FACULTY OF PHARMACY **Code No. D-8105/PCI**

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.

..2

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.

* * *

Code No. D-8116/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination, July 2022
Subject: Experimental pharmacology
(Pharmacological screening methods) (Elective-II)

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

PART - A

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

1. Name some common lab animals and their use in research.
2. Enlist some routes of drug administration in laboratory animals.
3. Write the importance of negative and positive control groups.
4. What are Anti-Psychotics? List out the screening models.
5. List out the drugs acting on the eye. Name the models.
6. Define parasympthomimetics. Write the principle of any one screening model.
7. Define anti-cancer drugs. Write the importance of cell lines for pre-clinical anti-cancer research.
8. Describe about aspirin induced ulceration model.
9. Write the mechanism of Alloxan induced diabetes model.
10. Write about preclinical data analysis.

PART - B

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

11. Describe the screening models for evaluation of a compound for Anti-hypertensive drugs.
12. Define inflammation. List out the methods available to induce inflammation. Describe one acute and one chronic model in the screening of Anti-inflammatory agents.
13. Describe in detail about regulations for laboratory animal care as per CPCSEA guidelines.

PART - C

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

14. Describe the techniques for collection of blood in the animals.
15. Write the applications of transgenic animals in preclinical research.
16. Explain in detail about one screening model for evaluating anti-asthmatics.
17. Discuss about screening models of Anti-depressant drugs.
18. What are local anesthetics? Enlist the screening models. Describe any model in detail.
19. Write any 2 screening models for sympathomimetics.
20. Write about screening methods for diuretics.
21. Write about One-way ANOVA.
22. Discuss about research hypothesis and study design in research.

****

Code No. D-8112/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII Semester (PCI) (Main & Backlog) Examination, July 2022
Subject: Cell & Molecular Biology (Elective-II)

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

PART - A

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

1. What is the function of Restriction endonucleases?
2. Differentiate microtubules and microfilaments.
3. Define chromatin.
4. What is osmosis and diffusion?
5. Differentiate SER and RER.
6. Discuss the role of the enzyme DNA ligase plays during DNA replication.
7. Mention different sub-stages of prophase-2 of meiotic cell division.
8. Write any two differences between Meiosis-1 and meiosis-2.
9. Give the sequence of events occurring during prophase of mitosis.
10. Write the characteristic feature of telophase M phase?

PART - B

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

11. What are chromosomes? Write a detailed account on discovery, structure, number and significance of chromosomes in prokaryotic and eukaryotic cells. Draw labelled diagrams wherever necessary.
12. What are the structural and regulatory genes? Explain genetic control of protein synthesis.
13. Briefly describe about giant chromosomes. Explain the structure and functions of nucleus and its components.

PART - C

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

14. Write an account on the types of RNA. Discuss their functions.
15. (i) Construct a complete transcription unit with promnoter and terminator on the basis A T G C A T G C A T A C
    (ii) Write the RNA strand transcribed from the above transcription unit along with its polarity.
16. Explain the role of DNA-dependent RNA polymerse in transcription.
17. What is Bacterial Transduction? Explain the process of Tansduction in Bacteria.
18. Distinguish between mitosis and meiosis with appropriate diagrams.
19. Describe the stages of prophase-1 of meiosis.
20. Describe the stages of mitosis.
21. Describe the Watson and Crick model of DNA structure with labelled diagram.
22. Define Cell cycle. Explain the sequence of events in cell cycle with the aid of a labelled diagram.

****

Code No.D-8113/PCI

FACULTY OF PHARMACY

B. Pharmacy VIII-Semester (PCI) (Main & Backlog) Examination, July 2022
Subject: Cosmetic Science (Elective – II)

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

PART – A

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

1. Write the classification of cosmetic.
2. What are meant by cosmetics as Quasi and OTC drugs?
3. Write a note on preservatives used in cosmetic formulations.
4. Write a note on mouth washes.
5. Write a note on role of clove in oral care.
6. Write the uses of clove.
7. Write a note on skin color measurement.
8. Write the uses of syndet bars.
9. Write about causes and prevention of acne.
10. Write a note on hair combing properties.

PART – B

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

11. Enlist the excipients used in cosmetics formulations. Describe the following excipients with examples (a) Surfactants (b) Emollients and (c) Rheology modifiers.
12. (a) Write the role of Henna and Amla in hair care.
    (b) Write the principles and applications of Sebumeter and Cornemeter.
13. Write the causes and prevention of following problems
    (a) Dry skin (b) Dandruff (c) Hair fall (d) Body odor.

PART – C

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

14. Write a note on evolution of cosmeceuticals from cosmetics.
15. Write a note on hair growth cycle.
16. Write formulation and mechanism of action of Antiperspirants & deodrants.
17. Write about toothpaste for bleeding gums and sensitive teeth.
18. Write about sun protection formulations.
19. Write role of Aloe and Turmeric in skin care.
20. Write BIs specifications analytical methods for skin creams.
21. Write a note on measurement of TEWL by Tewameter.
22. Write about causes and prevention of dry skin.

* * *

Code No: D-8115/PCI

FACULTY OF PHARMACY

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

Subject: Dietary Supplements and Nutraceuticals (Elective-II)

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

PART – A

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

1. Define nutraceuticals and dietary supplements.
2. Write short notes on Reactive Oxygen Species.
3. What are probiotics and give examples.
4. Give the occurrence and medical benefits of Lycopene.
5. Explain the importance of synthetic anti-oxidants.
6. Write about dietary fibres as functional food ingredients.
7. Give the source, chemical nature and uses of Oats and Rice bran.
8. Explain about enzymatic antioxidant defence.
9. What are Probiotics and prebiotics.
10. Write about AGMARK on food safety.

PART – B

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

11. Explain in detail the effect of processing, storage and interactions of various environmental factors on the potential of neutraceuticals.
12. a) Explain the role of Glutathione peroxidase and Superoxide dismutase.
    b) Write about public health nutritional benefits in a community.
13. Explain various mechanisms of free radicals involved in the treatment of disorders.

PART – C

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

14. Explain the role of anti-oxidants in the treatment of kidney damage.
15. Explain in detail about Carotenoids.
16. Explain the free radicals theory of ageing.
17. Give the pharmacopeial specifications for complex carbohydrates.
18. Give the occurrence, chemical nature and uses of Gingko and Ginseng.
19. Explain the regulatory aspects of FSSAI on food safety.
20. Explain the role of free radicals with lipids.
21. Define flavonoids and give the source and medicinal benefits of any two flavonoids.
22. Write in detail about adulteration of foods?

****

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?

*****

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.

*****

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.

* * *

Code No. D-8119/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.

****

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.

* * *

Code No: 12261/PCI

FACULTY OF PHARMACY

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

Subject: Social and Preventive Pharmacy

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 about nutritional deficiencies.
2. Define public health.
3. Write about personal hygiene and health care.
4. Write about drug addiction-drug substance abuse.
5. Write a short note on national programme for prevention and control of deafness Objectives and outcome.
6. Write about health promotion.
7. Write about social health programme.
8. Write a note on improvement in rural sanitation.
9. Write a note on integrated disease surveillance program.
10. Write a note on national urban health mission.

Part B (1x14=14 marks)

11. a) Explain about malnutrition and its prevention.
    b) Explain about balanced diet.
12. Explain general principles of prevention and control of cholera, dengue, pneumonia, hypertension and diabetes mellitus.
13. a) Explain national health program, its objectives, functioning and outcome of HIV&AIDS control programe.
    b) Explain about national leprosy control programe.

Part C (5x8=40 marks)

14. Explain universal immunization programme and pulse polio programe.
15. Explain national health intervention programe for mother and child.
16. Explain national tobacco control programme.
17. Explain national malaria prevention program.
18. Write a note on functions of PHC and improvement in rural sanitation.
19. Explain general principles of prevention and control of ebola virus and dengue.
20. Explain national mental health program objectives, functioning and outcomes.
21. Explain national programme for control of blindness objectives, functioning and outcomes.
22. Explain the concept of prevention and control of disease and social causes of diseases

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 labeled 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

****

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=14marks)

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) $^{C}_{LC}$ - 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?

****

Code No: 12271/PCI

FACULTY OF PHARMACY

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

Experimental Pharmacology

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.

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.

****

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?

****

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

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.

****

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?

****