.

Code No. D8059/PCI

FACULTY OF PHARMACY

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

Subject: Advanced Pharmacology – II

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

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

(3 x 25 = 75 Marks)

1 (a) Explain the synthesis, storage and release of thyroid hormones.
(b) Write short notes on oral contraceptives.

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

3 (a) Discuss about the antimetabolites used in cancer chemotherapy.
(b) Write short note on antifungal drugs.

4 (a) Discuss about the alkylating agents used in cancer chemotherapy.
(b) Write short notes on macrolide antibiotics.

5 (a) Explain the biochemical mediators of inflammation.
(b) Write the Pharmacotherapy of asthma and COPD.

6 (a) Write short notes on immunostimulants.
(b) What is peptic ulcer? Explain the different approaches in its treatment.

7 (a) What is chronotherapy? Explain the applications of chronotherapy.
(b) Discuss about the treatment for emesis.

8 (a) Explain about the recent advancement in the treatment of Alzheimer's.
(b) Discuss the role of free radicals in etiopathology of cancer.

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Code No. D8062/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research and Pharmacovigilance

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

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

1 (a) Define Pharmacovigilance. Add a note on its history and progress in India.
(b) Discuss the vaccine safety surveillance.

2 (a) Discuss the origin and principle of international conference on harmonization-good clinical practice.
(b) Write a note on Institutional review board.

3 (a) Define ADR. Classify ADR and write detection and reporting method.
(b) How to prevent ADR's?

4 (a) Write in detail about informed consent process.
(b) Add a note on ICMR guideline for biomedical research.

5 (a) Write the role of clinical trial personnel in contract research organization.
(b) List the difference between randomized and non-randomized control trials.

6 (a) Discuss about safety pharmacology and pharmacoepidemiology.
(b) Add a note n Pharmacoeconomics.

7 What are the guidelines followed for the preparation of investigational brochure and report forms.

8 (a) Discuss the statistical method for evaluating medical safety data.
(b) Write the types and design of clinical trials.

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Code No: 12133/PCI

FACULTY OF PHARMACY

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

Examination, August 2021

Subject: Advanced Pharmacology - II

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

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

1. a) How are thyroid hormones synthesized, Classify antithyroid drugs?
   b) Write short notes on sex hormones.

2. a) Discuss about various insulin preparations.
   b) What are corticosteroids and explain the pharmacology of glucocorticoids?

3. a) Explain the mechanism of resistance of β-lactam agents.
   b) Classify antifungal drugs. Discuss the pharmacology of nystatin.

4. a) Discuss about the alkylating agents used in cancer chemotherapy.
   b) Write short notes on macrolide antibiotics.

5. a) Classify allergic or hypersensitivity reactions.
   b) Discuss about bronchodilators and drugs used in treatment of COPD.

6. a) Write short notes on immunostimulants.
   b) What is peptic ulcer? Explain the different approaches in its treatment.

7. a) What is chronotherapy? Discuss about the chronotherapy of diabetes.
   b) Discuss about the treatment for constipation.

8. a) Explain about the recent advancements in the treatment of Alzheimer's. disease
   b) Discuss the role of free radicals in etiopathology of cancer.

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Code No: 12136/PCl

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCl) (Suppl.)

Examination, July 2021

Subject : Clinical Research and Pharmacovigilance

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

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

1. a) Discuss in detail about the ICH-GCP guidelines
   b) Discuss the composition and responsibilities of IRB?

2. a) Define clinical trials. Explain the different types of clinical trials
   b) What are the various safety monitoring in clinical trials.

3. Explain in detail about Randomised Controlled Trial (RCT) and Non Randomised Controlled Trial

4. Define pharmacovigilance. Add a note on history, Write about Pv programs in India

5. a) Enlist the International Classification of diseases
   b) Mention five international non - proprietary names of drugs

6. Explain in detail about Argus, Aris G Pharmacovigilance and vigiflow

7. a) What are the roles and responsibity of Investigator and sponsor in Clinical Trials
   b) What are the roles and responsibilities of Industy & National Programmes in Pharmacovigilance.

8. a) Write a note on Pharmacoeconomics.
   b) Write the importance of safety pharmacology

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Code No. 12135/PCl

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCl) (Supplementary) Examination, July 2021

Subject: Principles of Drug Discovery

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

Note: Answer any three questions. (3x25=75 Marks)

1 (a) Write a note on lead identification and optimization.
(b) Describe about the economics of drug discovery.

2 (a) Write the importance of Florence screening techniques in drug discovery.
(b) Write note on homology modeling

3 (a) Write a note on role of transgenic animals in target validation.
(b) Write a note on Pharmacophore based screening.

4 (a) Describe about the de-novo drug design.
(b) Write the role of log-pvalue in QSAR.

5 (a) Explain the concept of free Wilson analysis
(b) Write a note on types of prodrug design techniques.

6 (a) Explain in brief about significance of bio-informatics in drug discovery.
(b) Write the concept of combinatorial synthesis and its advantages.

7 (a) Describe the application of X-ray Crystallography in protein structure prediction.
(b) Write the role of stearic factors in QSAR.

8 (a) Explain about the high content screening techniques.
(b) Write a note on site specific prodrug delivery techniques.

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Code No. 12134/PCI

FACULTY OF PHARMACY

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

Examination, July 2021

Subject: Pharmacological and Toxicological Screening Methods - II

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

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

1. Explain the regulatory guidelines of ICH for conducting toxicity studies.

2. Write short notes on:
   (a) Dermal irritation studies
   (b) Acute eye irritation studies.

3. Write a note on:
   a) Genotoxicity studies.
   b) Carcinogenicity studies.

4. Define IND. Discuss the studies needed for IND submission.

5. Define safety pharmacology. Describe in detail the Tier1 and Tier2 safety pharmacology studies.

6. What is Toxicokinetics? Discuss its importance and applications in preclinical toxicity testing of drugs.

7. Explain the OECD guidelines for the conduct of acute, sub-acute and chronic toxicity studies.

8. Write brief notes on:
   (a) Male reproductive toxicity studies.
   (b) Teratogenicity studies.

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Code No.6348/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Main & Backlog) Examination, October 2020

Subject: Pharmacological Toxicological Screening Methods-II

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

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

1 Write a detailed note on determination of LD_{50} as per OECD-425 guideline.

2 What is test item? Describe the methods of characterization and importance of test item.

3 (a) Write about the risk assessment in female reproductive toxicity studies**.**
(b) Discuss in brief about in vivo genotoxicity studies.

4 Define IND. Elucidate the importance and industry perspectives of IND enabling studies

5 (a) Write in detail about safety pharmacology.
(b) Discuss in brief Tier 1 safety pharmacology studies.

6 Write short notes on:
(a) Alternative animal toxicity testing
(b) Importance and applications of toxicokinetic studies

7 Write brief notes on:
(a) Acute eye irritation testing
(b) Dermal toxicity studies

8 Explain various in vivo Carcinogenicity studies.

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Code No. 6350/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Main & Backlog) Examination, October 2020

Subject: Clinical Research & Pharmacovigilance

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

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

1 (a) Elaborate the various toxicity studies as per schedule Y guidelines.
(b) Explain the structure and content of an informed consent process.

2 (a) Write in detail about the role of contract research organization and its management.
(b) What are various types and designs of clinical trials.

3 Define ADR Add a note on its reporting and management methods.

4 Define Pharmacovigilane. Write about WHO international drug monitoring programme

5 Discuss the roles and responsibilities of Industry and national programme related to pharmacovigilance

6 (a) Write a note on spontaneous reporting system.
(b) Enlist the international classification of diseases.

7 What are the various statistical methods for evaluating medication safety data

8 (a) Write a note on pharmacoepidemiology
(b) Write the importance of safety pharmacology

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Code No. 6349/PCI

FACULTY OF PHARMACY

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

Examination, October 2020

Subject : Principles of Drug Discovery

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

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

1. a) Write a note on target identification and validation
   b) Describe in detail about role of genomics and proteomics in target discovery

2. a) Write the importance of reporter gene assay in drug discovery process.
   b) Write the levels of protein structure with neat labeled diagram.

3 a) Write a note on concept of rational drug design
   b) Write a note on Pharmacophore mapping

4. a) Describe the types of docking techniques
   b) Write a note on hammet constant

5. a) Explain the concept of 3D-QSAR
   b) Write a note on rational of prodrug design

6. a) Explain in brief about significance of si RNA in drug discovery
   b) Write the concept of solid phase synthesis and its advantages

7. a) Describe the application of NMR in protein structure prediction
   b) Write a note on hanch analysis

8. a) Explain about the scintillation proximity assay
   b) Write a note on statistical methods for QSAR.

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Code No. 6123 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Suppl.) Examination,

January 2020

Subject: Principles of Drug Discovery

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

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

1	a)	Discuss the role of transgenic animals in drug discovery.	10
	b)	Explain in brief the role of genomics in target identification.	5
2	a)	Describe the methods of lead optimization.	8
	b)	Write a note on protein structure prediction and molecular modelling.	7
3	a)	Write a note on 3D QSAR.	7
	b)	Explain in brief about electronic parameters used in QSAR.	8
4	a)	Explain about the identification of pharmacophore in computer aided drug design.	8
	b)	Write a note on CoMSIA.	7
5	a)	What do you understand about De Novo drug design?	7
	b)	Explain the role of physicochemical properties in relation to biological activity and drug design.	8
6	a)	Write a note on design of pro-drug with their application.	8
	b)	What do you understand about the molecular docking?	7
7	a)	Define pro-drug and advantages associated with pro-drug formation.	8
	b)	Explain about HTS and its importance.	7
8	a)	What is the role of nucleic acid and protein micro array in target discovery and validation.	10
	b)	Write a note on economy of drug discovery.	

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Code No. 6121 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Suppl.) Examination, January 2020

Subject: Advanced Pharmacology – II

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

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

1 a) Explain the drugs used in thyroid diseases. 8
b) What are oral contraceptives? Explain the main types of oral contraceptives. 7

2 a) What are β -lactam antibiotics? Explain the mechanism of action, therapeutic uses and adverse effects. 8
b) Explain the pharmacology of alkylating agents in cancer chemotherapy. 7

3 Explain the following:
a) Chemotherapy of tuberculosis 8
b) Treatment of fungal infection. 7

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

5 Write about the following:
a) Pathogenesis of Alzheimer's disease and the mechanism of action of cholinesterase inhibitors in its treatment. 10
b) Application of chromo therapy of cardiovascular disease. 5

6 a) What is parkinsonism? List out the drugs used in its treatment. Add a note on dopamine agonists and MOA-B inhibitors. 8
b) Write about Huntington's disease. 7

7 What is diabetes mellitus? Classify the drugs used in its treatment. Explain the pharmacology of any one class. 1+8+6

8 Explain the cellular mechanism of action of the following:
a) Corticosteroids 8
b) Growth hormone. 7

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Code. No: 6120/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Supply.) Examination,

January 2020

Subject : Clinical Research and Pharmacovigilance

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

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

1. a) Explain the structure and content of an informed consent process. 8
   b) Describe briefly ICH-GCP guidelines. 7

2. Explain the roles and responsibilities of
   a) Investigator. 7
   b) Contract research organization.

3. Define ADR. Explain the detection and reporting methods of ADRs. 15

4. a) Define pharmacovigilance. Write a note on role of pharmacovigilance in India. 10
   b) Describe briefly about spontaneous reporting system. 5

5. a) Write a note on pharmacoepidemiology. 8
   b) Discuss about the different types of adverse drug reactions with examples. 7

6. Describe the ICMR guidelines for biomedical research. 15

7. Explain the methods of Safety monitoring in clinical trials 15

8. a) Explain the significance of safety monitoring in clinical trials 7
   b) What are the various statistical methods for evaluating medication safety data. 8

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Code No. 6122 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Suppl.) Examination,

January 2020

Subject: Pharmacological & Toxicological Screening Methods – II

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

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

1	Discuss the ICH guidelines for toxicity studies in detail.	15
2	a) Write about various studies required for IND submission.	7
	b) Write the role and responsibilities of	
	i) Sponsorer	4
	ii) Investigator in clinical research	4
3	Write a note on:	
	a) Teratogenecity studies	8
	b) In vivo carcinogenicity studies.	7
4	a) Describe the spermatogenesis	7
	b) Explain the possible toxicity effects on reproductive endocrinology.	8
5	a) Explain the principles of GLP (Good Laboratory Practice) as per OECD guidelines for toxicity studies.	15
6	Write a note on:	
	a) Chromosomal aberration test	7
	b) In vivo micronucleus test	8
7	a) Explain principles of toxicokinetics.	8
	b) Write a note on dermal toxicity testing.	7
8	a) Explain the various factors influencing the toxicity evaluation studies with animal models.	8
	b) Write about acute, sub-acute and chronic toxicity studies as per OECD guidelines.	7

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Code No. 13327 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Main) Examination, August 2019

Subject: Advanced Pharmacology – II

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

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

1	a)	Discuss about insulin preparations.	5
	b)	Write the pharmacology of glucocorticoids.	10
2	a)	Write notes on oral contraceptives.	7
	b)	Explain the mechanisms of resistance of antimicrobial agents.	8
3	a)	Classify pencillins. Write the mechanism of action, adverse effects and therapeutic uses of pencillins.	8
	b)	Discuss about HAART therapy of HIV.	7
4	a)	Explain about unwanted inflammatory and immune responses.	7
	b)	Discuss about alkylating agents used in cancer therapy.	8
5	a)	Classify drugs used for bronchial asthma. Discuss about bronchodilators.	7
	b)	Explain about different approaches for treatment of peptic ulcer.	8
6	a)	Classify antifungal drugs. Discuss the pharmacology of amphotericin B.	8
	b)	Discuss about treatment of diarrhea.	7
7	a)	Write short notes on generation of free radicals.	7
	b)	What is chronotherapy? Discuss about chronotherapy of asthma.	8
8	a)	Discuss about role of free radicals in etiopathology of cancer.	7
	b)	Discuss about recent advances in treatment of Parkinsonism.	8

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Code No. 13330 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Main) Examination, August 2019

Subject: Clinical Research & Pharmacovigilance

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

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

1 a) Explain informed consent process.
   b) Write the elements of case report form.

2 a) Explain the principles of ICH-GCP Guidelines.
   b) What are the composition and responsibilities of IRB?

3 a) Discuss the various types and design of clinical trials.
   b) Explain roles and responsibilities of clinical investigator.

4 Write in detail about different types of observational studies in clinical trial.

5 Mention the detection and reporting methods of ADR. Write about management of ADRs.

6 What is pharmacovigilance. Write about WHO international drug monitoring programme.

7 Define ADR. Write the types of ADR. Explain how it can be monitored.

8 Write about:
   a) Argus
   b) Statistical methods for evaluating medication safety data.

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Code No. 13329 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Main) Examination, August 2019

Subject: Principles of Drug Discovery

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

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

1	a)	Write a note on target identification and validation.	7
	b)	Describe about role of transgenic animals in target validation.	8
2	a)	Write a note on solid phase synthesis.	8
	b)	Explain in brief about cell based high throughput screening.	7
3	a)	Write a note on traditional drug design.	5
	b)	Explain in detail about virtual screening techniques.	10
4	a)	Write a note on docking based screening.	7
	b)	Describe in brief about hansch analysis and free Wilson analysis.	8
5	a)	Write the advantages of prodrug design.	6
	b)	Describe the practical consideration of prodrug design.	9
6	a)	Explain in brief about role of protein micro array in drug discovery.	6
	b)	Describe in detail about types of protein structure.	9
7	a)	Write a note on types of fluorescence screens in HTS.	8
	b)	Describe the concept of rational drug design.	7
8	a)	Write a note on de-novo drug design.	7
	b)	Describe in brief about 3D-QSAR.	8

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Code No. 13328 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Main) Examination,

August 2019

Subject: Pharmacological & Toxicological Screening Methods – II

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

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

1 Discuss in detail the determination of LD^{50} in acute toxicity testing of drugs as per OECD. What is its significance? 15

2 Write short notes on:
a) Acute eye irritation testing. 8
b) Dermal toxicity studies. 7

3 What is carcinogenesis? How do you test the compounds for carcinogenicity? Give details. 15

4 Define IND. Discuss the studies needed for IND submission. 15

5 Define safety pharmacology? Explain the scope, importance and principles of safety pharmacology. 15

6 Write short notes on:
a) Alternatives to animal toxicity testing 8
b) Applications of toxicokinetic studies. 7

7 Explain the importance of OECD principles of good Laboratory Practice (GCP) in drug development. 15

8 Write notes on:
a) Ames test for genotoxicity 5
b) Teratogenicity studies. 10

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Code No. 13174/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research and Pharmacovigilance

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

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

1. (a) Explain the Ethical principles governing informed consent process. (7)
   (b) Describe the schedule Y guidelines for biomedical research (8)

2. (a) Explain Cohort and case studies. (8)
   (b) Define Clinical trials. Explain the different phases of clinical trials. (2+5)

3. (a) Write a note on case report forms. (6)
   (b) What are the various steps taken to manage adverse drug reaction. (9)

4. (a) Differentiate the active and passive surveillance of adverse drug reaction. (10)
   (b) Define Pharmacovigilance. What are the roles and responsibilities in Pharmacovigilance. (5)

5. What are the various guidelines followed for adverse drug reactions reporting. (15)

6. (a) Write a note on safety pharmacology (7)
   (b) What are the various statistical methods for evaluating medication safety data. (8)

7. (a) Write a note on Pharmacoeconomics. (5)
   (b) Describe briefly about spontaneous reporting system. (5)
   (c) National programmes related to pharmacovigilance. (5)

8. Explain the methods of safety monitoring in clinical trials. (15)

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Code No: 13173/PCI

FACULTY OF PHARMACY

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

Subject: Principles of Drug Discovery

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

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

1.	a) Write a note on economics of drug discovery.	7
	b) Describe about role of zinc finger proteins in target identification and validation.	8
2.	a) Write a note on combinatorial chemistry.	8
	b) Explain in brief about reporter gene assay.	7
3.	a) Write a note on drug likeness screening.	5
	b) Explain in detail about rational drug design.	10
4.	a) Write a note on rigid docking.	5
	b) Describe in brief about QSAR.	10
5.	a) Write the significance of Prodrug design.	5
	b) Describe about the COMFA and COMSIA.	10
6.	a) Explain in brief about role of bioinformatics in drug discovery.	6
	b) Describe the computational prediction of structure.	9
7.	a) Write a note on scintillation proximity assay.	6
	b) Describe the concept of pharmacophore based screening.	9
8.	a) Write a note on statistical methods in QSAR.	8
	b) Describe in brief about rational of Prodrug design.	7

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CODE NO: 13171/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Sem. (PCI) (Suppl.) Examination, February 2019

Subject: Advanced Pharmacology-II

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

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

1. a) Classify oral hypoglycemic drugs. Discuss the mechanism of action, adverse drug reactions and therapeutic uses of sulfonyl ureas (8)
   b) Discuss the mechanism of action and pharmacological actions of thyroid hormones (7)

2. a) Discuss the mechanism of action, adverse drug reactions of any two classes of antibiotics. (4+4)
   b) Discuss the mechanism of action, adverse drug reactions and therapeutic uses of
      i. Acyclovir ii. Zidovudine (4+3)

3. a) Classify immune suppressants. Write the pharmacology of cyclosporine (8)
   b) Discuss about microtubule damage agents used in cancer therapy (7)

4. Discuss the mechanism of action, adverse drug reactions and therapeutic uses of
   a) Ranitidine b) Sulfasalazine c) Metoclopramide (5+5+5)

5. a) Classify and explain about hypersensitivity reactions (7)
   b) Discuss about cellular events of innate immune response (8)

6. a) Write about the cellular & biochemical mediations of inflammation
   b) Write about the Pharmacotherapy of asthma and COPD. (8)

7. a) Write short notes on generation of free radicals. (7)
   b) Discuss about the concept of chronotherapy. (8)

8. a) Describe the role of free radicals in etiopathology of neurodegenerative diseases. (7)
   b) Discuss about recent advances in treatment of cancer. (8)

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Code No. 13172/PCI

FACULTY OF PHARMACY

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

Subject: Pharmacological and Toxicological Screening Methods - II

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

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

1. Explain the regulatory requirements of ICH for the new drug safety assessment. 15

2. Explain the OECD guidelines for the conduct of acute, sub-acute and chronic toxicity studies. 15

3. Write short notes on:
   a) Genotoxicity studies 8
   b) Carcinogenicity studies 7

4. Define IND. Elucidate the importance and industry perspectives of IND enabling studies. 15

5. Define safety pharmacology. Describe in detail the Tier1 and Tier2 safety pharmacology studies. 15

6. What is Toxicokinetics? Discuss its importance and applications in preclinical toxicity testing of drugs. 15

7. Discuss the study design and importance of reproductive toxicity testing. 15

8. Describe how skin sensitization studies are conducted. 15

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CODE NO: 1213/PCI

FACULTY OF PHARMACY

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

Subject : Advanced Pharmacology-II

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

Note: Answer Any Five Questions. All Questions Carry Equal marks

1. (a) What are glucocorticoids? Explain the biosynthesis and mechanism of action of glucocorticoids. (7M)
   (b) Write about (1) Insulin (2) Prolactin (4+4)

2. (a) Classify penicillin's. Explain their mechanism of action and therapeutic uses. (8)
   (b) Explain the pharmacology of antifungal drugs. (7)

3. Write a note on
   (a) Immunophormacology (8)
   (b) Immunosupressants (7)

4. (a) Explain the pharmacology of drugs used in treatment of peptic ulcers. (8)
   (b) What is chrono pharmacology. Explain the applications of chrono pharmacology in various diseases. (7)

5. (a) Explain the role of free radicals in various diseases. ($7^{1/2}$)
   (b) Explain the pathogenesis of Alzheimer's disease ($7^{1/2}$)

6. (a) Discuss the drug therapy for asthma. (8)
   (b) Explain the disease pathology and therapeutic agents for COPD. (7)

7. (a) Write a note on antibacterial resistance ($7^{1/2}$)
   (b) Add a note on antioxidants (5)

8. What is diabetes mellitus? Classify oral hypoglycemic agents. Explain the mechanism of action and therapeutic uses of sulphonylureas and biguanides. (15)

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CODE:1214/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II–Semester (PCI) Main Examination,
August 2018

Subject : Pharmacological and Toxicological Screening Methods-II

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

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

1. Write in detail on OECD guidelines for conducting toxicity studies. 15

2. (a) Describe in detail the flow chart of Preclinical studies. 10
   (b) Explain the dermal toxicity studies. 5

3. Write about the importance & Application of toxico kinetic's. 15

4. (a) Write in detail about safety pharmacology. 8
   (b) Discuss in brief tier –I safety pharmacology studies 7

5. Discuss in detail the importance of ICH guidelines for toxicity studies. 15

6. Write a note on
   (a) The principles of regulatory toxicology. 7
   (b) Alternative to animal models in preclinical toxicology studies. 8

7. (a) Write about the risk assessment in male reproductive toxicity. 8
   (b) Explain the single dose and repeat dose toxicity studies as per OECD guidelines 7

8. (a) Discuss in detail about IND studies 8
   (b) Write a note on determination of LD_{50} as per OECD- 423 guidelines 7

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Code No. 1216/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Main) Examination,

August 2018

Subject: Clinical Research and Pharmacovigilance

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

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

1. Define investigator brochure. Discuss about the contents of IB in clinical trial.

2. a) Explain the principles of ICH-GCP guidelines.
   b) What are the roles and responsibilities of sponsor and contract research organization in clinical trial?

3. Explain in detail about RCT and NRCT.

4. a) Write in detail about ethical principles governing informed consent process.
   b) Write about Schedule Y in clinical trials.

5. Write about safety monitoring in clinical trial.

6. Give an overview of the regulatory environment in National and International aspects.

7. Write about predictability and preventability assessment methods of ADR.

8. Write about
   a) Vigiflow
   b) Aris G of pharmacovigilance.

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CODE:1215/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II–Semester (PCI) Main Examination,

August 2018

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 15

2. (a) Explain rational approach for drug design. (8)
   (b) Explain in brief the role of proteomics in target identification. (7)

3. What is QSAR? Give advantages and disadvantages of QSAR. Explain Hantzsch analysis and Free Wilson analysis. (15)

4. (a) Write a note on CoMFA. (7)
   (b) How computer aided drug design is useful in new drug discovery and development. (8)

5. (a) Describe the methods of lead optimization. (8)
   (b) What do you understand about De Novo drug design? (7)

6. (a) Write a note on prediction of protein structure. (8)
   (b) Describe various lead seeking methods in drug design. (7)

7. Write a note on
   (a) Drug likeness screening (8)
   (b) pharmacophore based screening (7)

8. (a) Write a principle involved in design of pro-drug. (8)
   (b) Explain the term molecular docking. (7)

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CODE NO: 1213/PCI

FACULTY OF PHARMACY

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

Subject : Advanced Pharmacology-II

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

Note: Answer Any Five Questions. All Questions Carry Equal marks

1. (a) What are glucocorticoids? Explain the biosynthesis and mechanism of action of glucocorticoids. (7M)
   (b) Write about (1) Insulin (2) Prolactin (4+4)

2. (a) Classify penicillin's. Explain their mechanism of action and therapeutic uses. (8)
   (b) Explain the pharmacology of antifungal drugs. (7)

3. Write a note on
   (a) Immunophormacology (8)
   (b) Immunosupressants (7)

4. (a) Explain the pharmacology of drugs used in treatment of peptic ulcers. (8)
   (b) What is chrono pharmacology. Explain the applications of chrono pharmacology in various diseases. (7)

5. (a) Explain the role of free radicals in various diseases. ($7^{1/2}$)
   (b) Explain the pathogenesis of Alzheimer's disease ($7^{1/2}$)

6. (a) Discuss the drug therapy for asthma. (8)
   (b) Explain the disease pathology and therapeutic agents for COPD. (7)

7. (a) Write a note on antibacterial resistance ($7^{1/2}$)
   (b) Add a note on antioxidants (5)

8. What is diabetes mellitus? Classify oral hypoglycemic agents. Explain the mechanism of action and therapeutic uses of sulphonylureas and biguanides. (15)

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