Code No: E–12338/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, August 2023
Paper: Cell and Molecular Biology (Elective–II)

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

PART-A

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

1. Differentiate between Mitosis and Meiosis
2. Define genetic code
3. Enlist the functions of Okasaki fragments
4. What are SSB proteins?
5. Enlist the properties of the cells
6. Differentiate between prokaryotes and eukaryotes
7. Differentiate between DNA and RNA
8. Enlist the components of Lac –operon
9. Enlist any two concern branches of cell biology
10. What are spindle fibres?

PART-B

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

11. Write in details about definition, theory, basics and applications of cell and molecular Biology.
12. Describe in detail about the enzymes involved in DNA replication.
13. Write in detail about cell signaling pathways and its misregulation.

PART-C

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

14. Explain the mechanism of cell cycle.
15. Explain in detail the significance of protein synthesis.
16. Explain in detail functioning of protein kinases.
17. Explain the gene structure of prokaryotic cell.
18. Explain in detail the protein structure.
19. Explain Chargaff's law.
20. Write a short note on classification of cell types.
21. Explain the DNA replication mechanism in eukaryotes.
22. Explain in detail significance of protein synthesis.

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Code No: E-12339/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, August 2023
Sub: Advanced instrumentation techniques (Elective – II)

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

PART-A

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

1. List the different ionisation techniques in MS.
2. Explain the principle of Mass spectroscopy.
3. Define chemical shift.
4. What are the applications of DSC?
5. What is meant by thermal analysis? Name some techniques that are useful in drug Analysis.
6. Briefly explain the production of X-rays.
7. What are the calibration standards used in spectrofluorimeter and IR spectrophotometer?
8. List the parameters for HPLC calibration.
9. Briefly explain DTA.
10. List the important steps in solid phase extraction.

PART – B

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

11. Explain the principle of NMR spectroscopy. Add a note on chemical shift and spin-spin coupling.
12. Explain the principle of GC/MS/MS.
13. List and explain the thermal techniques. Explain the principle and instrumentation of DSC.

PART – C

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

14. Explain the principle and applications of RIA.
15. Explain the fragmentation rules in MS.
16. Explain the principle of X-ray crystallography.
17. Explain the calibration of HPLC.
18. Explain FAB and MALDI in MS
19. Explain the principle of solid phase extraction.
20. Explain the parts of NMR instrumentation with a diagram
21. What is the difference between calibration and validation? List the validation parameters as per ICH guidelines and explain any two.
22. With a neat labelled diagram explain the instrumentation and application of DSC.

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Code No: E-12336/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII- Semester (PCI) (Main & Backlog) Examination, August 2023
Subject: Cosmetic Science (Elective-II)

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

PART-A

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

1. Define Cosmetic and Cosmeceuticals.
2. Write a note on Quasi and OTC drugs.
3. Write a note on hair oils.
4. Write the uses of mouth washes.
5. Explain hair growth cycle.
6. Write a note on hair tensile strength study
7. Write a note on hair combing properties.
8. Differentiate between soaps and syndet bars.
9. Write a note on reasons and prevention of dry skin.
10. What is dermatitis?

PART-B

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

11. Write basic structure and function of skin. Explain formulation of Moisturizing cream, Cold Cream and Vanishing cream as skin care products.
12. Write the role of herbs in cosmetics. Write a brief note on the following herbs **i)** Aloe & Turmeric in skin care **ii)** Neem & Clove in oral care
13. Write the principles and applications of **a)** Sebumeter and Corneometer b**)** Tewameter (TEWL) and **c)** Hair tensile strength study

PART-C

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

14. Write briefly on evolution of cosmeceuticals from cosmetics.
15. Write a note on **i)** Surfactants **ii)** Rheology modifiers **iii)** Humectants
16. Write the common problems associated with teeth and gums. Explain formulation of toothpaste for bleeding gums and sensitive teeth as oral care products.
17. Classify sunscreens and explain SPF.
18. Write a note on BIS specifications and Analytical methods for evaluation of Shampoo and Tooth paste
19. Explain the role of Henna and Amla in hair care.
20. Write the cosmetic problems associated with hair and scalp.
21. Write about blemishes, wrinkles and acne in problems associated with skin.
22. Write formulation and mechanism of action of Antiperspirants & deodorants.

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Code No: E-12340/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, August 2023
Subject: (Pharmacological Screening Methods) Experimental Pharmacology (Elective-II)

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

PART-A

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

1. Write the composition of IAEC.
2. Write applications of Mutant animals.
3. Enlist preclinical screening methods for diuretics.
4. Define hypothesis with examples.
5. Enlist various techniques for collection of blood sample.
6. What are different techniques of Euthanasia.
7. List out screening methods for drugs acting on eye.
8. Enlist pre clinical screening methods for anti-inflammatory actvity.
9. What are parametric and non parametric tests.
10. Name different methods used for screening parasympatholytics.

PART-B

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

11. Write a note on CPCSEA guidelines for performing experiments on animals. Describe in detail about requirement for IAEC permission on animal studies.
12. Explain various methods to evaluate a compound for antidiabetic activity by invivo, invitro methods.
13. Give methods of screening for antihypertensives and anti arrhythmics.

PART-C

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

14. Explain different methods for collection of blood in laboratory animals.
15. Describe anyone preclinical screening method for diuretic activity.
16. Describe different routes of drug administration in laboratory animals.
17. Discuss one screening method for anticoagulant.
18. Write any two preclinical screening methods for antidepressant activity.
19. Explain the applications of transgenic animals in pharmacological research.
20. Explain significance of statistical analysis of student t-test.
21. Enumerate any two preclinical screening methods for local aneasthetics.
22. Discuss one screening method for antidiabetic activity.

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Code No. E-12337/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination, August 2023

Subject: Dietary Supplements & Nutraceuticals (Elective-II)

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

PART-A

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

1. Explain the term 'nutrition education' and its role in promotion of community health.
2. Write about any two nutraceuticals that slow ageing process.
3. Differentiate functional foods and nutraceuticals. Write about omega fatty acids
4. Write source, active constituents and health benefits of broccoli and ginseng.
5. Write source and markers for sulphide compounds in any two foods. How are they beneficial in the prevention or management of chronic diseases.
6. Explain AGMARK
7. How complex carbohydrates differ from simple sugars. What are their sources and health benefits?
8. How does stress impact health. Write interventions to minimize its pathological influence?
9. Write about any two antioxidant enzymes.
10. Write the health benefits of tocopherols.

PART-B

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

11. Write a note the detrimental effects of processing, storage and environment on the potential of nutraceuticals.
12. Write about: (i) Probiotics (ii) Nutraceuticals in cancer
13. Write about flavonoids and their Health benefits with examples.

PART-C

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

14. Discuss in detail adulteration of any five common foods. Pinpoint the health hazards of the adulterants.
15. Discuss the responsibilities of regulatory body FSSAI in ensuring safety of food.
16. Write in detail the mechanism of free radical induced damage to lipids.
17. Write about polyphenols as potential antioxidants with examples.
18. Write about sources and health benefits of lactobacillus and melatonin.
19. Write a note on exogenous factors influencing the quality of nutraceuticals.
20. Write a note on food supplements that help in the management of diabetes.
21. Write about the importance of nutrition in children, pregnant women.
22. Write about the nutritional value and health benefits of oats, rice bran, wheat bran.

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Code No: E-12331/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII- Semester (PCI) (Main & Backlog) Examination, July / August 2023

Subject: Pharmaceutical Marketing Management (Elective-I)

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

PART-A

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

1. Define marketing and mention its scope.
2. Write the elements of the product mix.
3. Define advertisement.
4. Classify products in pharmaceutical marketing.
5. Write objectives of medical exhibition.
6. Differentiate between consumer and buyer.
7. Write evaluation criteria for professional sales representatives.
8. Write the benefits and drawbacks of direct mailing.
9. What is industrial marketing?
10. What is the role of retailing in promotion?

PART-B

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

11. Explain various approaches to analyze the consumer behavior in pharmaceuticals.
12. Write in detail the steps involved in personal selling.
13. Describe the role of channels in physical distribution management and mention their merits and demerits.

PART-C

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

14. What is the consumer profile? Mention the approaches for consumer profiling.
15. Explain the factors and methods applicable to product portfolio management.
16. Differentiate between marketing and selling.
17. Describe different elements of the marketing environment.
18. Explain the role of marketing research on sales of pharmaceuticals.
19. Explain the motivational factors that influence the prescribing habit of physicians.
20. What is product portfolio analysis and mention its role in product positioning.
21. Write the salient features of DPCO and its significance in pharmaceutical business.
22. What is consumerism? Write the roles of pharmacist and physician in consumerism.

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Code No: E-12332/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, July / August 2023

Subject: Pharmaceutical regulatory science (Elective-I)

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

PART-A

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

1. List out the different applications used for approval in EU.
2. Write a note on orange book.
3. Define preclinical study.
4. Write a note on IND.
5. Explain the objectives of regulatory affairs department in pharma industry.
6. What is the importance of DMF?
7. Explain the functions of Japan drug regulatory authority.
8. What are the inclusion criteria for clinical trials?
9. Define a. TGA b. EMEA.
10. Define regulatory affairs.

PART-B

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

11. What are CTD and eCTD? Explain the different modules of CTD in detail.
12. Describe the contents of investigator brochure used in clinical studies.
13. Discuss various stages of drug discovery and drug development process.

PART-C

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

14. Discuss the criteria for human volunteer selection in clinical trial.
15. Explain organization and functions of CDSCO.
16. Describe good clinical practice.
17. Explain the changes made to approve NDA.
18. What are the steps involved in application and approval of ANDA?
19. Explain constitution and function of institutional review board.
20. What is independent ethics committee?
21. Explain the management of clinical trials.
22. What is the difference between innovator and generic product?

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Code No: E-12334/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, July / August 2023

Subject: Quality control and standardization of herbals (Elective-I)

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

PART-A

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

1. List out the various WHO guidelines for the safety of herbal drugs.
2. List out the contents of a protocol for a clinical trial for the safety of herbal medicines.
3. Define GACP and write its importance.
4. Define standardization and write its importance.
5. Name the various parameters for evaluation of commercial drugs intended for use.
6. Define monographic analysis.
7. How does FDA regulate natural products in the US.
8. What are the differences between HPLC and HPTLC?
9. What is an accelerated stability study?
10. Give the significance of ICH guidelines for the safety of herbal.

PART-B

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

11. Explain the advanced analytical methods of evaluation of crude drugs.
12. What are the challenges in the stability testing of herbal products? Explain a suitable protocol for testing the stability of herbal drug
13. What do you understand by 'Quality assurance in herbal Industry'? Explain the importance of GMP in the Herbal Industry.

PART-C

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

14. Explain the method to determine the microbial and aflatoxin content in the herbal drugs.
15. Explain the application of HPLC for the standardization of a herbal drug.
16. What are the WHO guidelines for safety monitoring of herbal drugs.
17. Explain briefly the good agriculture practices of herbal drugs.
18. Explain the identification and estimation of pesticide residues in plant products.
19. Give a protocol for clinical trials in herbal medicine.
20. Explain the role of chemical and biological markers in the standardization of herbal products.
21. What is a traditional system of medicine? What are the GLP requirements in the traditional system of medicine?
22. Mention the different types of Herbal Industries. Explain the importance of WHO. Guidelines for quality assurance in these herbal Industries.

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Code No: E-12333/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, July / August 2023

Subject: Pharmacovigilance (Elective –I)

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

PART-A

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

1. Write the steps involved in reporting ADR.
2. List out the genetically determined toxicities.
3. Write the responsibilities of CDSCO.
4. What is phase II of clinical trial?
5. Mention any six drugs contraindicated in pregnant and lactating women.
6. List out the objectives of ICH
7. Write the factors affecting immunization safety.
8. Describe cross sectional studies.
9. What are the factors affecting AEFI surveillance.
10. Mention the ADR following immunization.

PART – B

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

11. Define ADR. Enumerate the different methods of causality and severity assessment of ADR. Explain WHO scale.
12. Define pharmacovigilance. Discuss the role of pharmacist in detection, reporting and management of ADRs.
13. Explain in detail MedDRA. Compare and contrast various observation methods for vaccine safety study.

PART – C

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

14. Explain organization and function of ICH.
15. Describe standard MedDRA queries.
16. Discuss about individual case safety reports.
17. Explain CIOMS requirements for ADR reporting.
18. Write about drug event monitoring program.
19. What is Narinjo scale? Explain the importance of communication in pharmacovigilance.
20. Discuss in detail vaccine safety surveillance.
21. Explain in detail about spontaneous case reports and case series.
22. Explain drug safety evaluation in geriatric and pediatric populations.

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Code No: E-12335/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, July / August 2023

Subject: Computer Aided Drug Design (Elective-I)

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

PART-A

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

1. Define the term energy minimization.
2. Explain the significance of partition coefficient.
3. Differentiate between lead and drug.
4. What is the serendipitous drug discovery? Give an example.
5. Explain the significance of Taft's steric constant.
6. Differentiate between rigid and flexible docking studies.
7. Write about *de novo* drug design.
8. What are pharmaceutical databases? Give examples.
9. Give examples for ADME databases.
10. What is global conformational minima?

PART – B

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

11. Explain in detail about various physicochemical parameters used in QSAR analysis.
12. Describe the concept of pharmacophore-based virtual screening in drug design.
13. Explain the significance of bioisosterism in drug design and development with a specific example.

PART – C

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

14. Explain drug metabolism based lead discovery with examples.
15. Differentiate between classical and non-classical bioisosteres.
16. Highlight the significance of Hammet's substituent constant in QSAR analysis and Write its determination.
17. Differentiate between Hansch & Free-Wilson QSAR analysis.
18. Write in detail about drug-likeness screening.
19. Explain any one cheminformatics tool used in drug design.
20. What is PDB? Explain its features and applications in drug design.
21. Explain the role of molecular mechanics in drug design.
22. Write briefly about conformational analysis.

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Code No. E-12062/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Makeup) Examination,
November 2022
Subject: Biostatistics and Research Methodology

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

PART – A

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

1. Explain Null hypothesis and Alternative hypothesis.
2. Find the median of following data: 15, 36, 43, 23, 30, 52, 13.
3. Explain primary and secondary data.
4. Explain Cohorts studies.
5. Define parametric and non-parametric test.
6. Write the difference between histogram and bar diagram.
7. Define type-1 error.
8. Explain power of study.
9. Explain correlation coefficient.
10. Find the range of the data 2, 7, 16, 12, 19, 24, 25, 29, 30, 35.

PART – B

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

11. (a) Define mean and mode. Discuss their merits and demerits.
    (b) Calculate the mean and standard deviation from the following data of presence of urea in the blood samples of 110 patients in a hospital.

Range of urea (mgldl)	20-22	23-25	26-28	29-31	32-34	35-37	38-40
No. of Patients	6	16	21	10	19	21	17

12. (a) Explain 2^2 Factorial Design and write its advantages.
    (b) Write in detail about unpaired t-test with suitable example.

13. Write short notes on:
    (a) Regression analysis
    (b) Significance of t-test

PART – C

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

14. Explain one way-ANOVA with example.
15. Define Normal distribution and state its properties.
16. Explain basic principles of design of experiments.
17. Explain in detail about experimental studies in clinical study design.
18. Write a note on report writing in research methodology.
19. Explain Mann Whitney's U test with example.
20. Explain Software used for industrial and clinical trial approach.
21. Define sampling? Explain Simple random and Stratified sampling.
22. Explain response surface methodology.

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Code No: E-12064/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Make-up) Examination, November 2022

Subject: Pharma Marketing Management (Elective-I)

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

PART - A

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

1. Write about the general concepts of marketing.
2. What is consumer profile?
3. What is market segmentation and targeting?
4. Write about product life cycle.
5. What is sampling in promotion?
6. What is NPPA?
7. Give a note on promotional budget.
8. Define consumerism.
9. What are the future prospects of Professional sales representative?
10. What are the objectives of Pricing?

PART - B

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

11. (a) Write about industrial and global marketing.
    (b) Give the importance of pricing and write its objectives.

12. (a) What are the online promotional techniques for OTC products.
    (b) Write a note on Product decision.

13. Write about the quantitative and qualitative aspects of Pharmaceutical market.

PART - C

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

14. Write about the methods of promotion.
15. What are the duties of Professional sales representative (PSR)?
16. Discuss about packaging and labeling decisions.
17. Explain how the market segmentation and targeting is done.
18. Write about emerging concepts in marketing.
19. Give an overview of personal selling and advertising.
20. What are the tasks in Physical distribution management?
21. Write about global marketing.
22. Write about determinants of promotional mix.

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Code No: E-12065/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Makeup) Examination, November 2022

Subject: Pharmaceutical Regulatory Science (Elective-I)

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

PART - A

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

1. What are the stages of drug discovery and development process?
2. Define : a) Bioequivalence b) Bioavailability
3. Explain the need of non-clinical drug development.
4. Discuss about the supplements to approved NDA/ANDA.
5. Enlist the pharmaceutical products eligible for NDA filing.
6. What are the benefits of CTD?
7. List down the types of DMF.
8. What are the different phases involved in clinical trials?
9. Explain the term “Informed consent”.
10. Justify the need of regulations for drug products.

PART - B

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

11. Discuss the NDA approval process in detail, illustrate with the help of flow diagram.
12. Describe in detail the content of clinical trial protocol.
13. a) Explain the concept of innovator and generic products.
    b) Write a short note on orange book and purple book

PART - C

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

14. Discuss the different approaches for new drug discovery.
15. Discuss generic drug product development.
16. Describe the organizational structure, working and functions of CDSCO.
17. Explain the modules of common technical document.
18. Elucidate the functions of IRB.
19. Discuss the importance of Good clinical practices
20. Explain the procedure for export of pharmaceutical product.
21. Discuss in detail about the CFR.
22. Elaborate the content of new drug application.

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Code No: E-12066/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Make-up) Examination, November 2022

Subject: Pharmacovigilance (Elective-I)

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

PART - A

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

1. Define the terms a) Pharmacovigilance b) ADR c) ADE
2. Explain daily defined doses.
3. What is vaccine Pharmacovigilance?
4. Explain post approval phase in clinical trails.
5. What is PVPI? What are its objectives?
6. Give the importance of safety monitoring of medicine.
7. What is contract research organization?
8. Explain the importance of communication in Pharmacovigilance.
9. What are individual case safety reports?
10. Write about CIOMS.

PART - B

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

11. Write about a) genetic related ADR b) Management of ADR.
12. Explain a) Safety data generation in clinical phase b) periodic safety update reports.
13. Write about drug safety evaluation in geriatrics.

PART - C

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

14. Describe detection and reporting of ADR.
15. List out the information resources in Pharmacovigilance.
16. What is vaccine safety surveillance?
17. Describe the post approval expedited reporting.
18. Explain pharmacogenomics of ADR.
19. Write about the methods in causality assessment.
20. Describe the establishment of Pharmacovigilance in hospital.
21. Explain a) Active surveillance b) Passive surveillance.
22. Write about the differences in Indian and global Pharmacovigilance requirements.

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Code No: E-12068/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Make-up) Examination, November 2022
Subject: Computer Aided Drug Design (Elective-I)

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

PART - A

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

1. What is 3D QSAR?
2. What is serendipitous drug discovery?
3. Explain the role of bioinformatics in drug design?
4. Define quantum mechanics?
5. What is virtual screening?
6. Discuss about druglikeness screening?
7. What is conformational analysis in molecular modelling?
8. What is Taft steric constant?
9. What is similarity searching?
10. Write the examples for Chemical Databases?

PART - B

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

11. Discuss about Lipophilic and electronic parameters used in QSAR and give a hypothetical Hansch equation for predicting biological activity?
12. What is known as pharmacophore? Discuss the concepts of Pharmacophore based virtual screening?
13. What is molecular docking? Write a note on Scoring techniques in Molecular docking?

PART - C

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

14. Explain in detail about bioisosterism?
15. Explain briefly about the Stages of drug discovery and development?
16. Discuss various models for predicting ADMET properties?
17. Write a note on chemoinformatics?
18. Write a note on applications of Free Wilson analysis in drug design?
19. Discuss about molecular mechanics in drug design and write the applications of molecular mechanics?
20. Discuss about Random screening?
21. Write about COMFA and COMSIA?
22. Explain about Hansch and Freewilsm Analysis.

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Code No: E-12072/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Makeup) Examination, December 2022
Subject: Advanced Instrumentation Techniques (Elective - II)

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

PART - A

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

1. Define Chemical shift?
2. Write the principle involved DSC?
3. Write the importance of X-ray crystallography?
4. List out various Validation parameters?
5. Discuss the principle involved in Solid-liquid extraction technique?
6. Discuss the principle involved in DTA?
7. Write the principle involved in NMR?
8. List out various Ionization techniques of Radio immune Assay?
9. Write about various components of Radio immune Assay?
10. Write about basic aspects of crystals?

PART - B

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

11. (a) Explain spin-spin coupling and write the Instrumentation of NMR in detail.
    (b) Write about Coupling constant?

12. (a) Explain about MALDI and FAB analyzers.
    (b) Write about Chemical Ionization in detail?

13. Discuss the following hyphenated techniques: A) HPTLC-MS B) LC-MS/MS

PART - C

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

14. Explain the calibration procedure of HPLC in detail.
15. Write the instrumentation and applications DSC.
16. Write about Radio Immuno assay in detail?
17. Explain Mc-Lafferty Rearrangement in detail?
18. Explain about C-NMR?
19. Write the calibration of GC?
20. Write the instrumentation and applications TGA?
21. Explain about GC-MS/MS?
22. Write about various X-ray diffraction methods?

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Code No. D-8114/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination, July 2022

Subject: Advanced Instrumentation Techniques (Elective-II)

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

PART - A

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

1. Define coupling constant.
2. Explain FAB technique?
3. Write the principle involved in DSC.
4. Define accuracy and precision.
5. Write any two differences between H-NMR and C^{13} NMR.
6. Explain the principle involved in RIA.
7. Mention any four ICH guidelines?
8. Mention the advantages of LC-MS/MS.
9. Explain Chemical ionization technique.
10. Define LOD and LOQ.

PART - B

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

11. (a) Write in detail about USFDA guidelines for validation.
    (b) Write the instrumentation and applications of DSC.
12. Define chemical shift and explain about various factors affecting it. Draw a neat sketch of NMR with explanation.
13. Explain the working principle and instrumentation of GC-MS/MS.

PART - C

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

14. Explain fragmentation in mass spectroscopy.
15. Write the principle and procedure involved in SPE?
16. Write the importance and applications of HPTLC-MS.
17. Explain any three calibration parameters for UV VIS Spectroscopy?
18. Write the calibration procedure for fluorimeter?
19. Explain the importance and components of RIA.
20. Draw a neat sketch and explain X-Ray powder diffraction technique.
21. Write the instrumentation and applications of TGA?
22. Write the calibration procedure for HPLC.

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Code No. D-8105/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main & Backlog) Examination, July 2022

Subject: Biostatistics and Research Methodology

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

PART – A

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

1. Define type-I error.
2. Explain power of study.
3. Write the difference between histogram and bar diagram.
4. Define the term multiple regression.
5. Find the range of the data 9, 7, 21, 32, 18, 24, 26, 29, 39, 25.
6. Find the median of following data: 21, 36, 44, 23, 32, 52, 16.
7. Explain Null hypothesis and Alternative hypothesis.
8. Explain critical value.
9. Write the advantages of Minitab.
10. Write the significance of standard error of mean.

PART – B

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

11. (a) Explain in detail about observational studies in clinical study design.
    (b) Explain in detail about report writing in research methodology.

12. Two groups of rats were injected 0.5 and 1.0 mg of a tranquilizer respectively and the following are the number of seconds it took them to fall asleep.

0.5 mg dose (X)	1.0 mg dose (Y)
8	5
10	8
12	7
14	6
16	5

Use the Mann Whitney's U test at 0.01 level of significance to test the null hypothesis that the difference in dosage have no effect on the length of time it takes to fall asleep.

(Tabulated value at 0.01% is 2.33)

13. Explain in detail about one-way ANOVA with one example.

PART – C

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

14. Define Sampling? Explain sampling techniques.
15. Explain paired t-test in detail.
16. Define Normal distribution and state its properties.
17. Find the standard deviation of incubation period of smallpox in 9 patients where it was found to be 15, 12, 10, 15, 11, 7, 9, 17 and 14.
18. Explain in detail about theory of probability.
19. The following figure shows disease count from a region over a span of 6 months. Represent the data by a pie-diagram,

Disease	Disease Count
HIV	17
Malaria	28
Diarrhoea	30
Tuberculosis	25
Influenza	20

20. Find the coefficient of correlation between the variable X and Y using Karl Pearson's method.
21. Explain 2^2 Factorial Design and write its advantages.
22. Explain optimization techniques in response surface methodology.

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Code No. D-8107/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination,
July 2022
Subject: Pharma Marketing Management (Elective-I)

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

PART - A

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

1. Define Marketing.
2. Distinguish between marketing and selling.
3. Write in brief about product decision.
4. Give the importance of product management in Pharmaceutical industry.
5. Write the objectives of Drug Price Control Order.
6. What is Physical distribution management?
7. What is product branding?
8. Define advertising.
9. Write about the role of market research.
10. What is Pricing and give its importance?

PART - B

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

11(a) Describe various methodologies of promotion.
(b) Explain about product life cycle.
12(a) Describe in detail pricing methods and strategies.
(b) Explain the issues in price management in pharmaceutical industry.
13. Write about Pharmaceutical marketing channels.

PART - C

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

14. Write about marketing environment.
15. Discuss about the National Pharmaceutical Pricing Authority.
16. Explain various theories of motivation.
17. Write about global marketing.
18. Write about medical exhibition and public relations.
19. Write about new product decisions.
20. Write a note on product positioning.
21. Write the future prospects of the Professional sales representative (PSR).
22. What are tasks in physical distribution management?

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Code No. D-8108/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination,
July 2022
Subject: Pharmaceutical Regulatory Science (Elective-I)

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

PART - A

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

1. What are the stages in the drug development process.
2. Write down the difference between innovator and generics.
3. Name the regulatory authority of India, USA, European Union, Australia.
4. What is the difference between CTD & DMF.
5. What is the importance of the informed consent.
6. Write down the importance of the purple book.
7. Enlist the various guidelines under ICH.
8. Define Pharmacovigilance.
9. Write a note on Code of federal regulation.
10. What are the responsibilities of Institutional review board.

PART - B

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

11. Explain in detail about NDA approval process.
12. Explain the procedure for the export of pharmaceutical product.
13. Write in detail about the common technical document.

PART - C

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

14. Describe the purpose of IND and what are the types of IND.
15. Write about the different phases in clinical trials.
16. Define DMF and write down the types of DMF.
17. Give a brief note on pharmacovigilance and safety monitoring in clinical trials.
18. Explain the term organge book and what information does it provide.
19. Explain the regulatory requirement for ANDA approval process.
20. Discuss about the generic drug development.
21. Discuss about the differences between NDA & ANDA data submission.
22. Discuss the elements of clinical trial protocol.

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Code No. D-8109/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination,
June / July 2022
Subject: Pharmacovigilance (Elective-I)

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

PART - A

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

1. Write a note on Naranjo scale in assessing on ADR.
2. What is the causality assessment in ADR monitoring.
3. Write down the purpose of the ATC classification of drugs.
4. What are the basic drug information resources available.
5. Write a short note on method of passive surveillance in pharmacovigilance.
6. What are the principles of good pharmacovigilance communication.
7. What is the pre-clinical phase in clinical trails.
8. Write a short note on periodic safety update reports.
9. What are the differences in Indian and global pharmacovigilance requirements.
10. Write a short note on schedule “Y”.

PART - B

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

11. (a) Describe the organization and objectives of ICH.
    (b) Write about the WHO international drug monitoring programme.
12. (a) Detailed note on ADR’s with suitable examples.
    (b) Write a detailed note on Contrast Research Organizations [CRO].
13. (a) Write a detailed note on communication in Drug Safety crisis Management.
    (b) Detailed note on Drug Therapy for pregnancy and lactation.

PART - C

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

14. Write a note on CIOMS working groups.
15. Write in detail about clinical phase and post approval phase.
16. Write in detail about international classification of diseases.
17. Write a note on spontaneous reports and cohort study.
18. Write a note on communication with Regulatory Agencies and Healthcare facilities.
19. Write about the predictability and preventability assessment of ADR.
20. Write a detailed note on MedDRA.
21. Discuss regulatory considerations in pharmacovigilance and what are the outcomes pharmacovigilance.
22. Explain in detail about Drug interactions and ADR’s.

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Code No. D-8111/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination, July 2022

Subject: Computer Aided Drug Design (Elective-I)

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

PART - A

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

1. Write about free Wilson analysis?
2. Write the applications of chemoinformatics in drug design?
3. What is virtual screening?
4. Write the Describe the steps involved in Homology modeling of a protein?
5. Define QSAR?
6. Explain the Lipinski's rule of five?
7. Write the examples for protein database?
8. Define Bioisosterism?
9. What is Tafts steric constant?
10. What is flexible docking?

PART - B

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

11. Write a note on molecular mechanics and Discuss about the importance of energy minimization in molecular modelling?
12. Discuss about the in silico ADMET analysis in drug design?
13. What is 3D-QSAR and write about COMFA and COMSIA methods in 3D QSAR?

PART - C

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

14. Explain about various steps in molecular docking?
15. Explain the physicochemical properties which influence biological activity?
16. Write about Bioisosteric replacement with the help of case studies?
17. Write a short note on de novo drug design?
18. Explain lead discovery in drug design?
19. Discuss about druglikeness screening?
20. Write about different methods used to determine potential energy surface(PES) of a molecule?
21. Discuss the role of bioinformatics in drug design?
22. Explain about various parameters in druglikeness screening.

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Code No. D-8110/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination, July 2022

Subject: Quality Control & Standardization of Herbals (Elective-I)

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

PART - A

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

1. Give identification tests for any two medicinal plant material.
2. What are GACP guidelines? Write its objectives and significance.
3. Write the difference between GLP and GMP of herbal drugs.
4. Define the terms quality assurance and quality control of herbal drugs.
5. What is crude drug evaluation? Enumerate the various methods of evaluation of crude drugs.
6. What is organic forming? What are its benefits?
7. What is stability? Write the factors affecting the stability of herbal drugs.
8. What is herbl pharmacopoeia? Mention various herbal pharmacopoeias.
9. Give examples of chemical markers used in the standardization of herbal products.
10. What is herbal monograph? Write its contents.

PART - B

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

11. Explain WHO guidelines for the assessment of herbal drugs.
12. Describe WHO guidelines on GMP for herbal medicines.
13. Explain WHO guidelines for safety monitoring of herbal drugs.

PART - C

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

14. Explain the guidelines of GAP in the cultivation of medicinal plants.
15. Write in detail about any two methods of evaluation of crude drugs.
16. Explain different method of stability testing of herbal drugs.
17. Brief out the applications of any one chromatographic method in the standardization of herbal drugs.
18. Explain the role of chemical markers in the standardization of drugs with examples.
19. What is new drug application? How do you prepare the document of NDA?
20. Write a note on Efficacy of herbal medicines.
21. Give the comparison of various herbal pharmacopoeias.
22. Write a note on Good Laboratory drugs.

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Code No. D-8106/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, July 2022

Subject: Social & Preventive Pharmacy

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

PART – A

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

1. Write a note on nutritional deficiencies?
2. Explain different types of diabetes mellitus?
3. What is the difference between drug abuse and drug addiction?
4. Explain the social causes of the diseases?
5. Give the preventive measures for the control of malaria and dengue?
6. Write the objectives of AIDS control programme?
7. Write a note on role of WHO in Indian National programmes?
8. What are the objectives of national family welfare programme?
9. Write a note on school health program?
10. Write a note on functions of PHC?

PART – B

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

11. (a) Explain about Malnutrition and its prevention.
    (b) Explain prevention and control of acute respiratory infections.
12. (a) Explain in detail functioning and outcomes of National mental health program.
    (b) Write about national health intervention programme for mother and child.
13. (a) Discuss the community services available in rural and urban regions.
    (b) Write a note on treatment of TB.

PART – C

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

14. Write the socio-cultural factors related to health and disease.
15. Explain signs, symptoms, transmission and treatment of SARS.
16. Write about Universal Immunization programme.
17. Write a note on objectives and strategies of National Leprosy control programme.
18. Write a note on National programme for control of deafness.
19. Write a note on Family welfare program.
20. What are the aims and achievements of National Tobacco Program.
21. Explain about the general prevention, control and treatment of lymphatic filariasis.
22. Write about Health promotion and education in schools.

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Code No: 12260/PCI

FACULTY OF PHARMACY

B. Pharmacy - VIII - Semester (PCI) (Main.) Examination, July 2021

Subject: Biostatistics and Research Methodology

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

Note: Answer Seven questions from Part -A, any One questions from Part- B and any Five questions from Part- C

Part - A (7x3=21 marks)

1. What do you mean by biostatistics? Give its importance in pharmacy
2. Describe the types of dispersion
3. Calculate range for individual series – X : 120 170 240 100 105 205 300 160 150 180
4. What is the significance of probability?
5. Describe the properties of normal distribution
6. What is factorial design?
7. Name the open source graphical user interfaces supported by R.
8. What is observational study? Give an example.
9. What are the various statistical methods used in excel?
10. A random sample of size 100 is taken from the population with standard difference

    5.1 Calculate the standard error of mean

Part - B (1x14=14 marks)

11.a) Explain the applications, merits and demerits of correlation

b) Calculate the Karl person's coefficient of correlation for the following data:

X	7	6	5	4	3	2	1
Y	18	16	14	12	10	6	8

12.a) What is SPSS? Explain the important SPSS models

b) Explain 'Two Tailed test of hypotheses?

13. Two independent samples of 7 and 8 items respectively had the following readings. State, if the two estimates of population variance differ significantly?
    (Given the tabulated value = 4.21)

Sample A	10	8	9	13	11	12	9	
Sample B	15	13	14	11	12	10	8	6

Part - C (5x8=40 marks)

14. Discuss the procedure for wilcoxon – signal rank test for one sample
15. What is experimental design? Explain its principles
16. Write short notes on different types of ANOVA
17. What is population? Explain the difference between small sample test and large sample test.

18. Obtain a line of regression of Y on X for the following data

Age in Yrs (X)	66	38	56	42	72	36	63	47	55	45
Blood pressure (Y)	145	124	147	125	160	118	149	128	150	124

19. The average number of phone calls per minute coming between 2pm-4pm is 2.5 Determine the probability that during one particular minute there will be i) 4 or less ii) more than 6 calls.

20. The Height of 10 males of a given locality found to be 70, 67, 62, 68 61, 68, 70, 69, 64, 66 inches. Is it reasonable to believe that the average height is 64 inches? Test at 5% significance level for 9 degree of freedom. (Give t0.05 = 1.83 for 9 d.f)

21. The following figures shows disease count from a region over a span of 1 year. Represent the data by a pie diagram.

DISEASE	COUNT
Jaundice	22
Tuberculosis	18
Typhoid	32
Malaria	15
Dengue	26

22. An average of 5 cars arrives per hour at a restaurant. Assume that the number of cars arriving per hour follows Poisson distribution.
    i) What is the probability that exactly 5 cars will arrive in a given hour?
    ii) What is the probability that at least 3 cars arrive in a given hour?

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Code No: 12266/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Subject : Computer Aided Drug Design (Elective-I/II)

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

Note: Answer Seven questions from Part –A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. Define 'Bioisosterism', Explain its significance
2. What are independent and dependent variables in QSAR analysis? Provide a model QSAR equation
3. Explain the significance of partition coefficient
4. Write briefly about de novo drug design
5. Differentiate between lead and drug
6. What is a database? Give its advantages
7. Define the terms 'bioactive conformer' and 'energy minimization'.
8. Explain briefly about global conformational minima in molecular modeling
9. What is a pharmacophore? How its determination is useful in drug design.
10. What are pharmaceutical databases? Give examples

Part B (1x14=14 marks)

11. Define 'Virtual screening'. Write in detail about drug-likeness screening
12. Explain Hansch analysis and its role in predicting biological activity. Write its advantages & Disadvantages
13. Describe various stages involved in drug discovery and development.

Part C (5x8=40 marks)

14. Explain about lead discovery based on traditional medicine
15. Classify bioisosteres with examples
16. What is bioinformatics? Explain various bioinformatics tools used in drug design
17. Describe Free-Wilson QSAR analysis
18. Explain the significance and determination of Hammet's substituent constant in QSAR analysis
19. Explain molecular docking process and its significance in drug design
20. Explain drug metabolism based lead discovery with examples
21. List out various cheminformatics tools used in drug design. Explain any one
22. What is molecular mechanics? Explain its role in molecular modeling

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Code No. 12005 / CBCS

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (Backlog) Examination, July 2021

Subject : Current Good Manufacturing Practice
(Open Elective)

Time: 2 Hours **Max. Marks: 70**

Note: Answer any four questions. **(4 x 17 ½ = 70 Marks)**

1 Write the USFDA guidelines applicable for manufacturing of pharmaceuticals.

2 Explain the evolution and principles of cGMP.

3 Write Labelling requirements of liquid orals and parenterals.

4 Describe the procedures for maintenance of pharmaceutical equipment.

5 Describe various elements of Total Quality Management.

6 Describe the procedures and role of ISO 14000 in environmental management systems.

7 Explain the general principles of analytical method validation.

8 Define and write general principles of Qualification, Calibration and Validation.

9 a) Explain the procedures for handling of market complaints.
b) Explain the critical parameters for validation of water systems.

10 Write the significance and modules of Common Technical Documentation.

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Code No. 12262/ PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main) Examination, July 2021

Subject: Pharma Marketing Management (Elective – I)

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

PART - A

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

1 Define marketing.
2 List the factors influencing for the selection of physician.
3 What are product line and product mix?
4 What is product portfolio analysis?
5 Name the components of promotional mix.
6 Enlist the channel members in physical distribution management.
7 What is the importance of pricing?
8 What are functions of distribution in marketing?
9 Write the motivational factors influencing PSR performance.
10 Write the need of global marketing.

PART - B

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

11 Explain the product life cycle management and its importance in product portfolio analysis.
12 Explain different promotional techniques for OTC products and role of regulatory aspects.
13 Describe the various physical channels of distribution in pharmaceutical business and explain the conflict in channels.

PART - C

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

14 Describe different components in marketing environment.
15 Explain the approaches to analyze consumer behavior.
16 Explain the role of retail pharmacist in market research.
17 Write in detail about the prescribing habits of physician.
18 Describe critical aspects of product management in pharmaceutical industry.
19 What are the duties of professional sales representative?
20 Write the factors to be considered in selection and training of PSR.
21 Write the salient features of drug price control order.
22 Differentiate between vertical and horizontal marketing.

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Code No: 12263/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Subject : Pharmaceutical Regulatory Science (Elective-I)

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

Note: Answer Seven questions from Part –A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. What are the responsibilities of RA department in a pharmaceutical industry?
2. Write the differences between IND, NDA and ANDA
3. Define Pharmacovigilance
4. Write the names of Drug regulatory authorities of different regions all over the world
5. What is the difference between orange book and purple book?
6. What are the different Acts involved in regulatory filling of drug products?
7. Enlist obligations of investigator in clinical trials
8. What are the different types of DMF?
9. Enlist the elements of e-CTD document
10. What are the different types of changes to approved ANDA?

Part B (1x14=14 marks)

11. Explain in detail about generic drug product development process. Add a note on advantages of generic products.
12. Discuss about the different types of ANDA para filings and write in brief about GDUFA.
13. Describe in detail about the phases of clinical trials.

Part C (5x8=40 marks)

14. Explain the concept of innovator and generic drug product
15. Discuss IND approval process
16. Explain about different routes of regulatory filing through MHA.
17. Justify the importance of documentation in pharmaceutical industries
18. Discuss about the documents required under Module – 2 of CTD
19. Describe the requirements for filing abbreviated new drug application
20. Discuss the need and role of independent ethics committee
21. What is the importance of safety monitoring in clinical trials?
22. What are the different stages involved in a pharmaceutical product life – cycle?

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Code No: 12264/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Subject : Pharmacovigilance (Elective-I)

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

Note: Answer Seven questions from Part –A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. Write down the WHO definition of "ADR"
2. What is De challenging and Re challenging of drugs in ADR detection
3. Describe the importance of safety monitoring of medicine
4. Write a short note on Daily Defined Dose (DDD)
5. Write the importance of vaccine safety surveillance
6. Write a short note on methods of Stimulating Reports in pharmacovigilance
7. What are the steps involved in the process of communication in pharmacovigilance
8. Describe the objectives of ICH guidelines
9. Write a short note on Schedule "Y"?
10. What are the differences in Indian and Global pharmacovigilance requirements?

Part B (1x14=14 marks)

11. a) Write a note on CIOMS working groups
    b) Write about Drug safety evaluation in Geriatrics population

12. a) Write briefly about safety data generation
    b) Write a note on Adverse events following immunization

13. a) Write a note on History of Pharmacovigilance
    b) Write about the establishment and operation of Drug safety department in industry

Part C (5x8=40 marks)

14. Write a note on Anatomical and therapeutic and chemical classification of drugs
15. Write a detailed note on Pharmacovigilance programme of INDIA (PvIP)
16. Write about comparative observational studies
17. Explain about the management of ADR
18. Write a detailed note on MedDRA
19. Write a note on Periodic safety update reporting
20. Write about the specialization resources for ADR's
21. Write a note on Geriatric related ADR with example focusing on Pharmacokinetic parameters
22. Write a note on Schedule Y of D & C act

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Code No: 12265/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main.) Examination, July 2021

Subject : Quality Control and Standardization of Herbals (Elective-I)

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

Note: Answer Seven questions from Part -A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. Define the terms herbal drug and crude drug.
2. What does GACP means and what are its objectives.
3. What is traditional medicine and herbal medicine
4. Write basic tests used for identification of any one herbal dosage forms.
5. Write the advantages and disadvantages of organic farming.
6. Explain the terms GLP, GMP, GAP.
7. What is chromatography? Mention various chromatographic techniques used in the standardization of herbal drugs.
8. Write the concepts of quality assurance in herbal drug industry.
9. What are chemical and biological markers. Give examples.
10. What is importance of research guidelines.

Part B (1x14=14 marks)

11. Explain ICH guidelines for the quality control of herbal drugs.
12. Describe WHO guidelines on GACP for medicinal plants.
13. Explain the methods and WHO guidelines for stability testing of herbal drugs.

Part C (5x8=40 marks)

14. What is GAP? Explain the various parameters of GAP.
15. Explain any two methods of evaluation of crude drugs.
16. Briefly explain Various aspects of GLP in Herbal Drug Industry.
17. Explain the importance of HPTLC method in the standardization of herbal drugs.
18. Explain different measures in monitoring of safety of herbal products
19. Write a note on regulatory requirement of herbal drugs
20. Explain the documents required for new drug application.
21. Give a protocol of standardization of herbal drugs.
22. Write a note on Efficacy of herbal medicines.

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Code No: 12267/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Subject : Cell and Molecular Biology (Elective-II)

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

Note: Answer Seven questions from Part –A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. Name the Cell organelle responsible for
   a) Electron Transport Chain b) Autolysis
2. Name the two scientists who proposed the Cell theory
3. What is RNA polymerase?
4. Define phagocytosis
5. Write any two functions of nucleosomes
6. Write the major difference between transduction and translation
7. Write any two differences between prokaryoteic and eukaryotic cells
8. What are the functions of protien kinases
9. What is denaturation?
10. What is the role of Primer in DNA replication?

Part B (1x14=14 marks)

11. Define Genetic code. Write the characteristics of Genetic code and explain the Lac operon hypothesis
12. Give an account of double stranded DNA with respect to its structure, function and replication.
13. Write an essay on interphase nucleus with the help of labelled diagram

Part C (5x8=40 marks)

14. Define plasma memberane. Explain the singer and Nicholson's membrane model of plasma membrane structure
15. Explain the functions of Golgi bodies, Ribosomes with labelled diagrams
16. What is Central Dogma of Molecular Biology? Enumerate the process of Protein synthesis with appropriate diagrams
17 Give an account on the structure and functions of the RNA and DNA molecules
18. Describe the structure and functions of tRNA. How does it differ from mRNA?
19. Describe the Watson and Crick model of DNA structure with labelled diagram
20. Briefly explain the process of meiosis with emphasis on Anaphase stage
21. What is Bacterial Transduction? Explain the process of Transduction in Bacteria
22. Distinguish between metaphase of mitosis and metaphase-1 of meiosis.

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Code No: 12268/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Subject : Cosmetic Science (Elective-II)

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

Note: Answer Seven questions from Part –A, any One question from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. Define and classify cosmetics
2. Write applications of humectants
3. What is Ceramide?
4. What is facewash? Enlist the ingredients used in face wash
5. Define SPF (Sun protection factor)
6. Write role of turmeric in skin care
7. What is the role of Neem & Clove in oral care products
8. Explain hair combing properties
9. Give the symptoms and treatment of dry skin
10. What is prickly heat?

Part B (1x14=14 marks)

11. Explain basic structure of skin with neat labelled diagram. Write in detail functions of skin
12. Discuss the formulation building blocks of i) Hair care product ii) Oral care Product
13. Write a note on : a) Sebumeter b) Melanine pigmentation

Part C (5x8=40 marks)

14. Explain hair growth cycle
15. Write in detail about evolution of cosmeceuticals from cosmetics
16. Discuss various advantages and disadvantages of cold cream
17. Define and classify surfactants with example. Write applications of surfactant
18. Give BIS (Bureau of Indian Standards) specification for tooth paste
19. Explain analytical methods for skin cream
20. Write a note on Syndet bars
21. Explain mechanism of action of antiperspirants and deodorants
22. Explain various elements of healthy scalp

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Code No: 12269/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Subject : Advanced Instrumentation Techniques (Elective-II)

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

Note: Answer Seven questions from Part –A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. Define calibration?
2. Write the principle involved in differential thermal analysis
3. Write the importance of Radio Immunoassay?
4. Define Validation?
5. Discuss the principle involved in Liquid – liquid extraction technique?
6. Discuss the calibration procedure for electronic balance?
7. Write the principle involved in Mass spectrometry?
8. Write the principle involved in H-NMR?
9. Write about powder diffraction method?
10. Mention hyphenated Techniques and their advantages

Part B (1x14=14 marks)

11. a) What do you mean by chemical shift? Explain the various factors influencing it?
    b) Write about Spin-Spin Coupling and Coupling Constant?

12. a) Draw a sketch diagram and Explain the instrumentation of mass spectrometer
    b) Write about different Fragmentation techniques in mass spectrometry

13. a) Discuss the following hyphenated techniques

    a) $\frac{C}{LC}$ - MS/MS b) GC-MS/MS

Part C (5x8=40 marks)

14. Explain the calibration procedure of a) UV spectrophotometer
    b) IR Spectrophotometer
15. Write the instrumentation and applications TGA
16. Write about X-ray crystallography?
17. Explain MALDI & FAB ionization techniques in Mass Spectrometry
18. Explain Spin - Spin Coupling in NMR?
19. Write the calibration of fluorimeter & flame photometer?
20. Write the instrumentation and applications DSC?
21. Explain about HPTLC/MS?
22. Write about applications and limitations of Radio immunoassay?

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Code No: 12271/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII - Semester (PCI) (Main) Examination, July 2021

Experimental Pharma Cology

Subject : (Pharmacological Screening Methods) (Elective-II)

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

Note: Answer Seven questions from Part –A, any One questions from Part- B and any Five questions from Part- C

Part A (7x3=21 marks)

1. List the different species of animals used in laboratory
2. What are transgenic animals and mutant animals?
3. List the common routes of drug administration in animals
4. What is study design?
5. List various agents which cause inflammation
6. What are coagulants and anticoagulants?
7. What is Euthanasia and list the techniques of euthanasia
8. What is Students t test and where is it used?
9. How is does selected in preclinical screening methods?
10. What is preclinical data analysis?

Part B (1x14=14 marks)

11. Describe the preclinical screening procedures for antidiabetic drugs
12. Define inflammation. List out the methods available to induce inflammation and describe on acute and one chronic model in the screening of anti-inflammatory agents.
13. Discuss the *in vitro* and *in vivo* techniques for screening of anticancer agents

Part C (5x8=40 marks)

14. Write a brief note on screening methods of antinflammatory drugs.
15. Explain the screening methods for diuretics
16. What is Research? Mention the significance of selection of research topic
17. What are the OECD guidelines for maintenance and breeding of laboratory animals?
18. Explain the techniques of blood collection from animals
19. Write a note on methods involved in the screening of nootropics
20. What are antiasthamatic agents? Discuss the methods involved in their screening
21. Write the preclinical screening methods of sympathmimetics
22. Describe the preclinical screening methods of antihyperlipidemic drugs.

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