Code No: E-12465/PCI

FACULTY OF PHARMACY

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

Subject: Modern Bio Analytical Techniques

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

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

1. (a) Explain different sample preparation approaches involved in bioanalytical methods. [10]
   (b) Explain the following validation parameters in bioanalytical method validation as per USFDA guidelines. [5]
   (i) Linearity
   (ii) Recovery studies

2. (a) Describe the compedial methods of dissolution testing. [8]
   (b) Write about different experimental methods for soluibility determination. [7]

3. (a) Discuss drug-protein binding interaction with examples. [8]
   (b) What is enzyme induction? Discuss drug interaction due to enzyme induction. [7]

4. (a) Write about the basic equipment used in the cell culture lab. [7]
   (b) Describe different techniques for the characterization of cells along with their applications. [8]

5. (a) Write about the clinical significance of Bioequivalence studies. [5]
   (b) Explain different methods for assessment of the bioavailability of new drug products. [10]

6. (a) Discuss Biopharmaceutical factors affecting drug bioavailability. [10]
   (b) Write about cryopreservation and storage of cells. [5]

7. (a) Discuss different approaches for the quantification of metabolites. [9]
   (b) Write about different cell culture media. [6]

8. (a) Write about in-vivo and in-vitro methods for checking the cellular permeability of new drug products. [9]
   (b) Write in brief about drug interactions linked to transporters. [6]

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Code No: E-12464/PCI

FACULTY OF PHARMACY

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

Subject: Advanced Instrumental Analysis

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

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

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

   (b) Write about Preparative HPLC.

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

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

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

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

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

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

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

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Code No: E-12467/PCI

FACULTY OF PHARMACY

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

Subject: Herbal & Cosmetic Analysis

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

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

1. (a) Discuss the standardization of herbal drugs according to WHO guidelines. [10]
   (b) Differentiate between herbal drugs and conventional drugs. [5]

2. (a) Explain the determination of pesticide residues and microbial contamination in herbal formulations? [8]
   (b) Write a note on Global marketing management? [7]

3. (a) Discuss adulterant screening of herbal drugs using HPLC? [7]
   (b) Explain with an example the Ayurvedic Pharmacopoeia of India? [8]

4. (a) Explain WHO guidelines for safety monitoring of natural medicine. [10]
   (b) Write notes on bio drug-food interactions with suitable examples. [5]

5. (a) Explain the Indian standard specification laid down for sampling and testing of dental products. [8]
   (b) Write a note on analysis of skin creams as per BIS. [7]

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

7. Write about Indian patent law applicable for herbal drugs and natural products. [15]

8. Discuss the quality of raw materials and general methods of analysis of raw materials used in cosmetic manufacture as per BIS? [15]

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Code No: E-12466/PCI

FACULTY OF PHARMACY

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

Subject: Quality Control and Quality Assurance

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

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

1. (a) Write in detail about ICH Q series guidelines. [8]
   (b) Explain about Quality control and Quality assurance. [7]
2. Write about the following
   (a) Organization and personnel responsibilities. [5]
   (b) Maintenance of sterile areas. [5]
   (c) Personal records and environmental control. [5]
3. Define IPQC. Write in detail about different IPQC tests for tablets and parenterals. [15]
4. (a) What is SOP? Write about different techniques to write SOP. [8]
   (b) Write a note on Quality audit plan. [7]
5. (a) Write about mix-up and cross contamination. [8]
   (b) Explain about Expiry date calculation and calculation of yields. [7]
6. Explain various quality control tests for Glass as a packaging material. [15]
7. (a) Write a note on Production record review. [7]
   (b) Aspectic process control. [8]
8. Discuss Good laboratory practices for quality control laboratory in detail. [15]

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Code No: E-12260/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II-Semester (PCI) (Backlog) Examination,
April / May 2023
Subject: Regulatory Aspects of Drugs and Cosmetics

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

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

1. (a) Write a note on regulatory approval process for New Drug Application. [8]
   (b) Write a note on Hatch-Waxmann Act. [7]

2. (a) Write a note on Drug Master Files system in US. Add a note on Orange book and Purple Book. [8]
   (b) Write a note on legislations and regulations for import, manufacture and sale of cosmetics in Canada. [7]

3. (a) Describe Certificate of Suitability (CoS) in EU. [6]
   (b) Write a note on Marketing Authorization Procedures in EU. [9]

4. (a) Describe the organization and structure of EMA and EDQM. [8]
   (b) Write a note on WHO GMP. [7]

5. (a) Write a note on drug regulatory approval process in Japan. [10]
   (b) Write a note on regulatory considerations for packaging and labelling in Japan. [5]

6. (a) Explain Emerging Market. Write a note on Certificate of Pharmaceutical Product (CoPP). [8]
   (b) Write a note on ASEAN, PANDRH &SADC committees. [7]

7. (a) Write a note on legislations and regulations for import and sale of cosmetics in GCC countries. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region.[7]

8. (a) Write a note on marketing authorization requirements for drugs in Saudi Arabia & UAE. [8]
   (b) Write a note on ACTD. [7]

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CODE NO: E-12262/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Medical Devices

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

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

(5 x 15 = 75 Marks)

1. (a) Differentiate medical devices, IVDs and Combination Products. [6]
   (b) Write the organization structure, purpose, and functions of IMDRF. [9]

2. (a) What are the various working groups in GHTF. [8]
   (b) Briefly describe about Global Medical Device Nomenclature (GMDN). [7]

3. (a) Write about Quality System Regulations of Medical Devices: ISO 13485. [8]
   (b) Write about Adverse Event Reporting of Medical device. [7]

4. (a) Write the regulatory approval process for Medical Devices as Per USFDA & EU. [9]
   (b) Write about Investigational Device Exemption (IDE). [6]

5. (a) Write about the Labelling requirements for 21 CFR Part 801. [8]
   (b) Describe in detail about Unique Device Identification (UDI). [7]

6. (a) Write the regulatory approval process for In vitro Diagnostics (In Vitro Diagnostics Directive. [8]
   (b) Write a note on InVitro diagnostics classification and approval process. [7]

7. Write the Regulatory Registration procedure for Medical Devices as per ASEAN, China & Japan. [15]

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

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Code No: E-12261/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Backlog) Examination, April / May 2023

Subject: Regulatory Aspects of Herbal & Biologics

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

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

1. (a) Describe the data requirements in clinical trial application. [7]

   (b) What are similar biologics? Write about the present status and guidelines in India. [8]

2. (a) Write the differences between generics and biosimilars. [6]

   (b) Write about Pharmacovigilance. [9]

3. Describe the regulatory requirements and approval of biologics and biosimilars as per EU. [15]

4. Explain the procedure for approval of clinical trials, labeling and packing of similar biologics in India. [15]

5. (a) Write the regulations and safety of herbals in India. [9]

   (b) Discuss the labeling and packing of biologics in US. [6]

6. Write about:

   (a) IHN [5]

   (b) ISBT [5]

   (c) Post market data for similar biologics [5]

7. Discuss the regulations of blood and blood products in India and EU. [15]

8. (a) Describe the data requirements for preclinical studies of biologics in India. [7]

   (b) Write about development and approval of biosimilars products in US. [8]

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Code No: E-12263/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Food & Nutraceuticals

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

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

(5 x 15 = 75 Marks)

1. (a) What are medical foods , functional foods, and Nutraceuticals? Giving examples explain their role in health care. [9]
   (b) Write about the scope and opportunities in Nutraceuticals Market. [6]
2. (a) What is NSF certification? Write the role of NSF international in Nutraceuticals Industries. [8]
   (b) Mention the critical considerations about good manufacturing practices for Nutraceuticals. [7]
3. (a) Discuss the regulations for import of Nutraceuticals according to FSSAI. [8]
   (b) Write a note on Recommended Dietary Allowances (RDA) in India. [7]
4. (a) Write a note on Labelling requirements and claims for dietary supplements in the USA. [6]
   (b) Discuss the US FDA Food Safety Modernization Act. [9]
5. (a) What is EFSA? Explain its organization and functions. [8]
   (b) Write a note on Novel food ingredients in EU. [7]
6. Give an overview of the WHO guidelines on nutrition. [15]
7. (a) Describe the functions of Chief Executive Officer of Food Authority of India. [8]
   (b) Elaborate the Differences between Recommended dietary allowances (RDA) of India & US. [7]
8. Write short notes on
   (a) Labelling requirements for dietary supplements in the EU. [7.5]
   (b) Prebiotics and probiotics. [7.5]

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Code No: E-12115/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Drugs and Cosmetics

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

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

1. (a) Write a note on regulatory approval process for Investigational New Drug. [8]
   (b) Write a note on Organisation structure and functions of FDA. [7]

2. Write in detail about regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in USA. [15]

3. (a) Describe Active Substance Master Files (ASMF) system in EU. [7]
   (b) Write a note on Marketing Authorization Procedures in EU. [8]

4. (a) Explain the Legislations and regulations for manufacture and sale of cosmetics in Australia. [9]
   (b) Write a note on Eudralex directives for human medicines. [6]

5. (a) Write a note on drug regulatory approval process in Japan. [10]
   (b) Write a note on Organization of PMDA. [5]

6. (a) Explain Emerging Market. Discuss about various committees across the globe. [8]
   (b) Write a note on Certificate of Pharmaceutical Product (CoPP). [7]

7. (a) Write a note on ACTD. [8]
   (b) Describe the regulatory requirements for registration of drugs in ASEAN region. [7]

8. (a) Write a note on marketing authorization requirements for drugs in GCC countries. [8]
   (b) Write a note on legislations and regulations for import and sale of cosmetics in CIS countries. [7]

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Code No: E-12117/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Medical Devices

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

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

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

2. (a) Write Quality Principles and essential principles of Medical Devices & IVDs. [9]
   (b) Write a note on Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011). [6]

3. (a) Write a note on Quality Risk Management of Medical Devices: ISO 14971. [8]
   (b) Write a note on validation and verification of medical device. [7]

4. (a) Write the regulatory approval process for Medical Devices (510k). [8]
   (b) Briefly describe Premarket Notification, Pre-Market Approval (PMA). [7]

5. (a) Write about the Quality System Requirements for 21 CFR Part 820. [8]
   (b) Write the Classification of Medical Devices & IVD as per US FDA & EU & ASEAN. [7]

6. (a) Write in detail about the regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive). [8]
   (b) Write a note on CE Certification process. [7]

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

8. (a) Write a note on IMDRF Study groups. [7]
   (b) Write a note on post marketing survelliance of Medical devices. [8]

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Code No: E-12118/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Food & Nutraceuticals

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

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

1. (a) What are dietary supplements? Giving examples critically explain their role in human body. [7]

   (b) Discuss about the history of food and Nutraceutical Regulations. [8]

2. (a) Write briefly about GMP for Nutraceuticals. [7.5]

   (b) Give an account of the NSF standards for food and dietary supplements. [7.5]

3. (a) Describe the FSSAI regulations pertaining to import and sale of Nutraceutical products in India. [7]

   (b) Describe the organization and functions of food safety and standards authority of India. [8]

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

5. (a) Write about the organisation and functions of European Food safety Authority (EFSA). [8]

   (b) Explain EU regulations for sale of Nutraceuticals. [7]

6. (a) What are medical foods, functional foods and Nutraceuticals? Giving examples explain their role in health care. [8]

   (b) Discuss about the history of Food and Nutraceutical Regulations. [7]

7. Discuss the WHO guidelines on nutrition of pregnant women. [15]

8. Write short notes on:

   (a) Labelling requirements and claims for dietary supplements in the USA. [7.5]

   (b) Novel food ingredients in EU. [7.5]

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Code No: E-12116/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II Semester (PCI) (Main) Examination, December 2022

Subject: Regulatory Aspects of Herbal & Biologics

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

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

1. Discuss in detail about good manufacturing practices and its advantages. [15]

2. (a) What are different biological products? Give the differences between generic and biosimilars. [7]
   (b) Describe about post marketing data requirements for similar biologics. [8]

3. (a) Describe the data requirements in clinical trial application. [7]

   (b) What are similar biologics? Write about the present status and guidelines in India. [8]

4. Discuss the regulations of blood and blood products in India and EU. [15]

5. Explain the procedure and data requirements for approval of clinical trial in India. [15]

6. (a) Describe the regulation and safety of herbal in India. [8]

   (b) Write about the preclinical requirements for biologics in US. [7]

7. Write about:

   (a) International Haemovigilence network (IHN) [7]

   (b) International society of Blood transfusion (ISBT) [8]

8. Discuss about the development and regulations of biologics and similar biological in EU. [15]

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