JSS ACADEMY OF HIGHER EDUCATION & RESEARCH

(DEEMED TO BE UNIVERSITY) MYSURU

JSS AHER University Exam

Previous Question Papers

November 2025

(M. Pharm)

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QP Code: 6001

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Common for Industrial Pharmacy & Pharmaceutics

Subject: Modern Pharmaceutical Analytical Techniques

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Write the principle, instrumentation, interference and applications of flame emission spectroscopy.
2. a) Theory and applications of NMR spectroscopy.
   b) Write a note on solvent requirements in NMR.
3. Write in detail about various ionization techniques in mass spectroscopy.
4. Explain the principle, instrumentation and pharmaceutical applications of ultra-performance liquid chromatography (UPLC).

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the effect of solvents in UV absorption.
6. Write about the various factors influencing fluorescence intensity.
7. Explain spin-spin coupling and constant.
8. Write a short note on theory and applications of FT-NMR.
9. What is MALDI technique in mass spectroscopy? Explain its significance.
10. Draw a neat, labelled diagram of mass spectrophotometer. Add a note on applications of mass spectroscopy.
11. Detection techniques used in TLC.
12. Explain various columns used in GC.
13. Explain gel electrophoresis.
14. Write in detail about principle and applications of XRD.
15. Explain the principle and instrumentation of moving boundary electrophoresis.
16. Write a note on bioluminescence assays.

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QP Code: 6002

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Industrial Pharmacy

Subject: Pharmaceutical Formulation Development

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss the role of flow properties and drug excipient compatibility studies in formulation development of solid dosage forms.
2. Give a brief outline of Box Behnken design. How are the surface response morphology computed in Box Behnken design.
3. Explain the techniques to improve the solubility of a drug substance.
4. Write a note on dissolution testing for conventional and controlled release products.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Discuss crystal morphology in preformulation studies.
6. Discuss micromeritics in the development of solid oral dosage forms.
7. Explain factors influencing the addition of formulation additives.
8. Explain the factorial design for product and process development.
9. Write a note on phase-solubility analysis.
10. Write about the significance of solubility studies in product development.
11. Explain *in vitro* dissolution testing of controlled release products.
12. Explain theories of dissolution.
13. Explain the guidelines for photostability testing.
14. Write a note on solution stability.
15. Write briefly on ICH guidelines for long-term stability testing.
16. Explain the degradation kinetics in product stability.

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QP Code: 6003

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Industrial Pharmacy

Subject: Novel Drug Delivery Systems

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain classification of rate-controlled drug delivery systems (DDS) with suitable examples.
2. Discuss the formulation of pulmonary drug delivery systems. List the challenges involved.
3. Explain the concept of iontophoresis. List any four advantages.
4. Discuss the concept and biological processes involved in drug targeting.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. What are natural polymers? Give the advantages.
6. Biodegradable polymers are preferred, Justify.
7. Write a note on polymers used in ocular inserts.
8. Briefly explain pulsatile drug delivery systems.
9. List the limitations for drugs given by topical route (skin).
10. Enlist any five important QC tests for cold creams.
11. Briefly discuss formulation of liposomes.
12. Discuss stability testing of peptides.
13. What is gene therapy? List the uses.
14. Discuss monoclonal antibodies with examples.
15. Write a note on recent advances in 3D printing.
16. Write the applications of tele pharmacy.

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QP Code: 6004

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Industrial Pharmacy

Subject: Intellectual Property Rights

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Explain in detail the conditions that must be satisfied by an invention to be considered patentable. Discuss each condition with suitable examples. (10)
2. Explain in detail the role of GATT and TRIPS in establishing international standards for intellectual property rights. How have they influenced IP laws globally? (7+3)
3. Explain the importance of trademark protection in the pharmaceutical industry. Give examples of popular drug trademarks and discuss how trademarks help companies to differentiate their products. (6+4)
4. Explain in detail the role and functions of CDSCO in regulating the pharmaceutical industry in India. Elaborate on key areas it is involved in like drug approval, clinical trials, manufacturing and marketing regulations etc. (5+5)

Section B

II. SHORT ESSAY (Answer any NINE questions) 9x5=45 Marks

5. Highlight the key steps involved in filing a patent application.
6. Different parts of a typical patent document.
7. Impact of TRIPS on access to medicines in developing countries.
8. Berne Convention for the Protection of Literary and Artistic Works.
9. Major amendments brought in by Patents Amendment Act, 2005.
10. Objectives and functions of Central Drugs Standard Control Organization (CDSCO).
11. Differences between pre-market approval system of USFDA and notification system of CDSCO.
12. Challenges faced by generic drug manufacturers due to patent issues.
13. List the clinical evaluation parameters for a biosimilar as compared to the reference product.
14. Differentiate between the approval process of a biosimilar and a generic drug.
15. Highlight the importance of post marketing surveillance for biosimilars.
16. Regulations regarding biosimilar nomenclature and labeling.

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QP Code: 6005

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Analysis

Subject: Advanced Pharmaceutical Analysis

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Define and classify impurities. Enumerate the degradation products content of batches and their list.
2. Classify elemental impurities. Write the general analytical procedures for identification of elemental impurities.
3. Describe the different stages of qualification of impurities as per ICH guidelines.
4. Write the principle and procedures involved in the biological assays of:
   a) Adsorbed tetanus vaccine b) Antivenom.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Classify residual solvents with suitable examples.
6. Classify and write the reporting level of residual solvent impurities.
7. Describe the methods of C, H, N and S analysis with principle.
8. Write in detail about various sources of elemental impurities and also mention their identification tests.
9. Write a note on photostability testing of pharmaceuticals.
10. Explain the protocols and application of HPTLC finger printing in phytopharmaceuticals
11. Discuss the various regulatory requirements for herbal drugs.
12. Write the basic principle involved in PCR.
13. Enlist the applications of immunoassays (IA).
14. Explain any one method for production of antibodies.
15. Explain the basic principle involved in radioimmunoassay.
16. Discuss the concept of fluoroimmunoassay and mention its importance.

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QP Code: 6006

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Analysis

Subject: Pharmaceutical Validation

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Define validation and explain about User Requirement Specification (URS) and change management.
2. Write the qualification of analytical instruments of the following:
   a) Gas chromatography b) UV – visible spectrophotometer.
3. Discuss the importance of compressed air and nitrogen in validation process. Add a note on Cleaning in Place (CIP).
4. Discuss the role of 21CFR Part 11 in validation. Explain how electronic records are useful in validation process.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain about design qualification.
6. Write a note on calibration and preventive maintenance.
7. Describe the qualification of HPTLC instrument.
8. Write the calibration procedure for burette.
9. Describe the general principles of analytical method validation.
10. Write a note on validation of heating, ventilation, and air conditioning (HVAC) systems.
11. Explain in detail about the validation of analytical methods as per ICH guidelines with suitable examples.
12. Enumerate the validation of analytical methods as per USP guidelines.
13. Describe the patent application forms and guidelines.
14. Illustrate the role of IP in pharmaceutical industry.
15. Explain the mechanism for protection of intellectual property.
16. Illustrate the procedure and cost for international patenting requirement.

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QP Code: 6007

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Analysis

Subject: Food Analysis

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Classify carbohydrates. Explain how food carbohydrates are analyzed.
2. Write on determination of adulteration in fats and oils. Explain how vitamins are analyzed.
3. Discuss on analysis of preservatives and antioxidants.
4. What are the general analytical methods for milk? Comment on adulterants of milk.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write a note on proteins and any one method of analysis.
6. Explain on crude fibres.
7. Write the methods for measurement of spoilage of fats.
8. Explain on microbial assay of vitamin B series.
9. Analysis of thickening and gelling agent.
10. What are permitted and non-permitted dyes and how are they analyzed?
11. Analysis of wine.
12. Explain the analysis of ice cream.
13. Write on USFDA rules and regulations.
14. Describe pesticide cycle.
15. Comment on the use of pesticide in agriculture.
16. Explain on organophosphorus pesticide analysis.

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QP Code: 6008

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Biotechnology

Subject: Microbial and Cellular Biology

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Describe the chemistry and reproduction of virus.
2. Explain about the various repair mechanisms in mutated genes.
3. Define cell communication. Discuss on G-protein coupled receptors.
4. Discuss on the applications of animal cell culture in pharmaceutical industries.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Differential the gram positive and gram-negative bacterial cell wall.
6. Write a short note on cultivation of anaerobic bacteria.
7. Write a note on the methods of transcription process.
8. Write a note on the translational control process in prokaryotes.
9. Write a note on cell cycle.
10. Enumerate the difference between mitosis and meiosis.
11. Write about the anti-viral assay using animal cells.
12. Differentiate the primary and transformed cell culture.
13. Write a note on the etiology and pathology of any one bacterial disease.
14. Explain about the mechanism of action of antimicrobial agents.
15. Discuss the currently recommended therapies used in anyone fungal infections.
16. Explain the mode of action of antimicrobial agents.

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QP Code: 6009

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Biotechnology

Subject: Bioprocess Engineering and Technology

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Why is the foam formation not desirable in a fermenter. What are the three ways to approach this problem? Enlist the properties on ideal anti-foaming agents and give any two suitable examples for anti-foaming agents. (1+3+5+1)
2. Discuss the importance of determination of volumetric mass transfer coefficient in a bioreactor. Describe the gassing-out techniques for the determination of kLa. (4+6)
3. Provide an in-depth overview of immobilization techniques for whole cells. Discuss their applications in biotechnology and fine chemical production. (6+4)
4. Define filtration. Describe the theory of filtration. What are the criteria in selecting equipment for filtration? With a neat, labelled diagram, explain the working, advantages, disadvantages and applications of the plate and frame filters. (1+2+2+1+4)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Describe the different types of spargers and impellers used in a CSTR.
6. Write a note on the configuration and applications of hollow fiber and packed glass bead bioreactor.
7. Describe the difference between Newtonian and non-Newtonian fluids.
8. How is air cleaned sterilized in a fermenter?
9. Explain the techniques used in the scale-up of fermentation processes and their implications for process efficiency and product yield.
10. What are the differences between batch culture, fed batch culture and continuous culture. What are the merits and demerits of each of them.
11. What are the criteria for the selection of recovery processes for a fermentation product?
12. Describe the technique and application of bioautography.
13. Describe the fermentation of glycerol.
14. What is the medium composition, organism used, and fermentation techniques employed in the production and recovery of lactic acid by fermentation?
15. Write a note on fermentation of griseofulvin.
16. Give an account on the fermentation of glutamic acid.

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QP Code: 6010

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Biotechnology

Subject: Advanced Pharmaceutical Biotechnology

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss the chromatographic techniques used in enzyme purification.
2. Describe the process involved in genetic engineering.
3. Elaborate on techniques of controlled release parenteral delivery systems for the delivery of therapeutic peptides and proteins.
4. Discuss the factors affecting cell proliferation and write a note on inflammatory responses. (5+5)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Outline the process for production and purification of enzymes with an example.
6. Enzyme safety and enzyme therapy.
7. Variants of PCR.
8. Gel electrophoresis.
9. Recombinant proteins from transgenic rabbit milk.
10. Human genome project.
11. Proto-oncogene.
12. Types of signaling.
13. Applications of biotransformation.
14. Single cell protein – fermentation process.
15. Biodegradation of xenobiotic.
16. Components of biosensor.

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QP Code: 6011

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Chemistry

Subject: Advanced Organic Chemistry-I

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain the mechanism of elimination reactions with suitable examples. Add a note on Saytzeff's rule. (6+4)
2. Write a note on Sandmeyer reaction and Dieckmann reaction.
3. Explain the following reagents along with their applications.
   a) N-Bromo succinimide
   b) Osmium tetroxide.
4. Explain the general methods of synthesis of pyrazole and purine. Outline the synthesis of theophylline.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write a note on aliphatic nucleophilic substitution reactions.
6. What are carbanions? Explain their formation and stability.
7. Explain mechanism and synthetic applications of Suzuki reaction.
8. Explain mechanism and synthetic applications of Vilsmeier-Haack reaction.
9. Write a note on protection of carbonyl groups.
10. Write the synthetic applications of aluminium isopropoxide and diazomethane.
11. Explain general methods to synthesize imidazole.
12. Write a note on Bernthsen acridine synthesis.
13. Explain the role of (FGI & FGA) functional group interconversion and addition in organic synthesis.
14. Explain C-X disconnection with suitable example.
15. Explain the strategies for the synthesis of five membered rings.
16. Illustrate the general guidelines for disconnection of organic molecules.

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QP Code: 6012

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Chemistry

Subject: Advanced Medicinal Chemistry

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. What is drug discovery? Discuss on: a) Stages of drug discovery b) Validation and diversity of drug target.
2. Define and classify prodrugs by giving suitable examples. Describe the causes and strategies to combat drug resistance in anticancer therapy.
3. Classify anti-hypertensive drugs and discuss the SAR, mechanism of action and synthesis of any one anti-hypertensive drug.
4. Define enzymes. Outline the rational design of enzyme inhibitors along with their applications in medicine.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Outline the lead identification methods in drug discovery.
6. What are artificial enzymes. Discuss the applications of artificial enzymes with suitable examples.
7. Explain the genetic principles of drug resistance.
8. What is analog design. Discuss on bioisosteric replacement.
9. Outline the mechanism of action and synthesis of any one anti-neoplastic agent.
10. Explain the structure-activity relationship of COX-I inhibitors.
11. Explain the design of non-covalently binding enzyme inhibitors.
12. Discuss the role of enzyme inhibitors in basic research.
13. Explain the importance and applications of peptidomimetics in drug discovery.
14. Explain the chemistry of prostaglandins and leukotrienes.
15. Describe the modification of peptide backbone.
16. Explain the protocol for incorporation of conformational constraints locally and globally while designing peptidomimetics.

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QP Code: 6013

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Chemistry

Subject: Chemistry of Natural Products

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain briefly about chemistry of cardiac glycosides.
2. Write an account on general methods of structural determination of alkaloids.
3. Describe chemistry and physiological significance of Vitamin B12.
4. Write the principles of DNA and RNA estimations.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write the chemistry of teniposide.
6. Explain how natural product is used as lead in the development of new anti-malarial drugs and analogues.
7. Define and classify alkaloids with examples.
8. Discuss the chemistry of contraceptive agent for female sex hormones.
9. Explain the structural elucidation of squalene.
10. Explain the chemistry and physiological functions of vitamin B1.
11. Write an account of plant products used in anti-diabetic therapy.
12. Write the hybridoma technology.
13. Write the structural characterization of natural compounds of digitalis morphine in IR spectroscopy.
14. Write an account of structural characteristics of camphor using mass spectroscopy.
15. Explain the structural characteristics of quercetin using infra-red spectroscopy.
16. Explain the structural characteristics of ^{1}H NMR & ^{13}C NMR in structural characterization in penicillin.

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QP Code: 6014

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutics

Subject: Drug Delivery Systems

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain briefly about the biological approaches for sustained release/controlled release formulation.
2. Discuss about the feedback regulated drug delivery systems.
3. Write in detail about non-floating or high-density gastro retentive dosage forms.
4. Describe the formulation of transdermal drug delivery system.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write the applications of polymers in controlled drug delivery systems
6. Telepharmacy.
7. Enzyme activated drug delivery systems.
8. With neat diagram illustrate osmotic activated drug delivery systems.
9. Advantages and disadvantages of buccal drug delivery systems.
10. Methods of formulation of buccal drug delivery systems.
11. What are the different methods to overcome ocular barrier?
12. Barriers in transdermal drug delivery system.
13. Methods to enhance drug permeation through transdermal route.
14. Stability consideration for developing protein-based drug delivery systems.
15. Explain various barriers for delivering proteins and peptides.
16. Transdermal delivery of vaccines.

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QP Code: 6015

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutics

Subject: Modern Pharmaceutics

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Discuss the physiological and formulation considerations for large and small volume parenterals. Explain the manufacturing processes and quality control tests performed on parenteral formulations. (5+5)
2. Discuss in detail the types of validations performed for different pharmaceutical dosage forms as per regulatory guidelines. (10)
3. Discuss the importance of industrial and personnel management in a pharmaceutical company. Explain how concepts like total quality management can be implemented to improve efficiency and productivity. (4+6)
4. Compare and contrast the consolidation and compression phases of the compaction process. How does the distribution of forces vary in each phase? (4+6)

Section B

II. SHORT ESSAY (Answer any NINE questions) 9x5=45 Marks

5. What is response surface methodology? Explain its application in formulation development with an example.
6. Explain the kinetics of stability with suitable examples of degradation reactions.
7. List the key elements that are validated during equipment validation as per regulatory guidelines.
8. What are the objectives of facility validation? Explain.
9. Discuss the importance of inventory management and control systems.
10. Discuss the concept of total quality management in pharmaceutical industry.
11. Write short notes on the Heckel equation used for analysis of compression data.
12. Discuss the importance of pre-compression force in the compaction process.
13. Write the principle and applications of students t-test and ANOVA in pharmaceutical product development and quality control.
14. Explain the Higuchi model of drug release. What information can be obtained from Higuchi plot?
15. Write a note on linearity concept in pharmaceutical analysis.
16. Define pharmacokinetic parameters. List important pharmacokinetic parameters used to characterize drug absorption and disposition.

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QP Code: 6016

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutics

Subject: Regulatory Affairs

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss in detail the ANDA regulatory requirements for generic drugs.
2. Explain the regulatory approval process for APIs.
3. Discuss the ICH guidelines for quality, safety and efficacy.
4. Explain about the global submission of ANDA.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write the importance of Code of Federal Regulations (CFR).
6. Enumerate the master formula records documentation contents.
7. Write a short note on post marketing surveillance system.
8. Explain about the scale up process approval changes.
9. Enlist the regulatory requirements of MHRA.
10. Explain how FDA liaison with industry can be achieved?
11. Define dossier? Explain the different types of dossiers.
12. What is investigator's brochure? Brief its need in drug approval.
13. Explain the procedure of obtaining informed consent for clinical studies.
14. Define clinical trials. Explain the phases of clinical trials.
15. Write about HIPAA.
16. Explain the role of pharmacovigilance for safety monitoring of clinical trials.

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QP Code: 6017

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacognosy

Subject: Advanced Pharmacognosy – I

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss about *in-situ* and *ex-situ* conservation of medicinal plants.
2. Discuss recent advances and problems faced in research on marine drugs.
3. Define and classify nutraceuticals with examples. Write a note on spirulina. (6+4)
4. Write the source, method of isolation, chemical nature, medical and health benefits of a) Resveratrol b) Guggul lipids. (5+5)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write a note on current good collection practices.
6. Discuss Current Good Agricultural Practices.
7. Explain the biomedicines obtained from marine organisms used as an anti-inflammatory agent.
8. Discuss the problems in chemical screening of marine drugs.
9. Explain the regulatory aspects of nutraceuticals.
10. Write a note on polyunsaturated fatty acids as nutraceuticals.
11. Write the source, structure, medical uses and health benefits of Hesperidin.
12. Write about the chemical nature, identification test and health benefits of shatavarins.
13. Describe WHO guidelines for safety monitoring of natural medicines.
14. Write a note on pharmacovigilance of natural medicines.
15. WHO safety procedures for bio drug adverse reactions.
16. Discuss the bio drug-drug interactions with examples.

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QP Code: 6018

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacognosy

Subject: Phytochemistry

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. List the basic metabolic pathways and explain the shikimic acid pathway (4+6)
2. Write the biogenic pathway, method of isolation and characterization of ephedrine.
3. Explain the principle involved in separation of phytochemicals in counter current extraction techniques. Explain the construction and working of droplet counter current extraction. (5+5)
4. Explain the principle, instrumentation and applications of HPTLC.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Discuss the chemistry of glycyrrhizin.
6. Write the biosynthesis of sennosides.
7. Discuss the importance of natural products in discovery of drugs.
8. Explain the selection of lead structure and optimization.
9. Write a note on microwave assisted extraction.
10. Explain the concept of bioactivity guided isolation.
11. Discuss the applications of GCMS.
12. Write a note on LCMS.
13. Explain the role of IR spectroscopy in structure elucidation of phytoconstituents.
14. Describe the structural features and spectral characters of citral.
15. Discuss structural elucidation of caffeine.
16. Discuss spectral characters to elucidate the chemical structure of nicotine.

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QP Code: 6019

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacognosy

Subject: Industrial Pharmacognostical Technology

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. What is project selection? Describe in detail various steps for the selection of a project.
2. Describe in detail about the good manufacturing practices (GMP) for the production of phyto-medicines.
3. Write a note on: (4+3+3)
   a) Determination of pesticide residue in herbal raw materials.
   b) Determination of heavy metals in herbals.
   c) Ash values and its significance.
4. Give a descriptive note on clinical laboratory testing for herbal medicines.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Formulation and production management of herbals.
6. Current challenges in upgrading and modernization of herbal formulations.
7. Quality assurance of herbal/natural drugs.
8. Principles of Good laboratory practices (GLP).
9. Explain British herbal pharmacopoeia.
10. Comparative study of herbal monographs in different pharmacopoeias.
11. Explain accelerated stability study of natural product.
12. Explain long term stability testing.
13. Revocation of patents.
14. Amendments made in Indian patent law pertaining to natural products.
15. Define geographical indication. Discuss objectives of its development.
16. Describe the characteristics of patentable inventions.

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QP Code: 6020

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacology

Subject: Advanced Pharmacology - I

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Describe the types of drug interactions. Give examples of drug disease interaction. (8+2)
2. Classify neurotransmitters and explain the steps involved in cholinergic transmission. (2+8)
3. Explain various stages of anesthesia and discuss the factors that determine the speed of induction and recovery of anesthesia. (6+4)
4. Detail about mechanism of coagulation and discuss mechanism of action and adverse drug reaction of heparin. (5+5)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. What are the factors affecting drug absorption.
6. Explain the function of G-protein coupled receptors.
7. Classification of cholinergic receptor agonist and add a note on pilocarpine.
8. Write the mechanism of action of neuromuscular blocking drugs.
9. Write the pharmacological action of fentanyl citrate.
10. Classify anti-convulsant drugs and explain lamotrigine.
11. Explain platelet plug formation and clopidogrel.
12. Write a note on HMG Co A reductase inhibitors.
13. Explain the pathological role of histamine.
14. Explain the opioid autocoid action mediating through the receptors.
15. Write a note on non-sedative antihistamines.
16. Write about the mechanism of action involved in the ondansetron.

*****

QP Code: 6021

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacology

Subject: Pharmacological and Toxicological Screening Methods - I

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Outline the CPCSEA guidelines for conduct of animal experiments.
2. A new chemical entity needs to be evaluated for its effects on cognition and muscle co-ordination. Which tests would you perform and why? List the advantages and disadvantages of such tests.
3. Explain suitable animal models to screen the anti-inflammatory properties of an herbal formulation.
4. Describe the preliminary *in vitro* models for screening the anti-cancer effects of novel drugs.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Discuss the principle and method of four-point bioassay.
6. Enumerate the applications of transgenic animal models
7. A novel molecule holds promising effect for the treatment of grandmal epilepsy. What would be ideal screening techniques to assess this molecule?
8. Describe the chemical models employed to induce parkinsonism like effects in rodent experiments.
9. Discuss the *in vitro* methods to screen anti-allergic properties of a compound.
10. Explain the screening techniques to evaluate aphrodisiac effects.
11. Describe the principle underlying screening of an anti-hypertensive drug.
12. Elaborate the preclinical screening technique for anti-arrhythmic agents.
13. Write the principle underlying immunoassay of digoxin.
14. Mention the disadvantages of animal experimentation.
15. Discuss the screening models used to assess the immunomodulatory effects.
16. Write a note on *in vitro* data extrapolation to preclinical design.

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QP Code: 6022

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacology

Subject: Cellular and Molecular Pharmacology

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I.	**LONG ESSAY (Answer any THREE questions)**	**3x10=30 Marks**
1.	Discuss in detail about various processes of cell death and explain about apoptotic pathways.	(5+5)
2.	How does nuclear receptor intracellular signaling occur? Explain the STAT signaling pathway.	(5+5)
3.	Write about various types of vectors in rDNA technology and add a note on applications of rDNA technology.	(6+4)
4.	Explain types of immunotherapeutics and humanization antibody therapy.	(5+5)

Section B

II.	**SHORT ESSAY (Answer any NINE questions)**	**9x5=45 Marks**
5.	Explain the cell cycle regulation.	
6.	Write a note on gene expression regulation.	
7.	List out various secondary messengers and write a detail note on cAMP.	
8.	Discuss about mitogen-activated protein kinase (MAPK).	
9.	Explain Western blotting technique.	
10.	Write a note on viral vectors.	
11.	Explain gene mapping techniques.	
12.	Discuss about genetic variations and its role in pharmacology.	
13.	Explain culturing of primary cells and their limitations.	
14.	Explain biosimilars.	
15.	Write about various types of cell cultures.	
16.	Write the applications of cell viability assays.	

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QP Code: 6023

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacy Practice

Subject: Clinical Pharmacy Practice

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain the scenario of clinical pharmacy practice in India in comparison with other countries.
2. Explain the origin and evolution of pharmacovigilance in India.
3. Explain the renal function tests and their significances.
4. What are the tests associated with cardiac disorders? Provide the reference ranges for each test.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. What are the steps involved in pharmaceutical care?
6. What is a medication order review? Provide examples.
7. What are the steps involved in patient medication counseling?
8. How to assure the quality of clinical pharmacy services?
9. What is the significance of the patient's case history?
10. What are all the haematological tests performed in the laboratory?
11. How to detect hypothyroidism and hyperthyroidism?
12. What are the reasons to perform culture sensitivity tests?
13. Write the systematic approach in answering medicine information queries.
14. What is the organizational structure of the poison information centre?
15. What are the medicine information resources? Provide examples.
16. What is the procedure to be followed to answer medication related queries?

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QP Code: 6024

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacy Practice

Subject: Pharmacotherapeutics- I

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Define arrhythmias. Explain the pharmacotherapeutic management of cardiac arrhythmias. (2+8)
2. a) Write the symptoms and causes of asthma. (3+7)
   b) Describe the pharmacotherapeutic management of asthma.
3. Discuss pathophysiology of peptic ulcer disease. Mention the pharmacotherapy of *H. Pylori* induced ulcer. (5+5)
4. Write the clinical manifestations of anemia. Explain the pharmacological management of iron deficiency anemia and anemia of chronic disease. (2+8)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write the role of statins in the management of dyslipidemia.
6. Write the clinical manifestations and pathophysiology of congestive heart failure.
7. Discuss the micro and macro vascular complications that are associated with diabetes mellitus.
8. Write a note on drug induced pulmonary diseases.
9. Write the clinical manifestations and pharmacotherapy of ulcerative colitis.
10. Explain the pathogenesis of jaundice.
11. Write the signs, symptoms and complications associated with sickle cell anemia.
12. Discuss the pharmacological management of constipation.
13. Explain the clinical features and pathogenesis of osteoporosis.
14. Write the pharmacotherapy of gout.
15. Write a note on drug induced skin disorders.
16. Explain the management of open angle glaucoma.

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QP Code: 6025

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacy Practice

Subject: Hospital and Community Pharmacy

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss the roles and responsibilities of Infection Control Committee and Research and Ethics Committee in a NABH accredited hospital.
2. Discuss the importance of development of hospital formulary and therapeutic guidelines in a hospital setup. (5+5)
3. Explain the various aspects of community pharmacy management for effective dispensing practices.
4. Discuss the legal requirements and interpretation of prescription and related problems in patient care. (5+5)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write a note on Management of Medicines (MOM) as per NABH.
6. Write the roles of Pharmacy and Therapeutic Committee in a hospital.
7. Write a note on various methods of inventory control in hospitals.
8. Write a note on importance of intravenous admixtures in hospital setup.
9. Write a note on different software and databases used in community pharmacies.
10. Brief the importance of education and training for pharmacists.
11. Write a note on factors influencing medication adherence behaviour.
12. Write a note on medication counseling and use of patient information leaflets.
13. Write a note on role of community pharmacists in TB control programs.
14. Write a note on prevention of non-communicable diseases.
15. What are the methods and outcomes of home medication review program?
16. Write down the importance of first aid in health promotion.

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QP Code: 6026

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmacy Practice

Subject: Clinical Research

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss the various approaches to drug discovery in clinical research.
2. Explain the various phases of clinical trials with suitable examples.
3. Describe the guidelines in preparation of protocol for conducting a clinical trial.
4. Discuss the various filing procedures and documents for clinical trial.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write a note on principles of ethics in biomedical research.
6. Write a note on drug safety reporting in clinical trials.
7. Write a note on bioavailability and bioequivalence studies in clinical research.
8. Write a note on health outcome measures in clinical research.
9. Write a note on site and investigator selection for conduct of a clinical trial.
10. Write a note on clinical trial agreement execution.
11. Write a note on review of source documents.
12. Write a note on site initiation visit process.
13. Write a note on quality control and quality assurance in clinical trial data management.
14. Write a note on managing laboratory and ADR data in clinical trial data management.
15. Write a note on types of audits and audit criteria in clinical trials.
16. Write the role of electronic data capture systems in clinical trial data management.

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QP Code: 6027

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Quality Assurance

Subject: Quality Management Systems

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain cost of quality, categories of cost of quality and models of cost of quality.
2. Explain in detail NABL certification and accreditation.
3. Expand and explain and CAPA, OOT and concept of IPQC.
4. Explain ICH guidelines for stability testing of drug substance and drug products.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the dimensions of quality.
6. Write a note on meeting customer needs and expectations.
7. Write about OSHAS guidelines.
8. WHO-GMP requirements.
9. Concept of self-inspection.
10. Returns and recalls
11. ICH Q9 guidelines.
12. Expand and explain HACCP.
13. Statistical control charts-concept.
14. Advantages of statistical control.
15. Advantages and limitations of bench marking.
16. Write about regulatory compliance through quality management.

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QP Code: 6028

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Quality Assurance

Subject: Product Development and Technology Transfer

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain in detail scale up post approval changes (SUPAC) and bulk active post approval changes (BACPAC).
2. Define solubility. Describe mechanism of solubilization, list the various methods used to enhance the solubility of a substance, and explain in detail any three of those methods.
3. Define pilot plant scale-up, briefly explain its core concept, and summarize the key opportunities and challenges associated with it in the modern era.
4. Describe different types of containers and closures for pharmaceuticals.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the concept of preformulation.
6. CDSCO guidelines for product registration.
7. Discuss the significance of polymorphism in the preformulation studies.
8. What are surfactants? Write their importance in preformulation studies.
9. Explain enteral packaging.
10. Write a note on foils and films for packaging.
11. Explain the documentation in technology transfer.
12. Explain brief about pilot plant scale up for liquid orals.
13. Write a note on post marketing surveillance.
14. Explain the ideal properties of packaging materials.
15. Brief the development of technology by R and D.
16. Write quality control tests for pharmaceutical closures.

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QP Code: 6029

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Regulatory Affairs

Subject: Good Regulatory Practices

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Differentiate 21 CFR Part 210 and 21 CFR 211 and mention in brief the sections present in 21 CFR Part 210.
2. Explain Subpart B, C and E of USFDA Good Laboratory Practices guidelines.
3. Discuss the requirements and SOPs for Good Automated Laboratory Practices.
4. Discuss USFDA Good Distribution Practice (GDP) guidelines. Is it the manufacturer or the distributors, who should comply with GDP and why? (8+2)

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Write a brief note on Medical Device Harmonization initiative.
6. Discuss in brief WHO cGMP principles.
7. Discuss documentation of laboratory audit.
8. Write a short note on Quality Council of India (QCI) standards.
9. What is software evaluation check list of Good Automated Laboratory Practices?
10. Discuss the training requirements of GALP.
11. Specify the storage conditions of various pharmaceutical products. Add a note on its importance in distribution.
12. Write short notes on product returns. In what circumstances are the pharmaceutical products returned?
13. Discuss the concept of Six Sigma pertaining to quality.
14. What is validation? Add a note on validation master plan.
15. Why is change control necessary in pharmaceutical manufacturing? How do you comply with regulatory authorities when you anticipate changes in the pharmaceutical product?
16. Discuss in brief ICH safety guidelines.

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QP Code: 6030

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Regulatory Affairs

Subject: Documentation and Regulatory Writing

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss the significance of product development report. Describe its contents. (3+7)
2. Discuss planning electronic submission. Add a note on its requirements and regulatory bindings. (3+7)
3. What is audit? Discuss various types of audits. Add a note on check list of good manufacturing practices compliant audit. (1+5+4)
4. Describe root cause analysis and corrective and preventive action with appropriate examples.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Discuss batch manufacturing record. Add a note on batch reconciliation.
6. Write short notes on certificate of analysis.
7. Write short notes on electronic submission gateway.
8. Discuss in brief guidance on non-eCTD electronic submissions for human medicinal products.
9. Enlist the various study groups of Global Harmonization Task Force. Add a brief note on Study Group 4.
10. What is difference between audit and inspection? What is the importance of audit follow-up?
11. Write short notes on inspection criteria of drug distribution channels.
12. What is model certificate of good manufacturing practices (GMP)? Discuss its contents. Who issues the certificate of GMP?
13. Discuss the requirements for post marketing reporting.
14. Discuss with an example about warning letter. What is timeline for responding to a warning letter.
15. Write short notes on recalls and seizure.
16. Write a brief note on establishment inspection report. When and who issues it?

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QP Code: 6031

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Regulatory Affairs

Subject: Clinical Research Regulations

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. What are clinical trials? Explain in detail the Phase IV clinical studies.
2. Write about the origin of ICH. Discuss in brief the ICH- GCP guidelines for clinical practice.
3. Explain the EU clinical regulations for clinical studies.
4. Discuss the E8 regulations for general considerations of clinical trials.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the Phase 0 studies.
6. Write about the key concepts of medical device clinical evaluation.
7. Explain the ethics of clinical research in special population.
8. Write about the informed consent process.
9. Write the requirements for the submission of NDA 505 (b) (2) application to USFDA.
10. Discuss the regulations to conduct drug studies in USA.
11. Write about the GHTF study group 5 guidance documents.
12. Discuss the regulations for dose response information to support drug registration.
13. Discuss the bioavailability and bioequivalence requirements as per FDA.
14. Write about the FDA guidelines for financial disclosure by clinical investigators as per 21 CFR Part 54.
15. Discuss Eudralex Scientific Guidelines for medicines for human use.
16. Write a note on EU guidelines on annual safety report.

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QP Code: 6032

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Regulatory Affairs

Subject: Pharmaceutical Regulations & IPR

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Discuss the key acts and rules governing food and nutraceuticals, focusing on their latest amendments and their implications for the industry.
2. Discuss the roles and responsibilities of state licensing authority.
3. Explain the importance and practical implications of Bureau of Indian Standards (BIS) in various sectors and industries in India.
4. Examine the regulatory environment for medical devices, considering the interplay of rules, regulations, guidelines, and standards in the filing process.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the procedure of patent filing in India.
6. Explain the Drug Price Control Order (DPCO) and its significance in regulating drug prices in India.
7. Explain the format and key contents of a regulatory dossier filing for pharmaceutical products. How does this documentation contribute to the approval process.
8. Differentiate biosimilar and generic drugs.
9. Explain key features of Indian pharmacopeial standards.
10. Provide an overview of the ISO certification process in the Pharmaceutical Industry, highlighting its significance, requirements, and benefits.
11. Discuss the Biopharmaceutical Classification System (BCS) and its relevance in the field of pharmaceuticals, emphasizing its importance in drug development and regulatory processes.
12. What are the different categories of stem cell research defined in the DST-ICMR guidelines, and how do these categories impact the regulation and conduct of stem cell research in India?
13. Define infringement and outline strategies for protecting inventions from unauthorized use.
14. Explain the copyright acquisition process step by step.
15. Explain the various types of patents and the registration procedures for each.
16. Explore the interconnection between Intellectual Property Rights (IPR) and regulatory affairs.

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QP Code: 6037

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Common for Pharmaceutical Analysis, Pharmaceutical Chemistry, Pharmaceutical Quality Assurance, Pharmacognosy and Pharmacology

Subject: Modern Pharmaceutical Analytical Techniques

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Write the principle, instrumentation, interference and applications of flame emission spectroscopy.
2. a) Theory and applications of NMR spectroscopy.
   b) Write a note on solvent requirements in NMR.
3. Write in detail about various ionization techniques in mass spectroscopy.
4. Explain the principle, instrumentation and pharmaceutical applications of ultra-performance liquid chromatography (UPLC).

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the effect of solvents in UV absorption.
6. Write about the various factors influencing fluorescence intensity.
7. Explain spin-spin coupling and constant.
8. Write a short note on theory and applications of FT-NMR.
9. What is MALDI technique in mass spectroscopy? Explain its significance.
10. Draw a neat, labelled diagram of mass spectrophotometer. Add a note on applications of mass spectroscopy.
11. Detection techniques used in TLC.
12. Explain various columns used in GC.
13. Explain gel electrophoresis.
14. Write in detail about principle and applications of XRD.
15. Explain the principle and instrumentation of moving boundary electrophoresis.
16. Write a note on bioluminescence assays.

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QP Code: 6038

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Quality Assurance

Subject: Quality Control and Quality Assurance

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Explain in detail about ICH guidelines.
2. Explain cGMP guidelines according to schedule M.
3. Write in detail about in-process quality control tests for tablets and capsules.
4. Explain how to write and document SOP.

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Define the term quality assurance and quality control. Briefly explain their concept.
6. Explain CPCSEA guidelines.
7. Explain good warehousing practices.
8. Describe the role and functions of USFDA.
9. Explain the purchase specifications and store maintenance of raw materials.
10. Describe the analysis of packaging materials.
11. Electronic common technical documentation (eCTD).
12. Explain the concepts of controlled and uncontrolled documents.
13. How do you monitor mix ups and cross contamination in a pharmaceutical industry.
14. Explain the processes for handling of waste and scrap disposal.
15. What are all the scopes and importances of intellectual property rights.
16. Expiring date calculation.

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QP Code: 6039

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

I Semester M. Pharm Examination- November 2025

Branch: Pharmaceutical Biotechnology

Subject: Modern Pharmaceutical Analytical Techniques

Note: *Draw neat, labeled diagrams wherever necessary.*
Your answer should be specific to the questions asked.

Time: 3 hours **Max. Marks: 75**

Section A

I. LONG ESSAY (Answer any THREE questions) **3x10=30 Marks**

1. Write the principle, instrumentation, interference and applications of flame emission spectroscopy.
2. a) Theory and applications of NMR spectroscopy.
   b) Write a note on solvent requirements in NMR.
3. Write in detail about various ionization techniques in mass spectroscopy.
4. Explain the principle, instrumentation and pharmaceutical applications of ultra-performance liquid chromatography (UPLC).

Section B

II. SHORT ESSAY (Answer any NINE questions) **9x5=45 Marks**

5. Explain the effect of solvents in UV absorption.
6. Write about the various factors influencing fluorescence intensity.
7. Explain spin-spin coupling & constant.
8. Write a short note on theory and applications of FT-NMR.
9. What is MALDI technique in mass spectroscopy? Explain its significance.
10. Draw a neat, labelled diagram of mass spectrophotometer. Add a note on applications of mass spectroscopy.
11. Detection techniques used in TLC.
12. Explain various columns used in GC.
13. Explain gel electrophoresis.
14. Write in detail about principle and applications of XRD.
15. Explain the principle and instrumentation of moving boundary electrophoresis.
16. Write a note on bioluminescence assays.

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