

CODE NO: H-8109/PCI

**FACULTY OF PHARMACY**

**M. Pharmacy II-Sem.(PCI) (Pharm. Regulatory Affairs) (Main & Backlog)  
Examination, December 2025**

**Subject: Regulatory Aspects of Medical Devices**

**Time: 3 Hours**

**Max. Marks: 75**

**Note: Answer any Five following questions.**

**(5 x 15 = 75 Marks)**

1. (a) Differentiate medical devices, IVDs and Combination Products. (6)  
(b) Define Medical Device. Describe in detail about the risk-based classification of Medical Devices. (9)
2. (a) Write the organization structure, purpose, and its functions of IMDRF. (8)  
(b) What are the various working groups in GHTF. (7)
3. (a) Write a note on validation and verification of medical device. (7)  
(b) Write about Quality System Regulations of Medical Devices: ISO 13485. (8)
4. (a) Write the regulatory approval process for Medical Devices (510k). (8)  
(b) Write a note on Quality system requirements 21 CFR Part 820. (7)
5. (a) Write the regulatory approval process for In vitro Diagnostics (In Vitro Diagnostics Directive.) (7)  
(b) Write a note on CE Certification process. (8)
6. (a) Regulatory Registration procedure for Medical Devices as per ASEAN. (8)  
(b) Describe clinical evaluation of medical devices as per China. (7)
7. (a) Write a note on Good Clinical Practice for Clinical Investigation of medical Devices (ISO 14155:2011) (8)  
(b) Write a note on STED (Summary Technical Documentation). (7)
8. (a) Write a note on post marketing surveillance of Medical devices. (7)  
(b) Describe Essential principles of Medical Devices and IVDs. (8)

\*\*\*\*\*



Code No: H-8108/PCI

**FACULTY OF PHARMACY**  
**M.Pharmacy (Pharmacy Regulatory Affairs)- II Semester(PCI) (Main & Backlog)**  
**Examination, December 2025**

**Subject: Regulatory Aspects of Herbals and Biologicals**

**Time: 3 Hours**

**Max.Marks:75**

**Note: Answer any five questions.**

**(5 x 15 = 75 Marks)**

1. i) Write the differences between generics and biosimilars.  
ii) What are similar biologics? Write about the present status and guidelines in India.
2. Write a note on following
  - i) Principles for development of similar biologics.
  - ii) Post marketing data requirements for similar biologics
3. Write about
  - i) Development and regulatory approval of biologics (Investigational medicinal products and biosimilars) in EU.
  - ii) Pre-clinical and clinical development considerations for biologics in EU.
4. i) Discuss about the development and regulations of biologics and similar biological in EU.  
ii) Explain the procedure for approval of clinical trials, labeling and packing of similar biologics in India.
5. Write about
  - i) Plasma Master file
  - ii) TSE evaluation
6. (i) Explain labeling, packing requirements for biologics and biosimilars in USA.  
(ii) Write the regulations and safety of herbals in India.
7. Write about
  - i) International Haemovigilance network (IHN)
  - ii) International society of Blood transfusion (ISBT)
8. Write the quality, safety and legislations about the herbal products in India and USA.

\*\*\*\*\*



Code No. H-8107/ PCI

**FACULTY OF PHARMACY**

**M. Pharmacy II - Semester (PCI) (Pharm. Regulatory Affairs) (Main& Backlog)  
Examination, December 2025**

**Subject: Regulatory Aspects of Drugs and Cosmetics**

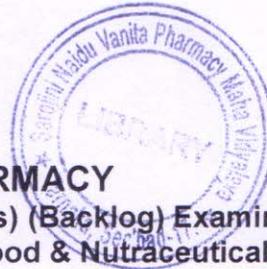
**Time: 3 Hours**

**Max. Marks: 75**

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

1. (a) Write a note on Drug Master Files system in US. (8)  
(b) Write a note on Code of Federal Regulations. (7)
2. (a) Describe Certificate of Suitability(CoS) in EU. (6)  
(b) Describe Active substance master files (ASMF) system in EU. (9)
3. (a) Write a note on regulatory considerations for packaging and labelling in Japan. (5)  
(b) Write a note on drug regulatory approval process in Japan. (10)
4. (a) Write a note on Certificate of Pharmaceutical Product(CoPP). (8)  
(b) Write a note on WHO-prequalification programme. (7)
5. (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)
6. (a) Write a note on regulatory approval process for New Drug Application. (9)  
(b) Write a note on Marketing Authorization Procedures in EU. (6)
7. (a) Write a note on Qualified person responsibilities in European Union. (8)  
(b) Write a note on Post marketing Surveillance in Japan. (7)
8. (a) Write a note on marketing authorization requirements for drugs in Saudi Arabia & UAE. (6)  
(b) Write a note on ACTD. (9)

\*\*\*\*\*



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]

\*\*\*