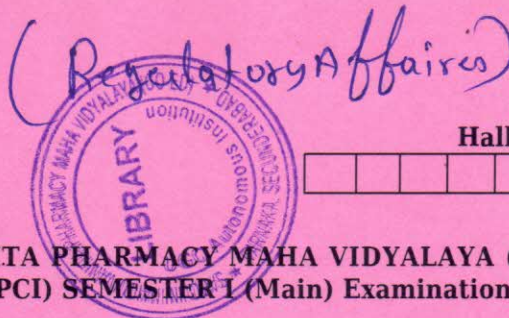


QP Code:44101



Hall Ticket Number

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SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed.)(Autonomous)
M.Pharmacy (PCI) SEMESTER I (Main) Examination, APRIL-2026

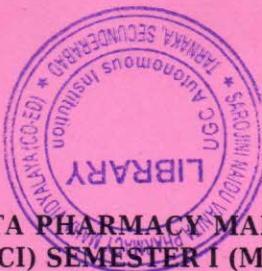
Course:Good Regulatory Practices

Time: 3 Hours Max.

Marks: 75

Question No.	Question	CO	BL
PART-A	Answer any 5 questions.	5 × 15 = 75	
1	Describe cGMP requirements for personnel, premises, equipment and documentation.	I	2
2	Describe relevant ISO standards and the role of the Quality Council of India in laboratory quality systems.	II	2
3	Define GALP and explain its principles, requirements, and SOPs.	III	1
4	Define Good Distribution Practices (GDP) and explain its principles, personnel requirements, documentation, and premises & equipment.	IV	1
5	Define quality and describe the concepts of Total Quality Management (TQM)	V	1
6	A pharmaceutical company is implementing a computerized Manufacturing Execution System (MES) for tablet production. Apply the principles of GAMP 5 to outline how the system should be validated and managed throughout its lifecycle.	I	3
7	Define Good Laboratory Practice (GLP) and describe its objectives, principles, and importance in non-clinical studies.	II	1
8	Define GDP. Assess the role of documentation and traceability in GDP and justify their importance in regulatory compliance.	IV	5

QP Code:44102



Hall Ticket Number

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M.Pharmacy (PCI) SEMESTER I (Main) Examination, APRIL-2026

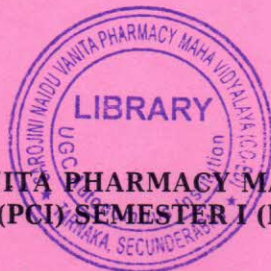
Course:Documentation and Regulatory Writing

Time: 3 Hours Max.

Marks: 75

Question No.	Question	CO	BL
PART-A	Answer any 5 questions.	5 × 15 = 75	
1	Explain in detail about drug distribution records in a pharmaceutical company. (15 marks)	I	2
2	Design a Batch Manufacturing Record (BMR) format for a tablet dosage form including necessary calculations. (15 marks)	I	6
3	Explain in detail about eCTD submissions in pharmaceuticals	II	2
4	Explain in detail how organizing, preparing, and validating pharmaceutical submissions ensures technical accuracy and regulatory compliance.	II	2
5	Explain the differences between internal and external audits in a pharmaceutical or medical device manufacturing company?	III	2
6	Explain an inspection report from a drug distribution channel?	IV	2
7	Define pre-approval inspections in the context of pharmaceutical manufacturing and explain their purpose.	IV	1
8	Compare different FDA enforcement actions and evaluate their impact on pharmaceutical operations.	V	4

QP Code:44103



Hall Ticket Number

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M.Pharmacy (PCI) SEMESTER I (Main) Examination, APRIL-2026

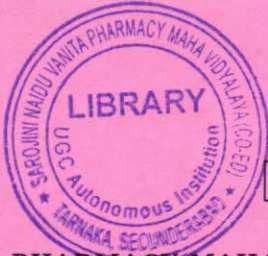
Course: Clinical Research Regulations

Time: 3 Hours Max.

Marks: 75

Question No.	Question	CO	BL
PART-A	Answer any 5 questions.	5 × 15 = 75	
1	Explain in detail the various stages of the drug development process, including different types of clinical studies.	I	2
2	Discuss the composition of an Ethics Committee/IRB and explain its roles and responsibilities in clinical trials.	II	2
3	Enlist different types of Marketing Authorization applications (MAA) in Europe and explain Mutual Recognition Procedure.	III	4
4	Explain the role of GHTF guidance documents in ensuring the safety and effectiveness of medical devices.	IV	4
5	Discuss FDA safety reporting requirements and analyze the role of MedWatch in pharmacovigilance.	V	4
6	Evaluate the ethical considerations involved in conducting clinical trials on human subjects, as per ICH- GCP.	I	5
7	Explain the responsibilities of a sponsor in maintaining ethical standards of clinical trials.	II	4
8	Describe CFR 21 Part 50 (Protection of Human Subjects) and explain the importance of informed consent in clinical trials.	V	2

QP Code:44104



Hall Ticket Number

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SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed.) (Autonomous)
M.Pharmacy (PCI) SEMESTER I (Main) Examination, APRIL-2026

**Course: Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals,
and Food & Nutraceuticals In India and Intellectual Property Rights**

Time: 3 Hours Max.

Marks: 75

Question No.	Question	CO	BL
PART-A	Answer any 5 questions.	5 × 15 = 75	
1	a) State the objectives of the Pharmacy Act and give a note on pharmaceutical ethics.(7) b) Describe the constitution of the Central Pharmacy Council and explain its functions.(8)	<i>I</i>	2
2	Evaluate the organizational structure, responsibilities, and coordination mechanisms between Central Drugs Standard Control Organization and State Licensing Authorities in ensuring drug safety and quality.	<i>II</i>	5
3	Explain the concept of international standardization. Discuss the role and functions of the International Organization for Standardization (ISO) in pharmaceutical industries.	<i>III</i>	2
4	Describe the regulatory requirements for conducting a bioequivalence study in India. Highlight study design, sample size considerations, and documentation needed for submission to regulatory authorities.	<i>IV</i>	2
5	Explain trademarks in detail, including their types, functions, registration procedure and cases of infringement, with appropriate examples.	<i>V</i>	4
6	Explain the provisions of the Narcotic Drugs and Psychotropic Substances (NDPS) Act in the context of drug regulation and control in India.	<i>I</i>	2
7	Describe in detail the format and contents of a regulatory dossier for drug approval in India, including administrative, quality, non-clinical, and clinical data.	<i>II</i>	4
8	Describe the ICMR-DBT Guidelines for Stem Cell Research. Highlight key requirements for ethical and safe conduct of stem cell research in India.	<i>IV</i>	4
