(Regulatory Affairs)

QP Code:44101

Hall Ticket Number

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*

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QP Code:44102

Hall Ticket Number

SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed.)(Autonomous)
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*

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QP Code:44103

Hall Ticket Number

SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed.)(Autonomous)
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*

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QP Code:44104

Hall Ticket Number

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

Course:Regulations and Legislationfor 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*	*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.	*II*	*5*
3	Explain the concept of international standardization. Discuss the role and functions of the International Organization for Standardization (ISO) in pharmaceutical industries.	*III*	*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.	*IV*	*2*
5	Explain trademarks in detail, including their types, functions, registration procedure and cases of infringement, with appropriate examples.	*V*	*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*	*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.	*II*	*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.	*IV*	*4*

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