Code No: G-13170/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Regulatory Affairs) (Backlog) Examination, June 2025

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 Abbreviated New drug Application (ANDA). (8)
   (b) Write a note on organization structure and functions of FDA. (7)

2. (a) Describe Active substance master files (ASMF) system in EU. (6)
   (b) Write a note on Marketing Authorization Procedures in EU. (9)

3. (a) Write a note on Post marketing Surveillance in Japan. (6)
   (b) Write a note on regulations for Manufacture and sale of cosmetics in Japan. (9)

4. (a) Explain Emerging Market. Discuss about various committees across the globe. (6)
   (b) Write a note on WHO-GMP. (9)

5. (a) Write a note on ACTD. (8)
   (b) Write a note on marketing authorization requirements for drugs in GCC countries. (7)

6. (a) Write a note on regulatory requirements for changes to an approved NDA/ANDA. (6)
   (b) Explain the Legislations and regulations for manufacture and sale of cosmetics in Australia. (9)

7. (a) Describe drug regulatory approval process in Japan. (9)
   (b) Write a note on WHO-prequalification programme. (6)

8. (a) Write a note on legislations and regulations for import and sale of cosmetics in CIS countries. (7)
   (b) Write a note on regulatory requirements for registration of drugs in ASEAN countries. (8)

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Code No. G-13173/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Regulatory Affairs) (Backlog) Examination, June 2025

Subject: Regulatory Aspects of Food & Nutraceuticals

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

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

1. (a) Define nutraceuticals. Write a detailed note on history, scope and classification of Nutraceuticals. [9 Marks]
   (b) Explain the role of dietary supplements in healthcare giving suitable examples. [6 Marks]

2. (a) What is NSF Certification? Explain the history and process for NSF Certification. [8 Marks]
   (b) Explain GMP of manufacturing, import and sale of Nutraceutical product in India. [7 Marks]

3. (a) Explain the role and responsibilities of WHO Nutrition Guidance Expert Advisory Group (NUGAG). [8 Marks]
   (b) Give a brief WHO guideline on 'Sugar intake of Adults and Children for protection against diabetics" [7 Marks]

4. (a) Explain in detail of FSSAI organization and Functions. [8 Marks]
   (b) Write a note on Recommended Dietary Allowances (RDA) in India. [7 Marks]

5. (a) Write a note on Labelling requirements and claims for dietary supplements in the USA. [6 Marks]
   (b) Discuss the US FDA Food Safety Modernization Act. [9 Marks]

6. (a) What is EFSA. Explain its organization and functions. [8 Marks]
   (b) Explain EU regulations for sale of nutraceuticals. [7 Marks]

7. (a) Explain the role of prebiotics and probiotics in healthcare giving suitable examples. [8 Marks]
   (b) Elaborate the Difference between Recommended dietary allowances (RDA) of EU and US. [7 Marks]

8. Write short notes on
   (a) Dietary Supplement Health and Education Act. [7.5 Marks]
   (b) Novel foods and their regulations [7.5 Marks]

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Code No: G–13172/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Regulatory Affairs) (Backlog) Examination, June 2025

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) Briefly describe about Global Medical Device Nomenclature (GMDN). (7)
   (b) Write a note on history of Medical Device Regulation. (8)

2. (a) Write a note on Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011). (8)
   (b) Write a note on clinical investigation Plan (CIP) of Medical Devices. (7)

3. (a) Write about Investigational Device Exemption (IDE). (8)
   (b) Briefly describe Pre-Market Approval (PMA). (7)

4. (a) Write the regulatory approval process for In vitro Diagnostics for EU. (7)
   (b) Write the regulatory approval process for Medical Devices as Per EU. (8)

5 (a) Write a note on IMDRF Study groups. (8)
   (b) Write a note on Quality system requirements for medical devices for ASEAN region. (7)

6. (a) Differentiate medical devices and combination products. (6)
   (b) Write a note on ISO 13485. (9)

7. (a) Describe in detail about Unique Device Identification (UDI) (8)
   (b) Write a note on 21 CFR part 801. (7)

8. (a) Write a note on CE certification process. (6)
   (b) Write the Regulatory Registration procedure for Medical Devices as per Japan. (9)

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Code No: G-13171/PCI

FACULTY OF PHARMACY

M. Pharm (Pharma. Regulatory Affairs) II - Semester (PCI) (Backlog) Examination, June 2025

Subject: Regulatory Aspects of Herbal & Biologicals

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

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

1. Describe in detail about the regulatory requirements and legislations of herbal products in India and USA. (15)

2. Describe the registration, licensing procedure and quality assessment of vaccines in India. (15)

3. Write about (5+5+5)
   (a) Plasma Master file
   (b) TSE evaluation
   (c) Stability testing of biologics

4. Write about development and regulatory approvals of biologics and similar biologics in European Union. (15)

5. (a) Write about Pharmacovigilance. (5+10)
   (b) Write about NDA of biosimilars in USA

6. Describe the Good manufacturing practices in similar biologics in INDIA. (15)

7. Write about (5+5+5)
   (a) IHN
   (b) ISBT
   (c) Post market data for similar biologics

8. Give the differences between (5+5+5)
   (a) Generic drugs and biosimilars
   (b) Biologics and Similar Biologics
   (c) Generic drugs and branded drugs.

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Code No: G-13057/PCI

FACULTY OF PHARMACY

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

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 Hatch-Waxmann Act. (8)
   (b) Write a note on Code of Federal Regulations. (7)

2. (a) Describe Certificate of Suitability (CoS) in EU. (6)
   (b) Describe Eudralex directives for human medicines. (9)

3. (a) Write a note on drug regulatory approval process in Japan. (10)
   (b) Write a note on organization of PMDA. (5)

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

5. (a) Write a note on legislations and regulations for import and sale of cosmetics in Brazil. (8)
   (b) Describe the regulatory requirements for registration of drugs in China and South Korea. (7)

6. (a) Write a note on legislations and regulations for import, manufacture and sale of cosmetics in Canada. (9)
   (b) Describe the content of IMPD. (6)

7. (a) Write a note on regulatory considerations for packaging and labelling in Japan. (8)
   (b) Write a note on WHO GMP. (7)

8. (a) Write a note on Orange book and Purple Book. (6)
   (b) Write a note on ACTD. (9)

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Code No: G-13058/PCI

FACULTY OF PHARMACY

M. Pharm (Pharma. Regulatory Affairs) II - Semester (PCI) (Main & Backlog) Examination, December 2024

Subject: Regulatory Aspects of Herbal & Biologicals

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

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

1. (a) What are biologics and similar biologics? Write the regulatory requirements for development of similar biologics. (10+5)
   (b) Data requirement for preclinical studies.

2. (a) Write about labeling and packing of biologics and similar biologics. (5+5+5)
   (b) Post market requirements for similar biologics
   (c) Difference between generic drugs and biosimilars.

3. Describe in detail about the development and approval of biologics and biosimilars in USA. (15)

4. Write about (5+5+5)
   (a) Plasma Master file
   (b) TSE evaluation
   (c) Stability testing of biologics

5. (a) Describe the regulatory requirement for blood and blood products. (9+6)
   (b) Write the clinical evaluation of vaccines in India.

6. Give an informative note on (8+7)
   (a) International society of blood transfusion
   (b) International Haemovigilence Network

7. Describe the safety and quality regulations of herbal products in India. (15)

8. (a) Write about Pharmacovigilance. (5+10)
   (b) Write about NDA of biosimilars in USA.

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Code No: G-13059/PCI

FACULTY OF PHARMACY

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

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) Define Medical Device. Describe in detail about the risk based classification of Medical Devices. (8)
   (b) Write the product lifecycle of Medical Devices. (7)

2. (a) Write a note on Quality Risk Management of Medical Devices: ISO 14971. (8)
   (b) Write about Adverse Event Reporting of Medical device. (7)

3. (a) Write the regulatory approval process for Medical Devices (510k). (8)
   (b) Write a note on Quality system requirements 21 CFR Part 820. (7)

4. (a) Write a note on CE Certification process. (6)
   (b) Write the Classification of Medical Devices & IVD as per US FDA & EU & ASEAN. (9)

5. (a) Write a note on IMDRF guidance documents. (8)
   (b) Describe clinical evaluation of medical devices as per China. (7)

6. (a) Describe Essential principles of Medical Devices and IVDs. (8)
   (b) Write about Quality System Regulations of Medical Devices: ISO 13485. (7)

7. (a) Describe organization structure and functions of IMDRF. (7)
   (b) Write about the Labelling requirements 21 CFR Part 801. (8)

8. (a) Write in detail about the regulatory approval process for Active Implantable Medical Device Directive. (8)
   (b) Write the Quality System requirements for Medical Devices for ASEAN. (7)

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Code No. G-13060/PCI

FACULTY OF PHARMACY

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

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 is the scope of nutraceutical market in India. [5]
   (b) Explain with examples, the role of functional foods and medical foods in healthcare. [10]

2. (a) Write a note on Good manufacturing practices for Nutraceuticals & dietary supplement production. [7.5]
   (b) Give an account of the NSF standards for food and dietary supplements. [7.5]

3. (a) Write note on food safety standard act 2006 enlist the problem for implementation of acts. [7]
   (b) Describe the functions of Chief Executive Officer of Food Authority of India. [8]

4. (a) Summarize the USFDA Food Safety and Modernization Act regulations with respect to dietary supplements . [8]
   (b) Write a note on Dietary Supplement Health and Education Act. [7]

5. Write about the organization and functions of European Food Safety Authority (EFSA). Explain EU regulations for sale of nutraceuticals. [15]

6. (a) Write a note on Prebiotics and Probiotics. [8]
   (b) Discuss about the history of Food and Nutraceutical Regulations. [7]

7. (a) Explain European regulation on Novel Foods [8]
   (b) Write a note on Novel food ingredients in EU. [7]

8. Write short notes on
   (a) Labelling requirements and claims for dietary supplements in the USA [7.5]
   (b) WHO guidelines for iron in pregnancy [7.5]

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Code No: F-7236/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) II - Semester (PCI) (Backlog) Examination, June 2024

Subject: Regulatory Aspects of Herbal & Biologicals

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

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

1. Discuss in detail about Good manufacturing practices India. [15]

2. What is Herbal medicine? Write quality, safety and legislations about herbal products in India. [15]

3. Discuss about regulatory requirements for blood, blood components and blood products in USA and India. [15]

4. Write about [8+7]
   (a) Post market data requirements for Similar Biologics.
   (b) Data requirements for clinical trials applications.

5. Give an informative note on [9+6]
   (a) Good document practices in India.
   (b) What are biologics, biosimilars, Reference product, interchangeable product?

6. Explain the regulations, approval, labeling and packing of biologics and biosimilars in US. [15]

7. Explain the safety, stability, labeling and packing protocols of Biosimilars in EU. [15]

8. (a) Explain data requirement of Market authorization of Biosimilars and Biologics in India. [8+7]
   (b) Explain labeling, packing requirements for biologics and biosimilars in India.

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Code No: F-7235/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) II - Semester (PCI) (Backlog) Examination, June 2024
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 Abbreviated New Drug Application. [8]
   (b) Write a note on Code of Federal Regulations. [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 Eudralex directives for human medicines. [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 CIS countries. [8]
   (b) Describe the regulatory requirements for registration of drugs in China and South Korea. [7]

8. (a) Write a note on marketing authorization requirements for drugs in GCC countries. [8]
   (b) Write a note on ACTD. [7]

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Code No: F-7237/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Medical Devices

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

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

1. (a) Describe Essential principles of Medical Devices and IVDs. [6]
   (b) Write the product lifecycle of Medical Devices. [9]

2. (a) Describe Summary Technical Document (STED). [8]
   (b) Briefly describe about Global Medical Device Nomenclature (GMDN). [7]

3. (a) Write a note on Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011). [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) Briefly describe Premarket Notification, Pre-Market Approval (PMA). [6]

5. (a) Write about the Quality System Requirements 21 CFR Part 820. [8]
   (b) Describe in detail about Unique Device Identification (UDI). [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 InVitro diagnostics classification and approval process. [7]

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

8. (a) Write a note on post marketing surveliance of Medical devices. [8]
   (b) Write a note on IMDRF guidance documents. [7]

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Code No: F-7238/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) II-Semester (PCI) (Backlog) Examination, June 2024

Subject: Regulatory Aspects of Food & Nutraceuticals

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

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

1. (a) Write a note on classification of Nutraceuticals. [7]
   (b) Write about the Scope and Opportunities in Nutraceutical Market. [8]

2. (a) Mention the critical considerations about good manufacturing practices for Nutraceuticals. [8]
   (b) Give an account of the NSF standards for food and dietary supplements. [7]

3. (a) Write a brief note on Food Safety and Standards Act. [8]
   (b) Explain the regulations for import, manufacture and sale of nutraceutical products in India. [7]

4. (a) Explain U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements. [8]
   (b) Write a note on Labelling Requirements and Label Claims for Dietary Supplements as per US regulations. [7]

5. (a) Explain the organization and functions of European Food Safety Authority (EFSA). [8]
   (b) Write a note on EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. [7]

6. What is NSF Certification? Explain the benefits, policies and the process for SF certification. [15]

7. Discuss the WHO guidelines on nutrition. [15]

8. Write short notes on
   (a) Role of Medical foods and functional foods in healthcare [7.5]
   (b) Recommended Dietary Allowances (RDA) in Europe. [7.5]

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Code No: E-12477/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Herbal & Biologicals

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

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

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

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

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

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

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

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

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

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

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Code No: E-12476/PCI

FACULTY OF PHARMACY

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

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 history and evolution of United States Federal Food Drug and Cosmetics Act (FFDCA). [7]

2. Write in detail about Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA. [15]

3. (a) Describe content and approval process of IMPD. [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 Pharmaceutical Laws and regulations in Japan. [9]
   (b) Write a note on Organization of PMDA. [6]

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-12479/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Food & Nutraceuticals

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

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

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

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

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

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

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

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

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

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

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Code No: E-12478/PCI

FACULTY OF PHARMACY

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

Subject: Regulatory Aspects of Medical Devices

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

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

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

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

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

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

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

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

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

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

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Code No: E-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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