



**G. PULLA REDDY COLLEGE OF PHARMACY
AUTONOMOUS**

Affiliated to **Osmania University** Approved by **PCI** & Accredited by **NAAC**
Mehdipatnam, Hyderabad - 500028. Telangana State.

M. PHARM SECOND SEMESTER (PCI) REGULAR EXAMINATIONS, OCT- 2026

Branch: REGULATORY AFFAIRS

Subject: REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

QP Code: MRAII04TE26

Time: 03 Hours

Max Marks: 75

Note: Answer Any **FIVE** Questions.

5 X 15 = 75M

S. No	Questions
1	(a) Explain the history and evolution of food and nutraceutical regulations. (8)
	(b) Assess the therapeutic and commercial significance of probiotics and prebiotics in modern healthcare. (7)
2	Analyse the role of WHO and NSF International in regulating nutraceuticals. Compare WHO nutrition guidelines with NSF certification and standards. (15)
3	(a) Demonstrate the application of Good Manufacturing Practices (GMP) in nutraceutical manufacturing with suitable examples. (10)
	(b) Define nutraceuticals, dietary supplements, functional foods, and medical foods with one example each. (6)
4	(a) Analyse the organisation and functions of the Food Safety and Standards Authority of India (FSSAI). (8)
	(b) Demonstrate the procedure for submission of an application through the FoSCoS portal for obtaining a nutraceutical license. (7)
5	(a) Compare labelling requirements and label claims permitted for dietary supplements in the USA. (8)
	(b) Explain the U.S. regulations governing the manufacture and sale of dietary supplements. (7)
6	(a) Define DSHEA, FSMA, dietary supplement, and RDA in the United States. (6)
	(b) Explain Recommended Dietary Allowances (RDA) in India. (9)
7	Design a regulatory strategy for launching a novel nutraceutical product in the European Union, considering EFSA approval, novel food regulations, and nutrition labelling. (15)
8	(a) Discuss Recommended Dietary Allowances (RDA) in Europe. (8)
	(b) Discuss Recommended Dietary Allowances (RDA) in India. (7)



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M. PHARM SECOND SEMESTER (PCI) REGULAR EXAMINATIONS, OCT- 2026

Branch: REGULATORY AFFAIRS

Subject: REGULATORY ASPECTS OF MEDICAL DEVICES

QP Code: MRAII03TE26

Time: 03 Hours

Max Marks: 75

Note: Answer Any **FIVE** Questions.

5 X 15 = 75M

S. No	Questions
1	A) Explain the evolution of Medical Device Regulation (7) B) Compare medical devices, IVDs and Combination Products from pharmaceuticals. (8)
2	A) Evaluate how GHTF Study Groups handle the complete medical-device lifecycle. (8) B) Briefly describe about Global Medical Device Nomenclature (GMDN). (7)
3	A) Apply the principles of Good Clinical Practice (GCP) as per ISO 14155:2011 to the conduct of clinical investigations of medical devices. (8) B) Describe how adverse events associated with medical devices are identified, documented, and reported to regulatory authorities with suitable example. (7)
4	A) Explain the key labelling requirements for medical devices as specified under 21 CFR Part 801, with suitable examples. (8) B) Explain the regulatory approval process for medical devices through the FDA 510(k) pathway. (7)
5	A) Explain the European regulatory framework and approval requirements for medical devices and IVDs (8) B) Classify the medical devices in the European Union with suitable examples. (7)
6	A) Describe the Regulatory Registration procedure for Medical Devices as per JAPAN. (8) B) Describe the important IMDRF guidance documents related to medical devices and IVDs and Justify their regulatory significance. (7)
7	A) Develop a regulatory submission pathway for a high-risk medical device intended for marketing in China. (8) B) Discuss the different methods of post-marketing surveillance of medical devices with suitable examples. (7)
8	A) Explain the significance of Unique Device Identification (UDI) for medical device registration in USA. (8) B) Explain Clinical Investigation Plan for Medical Devices. (7)



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M. PHARM SECOND SEMESTER (PCI) REGULAR EXAMINATIONS, OCT- 2026

Branch: REGULATORY AFFAIRS

Subject: REGULATORY ASPECTS OF HERBAL & BIOLOGICALS

QP Code: MRAII02TE26

Time: 03 Hours

Max Marks: 75

Note: Answer Any **FIVE** Questions.

5X15 = 75M

S.No	Questions	BTL	CO
1	(a) Analyze the role, functions, and significance of the International Society of Blood Transfusion (ISBT). (8)	L4	CO4
	(b) Examine the role and major functions of International Haemovigilance Network (IHN). (7)	L4	CO4
2	(a) Describe the GMP requirements for similar biologics in India. (9)	L2	CO1
	(b) Explain the data requirements for preclinical studies of biologics in India. (6)	L2	CO1
3	Develop a comprehensive framework for the quality, safety and legislations about the herbal products in India and European Union. (15)	L6	CO5
4	(a) Apply the regulatory requirements to outline the New Drug Application process for biosimilars in the USA. (7)	L3	CO2
	(b) Demonstrate the application of regulatory requirements to the labelling and packing of biologics and biosimilars in USA. (8)	L3	CO2
5	Evaluate the development and regulatory approvals of biologics and similar biologics in European Union. (15)	L5	CO3
6	(a) Identify the regulatory authorities responsible for vaccine regulations in India, USA, and the European Union. (8)	L1	CO4
	(b) List the essential labelling requirements for blood and blood products. (7)	L1	CO4
7	Apply the relevant regulatory requirements to outline the development and approval of biologics and biosimilars in USA. (15)	L3	CO2
8	(a) Describe the development and approval of biosimilars in the EU. (7)	L2	CO3
	(b) Explain the pre-clinical and clinical development considerations of biologics in EU. (8)	L2	CO3



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Branch: REGULATORY AFFAIRS

Subject: REGULATORY ASPECTS OF DRUGS & COSMETICS

QP Code: MRAII01TE26

Time: 03 Hours

Max Marks: 75

Note: Answer any **FIVE** questions

5 X 15= 75M

S. No.	Question
1	(a) Describe Marketing Authorization Procedures in EU (8M) (b) Describe content and approval process of IMPD (7M)
2	(a) Explain Certificate of Pharmaceutical Product (CoPP) (8M) (b) Describe WHO & GMP (7M)
3	Explain the Legislations and regulations for manufacture and sale of cosmetics in Australia (15M)
4	(a) Describe Eudralex directives for human medicines (8M) (b) Explain drug regulatory approval process in Japan (7M)
5	Explain the Regulatory approval process for NDA (15M)
6	(a) Write a note on legislations and regulations for import and sale of cosmetics in ACC countries (8M) (b) Describe the regulatory requirements for registration of drugs in China and South Korea (7M)
7	(a) Describe DMF in USFDA (8M) (b) Write a note on Post marketing Surveillance in Japan (7M)
8	(a) Explain regulations for Orphan drugs in USA (8M) B) Explain CFR (7M)