(Quality Assurance)

QP Code:42101/43101/45101

Hall Ticket Number

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

Course:Modern Pharmaceutical Analytical Techniques

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 principle and instrumentation of a double beam spectrophotometer with a neat labelled diagram.	*I*	*2*
2	Justify the role of quantum numbers in NMR spectroscopy and explain the principle and instrumentation of NMR spectrometer	*II*	*5*
3	Write the principle, theory, and instrumentation of Mass Spectrometry with suitable explanations and diagrams.	*III*	*1*
4	Classify the various chromatographic techniques and discuss the factors affecting resolution and the isolation of drugs in column chromatography with suitable explanations.	*IV*	*2*
5	Illustrate the principle, instrumentation, factors affecting separation, and applications of gel electrophoresis with suitable diagrams	*V*	*2*
6	Compare the instrumentation and applications of Differential Thermal Analysis (DTA) and Thermogravimetric Analysis (TGA).	*VI*	*4*
7	Organize the information on quenchers, instrumentation, and applications of a fluorescence spectrophotometer, highlighting their principles and significance in analysis	*I*	*3*
8	Explain High Performance Liquid Chromatography (HPLC), with neat and well-labeled diagrams, explaining their principles and working mechanisms	*IV*	*2*

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QP Code:43103

Hall Ticket Number

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

Course:Quality Control and Quality Assurance

Time: 3 Hours Max. Marks: 75

Question No.	Question	CO	BL
PART-A	**Answer any 5 questions.**	**5 × 15 = 75**	
1	List the objectives and scope of Quality Assurance in the pharmaceutical industries.	*I*	*1*
2	Define cGMP and explain its objectives in pharmaceutical manufacturing	*II*	*1*
3	Explain procedures for analysis of raw materials	*III*	*2*
4	Explain Batch Manufacturing Record (BMR) in detail with its format, contents, and significance	*IV*	*2*
5	Explain sterile products and aseptic process control in detail	*V*	*4*
6	Create a GLP-compliant laboratory setup for pharmaceutical testing	*I*	*6*
7	Explain In-Process Quality Control (IPQC) tests for tablets	*III*	*2*
8	Explain Intellectual Property Rights (IPR) and discuss patents, trademarks, and copyrights.	*V*	*2*

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QP Code:43102

Hall Ticket Number

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

Course:Quality Management System

Time: 3 Hours Max. Marks: 75

Question No.	Question	CO	BL
PART-A	**Answer any 5 questions.**	**5 × 15 = 75**	
1	a. Classify customers. (5M) b. Explain the importance of customer focus in Quality Management Systems. (10M)	*I*	*2*
2	What is cost of quality? Classify the components of cost of quality with relevant example.	*I*	*4*
3	Compare ISO 9001: 2008 and ISO 9001:2015 standards. Illustrate its importance in Pharma QA.	*II*	*4*
4	Explain the concept of Self inspection and its role in GMP Compliance. Design a self inspection schedule covering six systems.	*III*	*6*
5	Explain IPQC for Solid dosage forms with acceptance criteria.	*III*	*1*
6	a. Describe elements of ICHQ8 Quality by Design guidelines. (7M) b. Develop a Quality by Design approach for tablet formulation. (8M)	*IV*	*6*
7	Describe how the pursuit of decreased process variability is supported by Statistical Process Control techniques	*V*	*2*
8	Compare and contrast advantages and limitations of benchmarking.	*VI*	*2*

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QP Code:43104

Hall Ticket Number

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

Course:Product Development and Technology Transfer

Time: 3 Hours Max. Marks: 75

Question No.	Question	CO	BL
PART-A	**Answer any 5 questions.**	**5 × 15 = 75**	
1	Write a note on the scope and purpose of the IND application and discuss the stages of the IND application process in India.	*I*	*2*
2	What do you understand by the term BACPAC? Discuss the guidelines for bulk APIs (10 m)	*I*	*1*
3	Discuss the concept of Co-solvency for improving the solubility. List out various cosolvents and explain how to select a cosolvent.	*II*	*2*
4	Define polymorphism and explain its impact on drug properties and formulation	*II*	*2*
5	Explain the concept and significance of pilot plant Scale up in pharmaceutical manufacturing	*III*	*2*
6	A)Enlist the various quality control tests for pharmaceutical containers and closures (7M) B). Discuss the tests generally conducted on plastic containers and metal containers .(8M)	*IV*	*2*
7	Summarize the packaging requirements for Pharmaceutical Dosage Forms (7M)	*IV*	*2*
8	Discuss the Qualitative and quantitative technology models	*V*	*1*

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