



**JSS
ACADEMY
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M Y S U R U

JSS AHER University Exam Previous

Question Papers

**June 2026
(M Pharm)**

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JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Biotechnology

Subject: Immunotechnology

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. SHORT ESSAY (Answer any THREE questions)

3x10=30 Marks

1. Write an elaborate note on antibody production.
2. Write a note on type I and type II hypersensitivity reactions.
3. Discuss stem cell therapy and its applications.
4. Explain purification of monoclonal antibodies and their applications.

Section B

II. SHORT NOTES (Answer any NINE questions)

9x5=45 Marks

5. Structure and functions of immunoglobulins.
6. Events of phagocytosis.
7. Role of cytokines in immune response.
8. Hypersensitivity type III reactions.
9. DNA vaccines.
10. Immunodiagnostic methods.
11. Screening methods involved in monoclonal antibody production.
12. Method of production of hybridoma cells.
13. Complement fixation reaction.
14. Agglutination reactions.
15. Immunoelectrophoresis.
16. Radioimmunoassays.

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Biotechnology

Subject: Proteins and Protein Formulation

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

1. Detail the methods of protein engineering.
2. Classify peptidomimetics and add a note on the development of non-peptide peptidomimetics.
3. Explain the methods of 2-dimensional gel electrophoresis.
4. List and describe the methods for analyzing protein and DNA formulations.

Section B

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

5. Isolation and purification of proteins.
6. Classify peptidomimetics and add a note on each class.
7. Importance of direct evolution in protein engineering.
8. Stability and activity-based approaches in protein engineering.
9. Isotope protein labelling.
10. N and C terminal amino acid sequence analysis.
11. Define neon particulate systems. List three common types used in drug delivery.
12. Determination of biophysical parameters of proteins.
13. Protein sequencing by Edman degradation.
14. Conventional methods of protein sequencing.
15. Tryptic and chymotryptic peptide mapping.
16. Importance of protein sequencing in the field of medicine.

JSS Academy of Higher Education & Research, Mysuru
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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Analysis

Subject: Herbal and Cosmetic 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Explain the regulatory framework for evaluation and validation of herbal medicinal products under WHO and AYUSH guidelines.
2. Discuss the principles, methodology, and regulatory significance of DNA fingerprinting techniques used in authentication of herbal drugs.
3. Describe the stability testing protocol for herbal and natural products with reference to international and Indian regulatory requirements.
4. Elaborate on herbal drug–drug and herbal drug–food interactions with suitable mechanistic and clinical examples.

Section B

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

5. Differentiate between herbal medicines and conventional synthetic drugs with respect to pharmacokinetic parameters.
6. Explain sources, health risks, and analytical methods employed for detection of heavy metals in herbal formulations.
7. Describe analytical approaches used for pesticide residue analysis in crude herbal drugs.
8. Explain the structure and functioning of spontaneous adverse drug reaction reporting systems applicable to herbal medicines.
9. Discuss WHO guidelines for quality assessment and standardization of herbal raw materials.
10. Explain the principle and procedure for determination of saponification value of cosmetic raw materials.
11. Describe laboratory methods employed for rancidity testing in cosmetic preparations.
12. Outline the Bureau of Indian Standards specifications for sampling of cosmetic finished products.
13. Explain evaluation of viscosity of cosmetic creams and its significance in product performance.
14. Describe methods for determination of moisture content in cosmetic formulations.
15. Explain the significance and determination of ash values in cosmetic raw materials.
16. Discuss quality testing requirements for dental care cosmetic products as per BIS standards.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Analysis

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. SHORT ESSAY (Answer any THREE questions)

3x10=30 Marks

1. Explain the overview of ICH guidelines and write in detail about Quality, Safety, Efficiency and Multidisciplinary guidelines.
2. Write in detail about the organization, personnel responsibilities, training, hygiene and personal records required for pharmaceutical industry as per current good manufacturing practice.
3. Describe in process quality control tests for tablets and capsules as per Indian pharmacopoeia.
4. a) Write a note on standard operating procedures.
b) Explain quality audit plan and reports.

Section B

II. SHORT NOTES (Answer any NINE questions)

9x5=45 Marks

5. Describe current good manufacturing practice.
6. Write a note on good laboratory practice.
7. Write a note on good warehousing practice.
8. How will you design and construct the sterile manufacturing units with specifications.
9. Write a note on in process quality control tests of ophthalmic and surgical products.
10. Write in detail about purchase specifications and raw material storage maintenance.
11. Write about master formula record.
12. Explain about batch formula record.
13. Explain the sanitation procedures in sterile manufacturing premises.
14. Write in detail about the process deviation in pharmaceutical industry.
15. Write about time limitations on production in pharmaceutical industry.
16. Write a note on release of finished products in pharmaceutical industry.

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Analysis

Subject: Modern Bio-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. SHORT ESSAY (Answer any THREE questions)

3x10=30 Marks

1. Explain the principle, procedure involved in extraction of drugs and metabolites from biological matrices by liquid liquid extraction.
2. Explain the various methods of drug permeability.
3. Write in detail about toxicokinetic evaluation in preclinical studies.
4. Elaborate on general procedure for cell cultures.

Section B

II. SHORT NOTES (Answer any NINE questions)

9x5=45 Marks

5. Write a note on USFDA guidelines for bioanalytical method validation.
6. Compare LLE and SPE methods.
7. What are the alternative methods of dissolution testing?
8. Briefly enlist the importance and applications of toxicokinetic studies.
9. Write notes on transport mediated drug-drug interactions.
10. Describe the effect of tissue-binding interactions
11. How do you perform characterization of cells? Give their applications.
12. Write the principles and applications of flow cytometry.
13. Write short notes on rat liver microsomes.
14. What do you mean by generic biologics?
15. Briefly describe the *in-vitro* assay of drug metabolites.
16. What are the methods for assessing bioavailability?

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Second Semester M. Pharm Examination – June 2026**Branch: Pharmaceutical Analysis****Subject: Advanced Instrumental 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. SHORT ESSAY (Answer any THREE questions) | 3x10=30 Marks |
| 1. Discuss the different types of pumps and detectors used in HPLC | (5+5) |
| 2. Write the principle and explain the procedure and instrumentation of size-exclusion chromatography (SEC) with neat diagram. | (3+3+4) |
| 3. Explain the principle involved in capillary electrophoresis and add a note on CE-MS hyphenation. | (5+5) |
| 4. With a neat diagram explain any two mass analyzers. | (5+5) |

Section B

- | | |
|--|---------------------|
| II. SHORT NOTES (Answer any NINE questions) | 9x5=45 Marks |
| 5. Discuss the practical aspects of preparative HPLC. | |
| 6. Explain the difference between ultra and nano liquid chromatography. | |
| 7. Enlist the various derivatization techniques in gas chromatography | |
| 8. Explain ligand and matrix in affinity chromatography with examples. | |
| 9. Discuss the use of crown ethers as buffer additives in capillary electrophoresis. | |
| 10. Enlist the applications of super critical fluid chromatography. | |
| 11. Discuss the various mass fragmentation rules. | |
| 12. Explain the principle involved in FAB mass. | |
| 13. Discuss the importance of quantum numbers and their role in NMR. | |
| 14. Differentiate between 1-D and 2-D NMR. | |
| 15. Classify coupling constant with examples. | |
| 16. Explain the importance of ^{13}C NMR. | |

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Industrial Pharmacy

Subject: Entrepreneurship Management

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. SHORT ESSAY (Answer any THREE questions)

3x10=30 Marks

1. Explain the merits and demerits of different types of enterprise. Add a note on role of enterprise in national and global economy.
2. Discuss the factors affecting entrepreneur role.
3. Discuss in detail the launch and organizing of an enterprise.
4. Explain the techniques of expansion and diversification.

Section B

II. SHORT NOTES (Answer any NINE questions)

9x5=45 Marks

5. What are the government schemes for enterprise development?
6. Explain the institutional support in enterprise development.
7. Write a short note on entrepreneurial motivation.
8. Explain the factors affecting entrepreneur role.
9. Explain the feedback, monitoring and evaluation in an enterprise.
10. Explain the significance of SWOT analysis.
11. Write a short note on joint venture.
12. Write short notes on profitability and control measures in an enterprise.
13. Explain the steps involved in the preparation of project proposal to start a new enterprise.
14. Explain the preparation of feasibility report of a new project.
15. Explain the procedure for implementation of a new project.
16. Write short notes on resource mobilization to start new enterprise.

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Second Semester M. Pharm Examination – June 2026

Branch: Industrial Pharmacy

Subject: Pharmaceutical Production 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Explain in detail tablet production process. Emphasize on specialized granulation technique.
2. Discuss area of planning and environmental control for parenteral.
3. Explain in detail spray drying technology.
4. Explain filling of soft gelatine capsules.

Section B

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

5. Spheronizers and marumerizer.
6. Fluidized bed coating technique.
7. Fixtures and floor treatment for parenteral unit.
8. Equipment location and change room in parenteral production.
9. Lyophilization process.
10. Working conditions of freeze drying.
11. Application of mixers and mills.
12. Packaging materials in pharma industry.
13. Processes of water treatment.
14. Air filter system.
15. Dust collectors.
16. Air handling system.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Industrial Pharmacy

Subject: Scale Up 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. SHORT ESSAY (Answer any THREE questions)

3x10=30 Marks

1. Explain in detail process scale up of semisolids.
2. Explain the protocol for analytical validation.
3. Explain in detail the IQ, OQ and PQ for fluidized bed dryer.
4. Explain the validation process for tablet compression.

Section B

II. SHORT NOTES (Answer any NINE questions)

9x5=45 Marks

5. Problems encountered during technology transfer.
6. Finished product specification for parenterals.
7. Validation master file.
8. Importance of vendor qualification.
9. Process validation of tablet coating.
10. Water process system.
11. Process validation of mixing.
12. Importance of environmental control.
13. Electric hazard.
14. Monitoring and prevention of fire hazard.
15. Industrial effluent testing.
16. Environmental pollution control.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026**Branch: Industrial Pharmacy****Subject: Advanced Biopharmaceutics & Pharmacokinetics***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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks**

1. Discuss the Noyes-Whitney equation and describe how various formulation and physicochemical factors affect the dissolution rate of drugs.
2. Explain *invitro*–*invivo* correlation and its significance in drug development. Explain drug formulation factors affecting drug product performance.
3. Discuss non-linear pharmacokinetics, highlighting the causes of non-linearity in drug absorption and elimination. Explain the Michaelis-Menten equation and how K_{max} and V_{max} are estimated.
4. Explain the design and evaluation of bioequivalence studies, focusing on the crossover study design. How is bioequivalence determined, and what are its implications for generic drug products?

Section B**II. SHORT NOTES (Answer any NINE questions) 9x5=45 Marks**

5. Explain the impact of type of dosage form on the rate of drug absorption in the gastrointestinal tract.
6. Describe the *in vitro* dissolution methods used to assess drug dissolution and their significance in correlating with *in vivo* data.
7. Explain the importance of dissolution profile comparisons in evaluating the bioequivalence.
8. Discuss the stability considerations in the design of a drug product and their impact on its biopharmaceutical performance.
9. Discuss the effect of protein-binding interactions on the pharmacokinetics of drugs.
10. Describe the concept of two-compartment model and their relevance in pharmacokinetics.
11. Write a note on the Biopharmaceutics Classification System (BCS) and its role in predicting drug bioavailability.
12. Define relative and absolute bioavailability. Explain the methods for assessing bioavailability.
13. Explain the concept of targeted drug delivery systems and their relevance in enhancing therapeutic outcomes.
14. Briefly discuss the pharmacokinetics and pharmacodynamics of monoclonal antibodies in therapeutic applications.
15. Write a note on the pharmacokinetics and pharmacodynamics of vaccines, focusing on their role in immunotherapy.
16. Explain the pharmacokinetic and pharmacodynamic interactions of biotechnology drugs and how these interactions affect their efficacy and safety.

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I Semester M. Pharm Examination- June 2026

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 how lead from natural products is used in the development of new cardiovascular agents.
2. Write an account on general methods of structural determination of flavonoids.
3. Explain the general methods of structural elucidation of terpenoids and add a note on structural elucidation of ginsenoside
4. What is oligonucleotide therapy? Explain the tools used in hybridoma technology.

Section B

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

5. Explain how curare alkaloids are used as lead in the development of new neuromuscular blocking agents.
6. Explain the development of paclitaxel as anticancer agent.
7. Explain the chemistry and structural elucidation of reserpine.
8. Explain the chemistry of adrenocorticoids.
9. Explain the chemistry and physiological functions of vitamin C.
10. Explain the structural elucidation of β carotene.
11. Write an account on new pharmaceuticals developed from biotechnology.
12. Write an account of plant products used as anti-cancer agent.
13. Explain the structural characteristics of vitamin D using infra-red spectroscopy.
14. Explain the structural characteristics of penicillin using ^1H NMR.
15. Write an account of structural characteristics of morphine using mass spectroscopy.
16. Explain the structural characteristics of camphor using infra-red spectroscopy.

JSS Academy of Higher Education & Research, Mysuru

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I Semester M. Pharm Examination- June 2026

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. With a neat, labelled diagram, describe the automation and operation of a packed glass bead fermenter.
2. Explain the methods for testing air purity.
3. How will you process milk by HTST sterilization.
4. Explain the role of TLC in the separation and identification of fermented products.

Section B

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

5. How will you control foam during fermentation process?
6. How does a bubble column work?
7. How do oxygen requirements affect microbial growth during fermentation?
8. Explain the types of air compression.
9. Explain the different techniques for immobilization.
10. Explain batch culture.
11. Explain chromatogram.
12. Differentiate primary and secondary culture.
13. How will you prepare alcohol using fermentation process?
14. Explain the regulations governed for the manufacturing of biological products.
15. Explain the process for synthesizing secondary metabolites
16. What is meant by microbial transformation?

JSS Academy of Higher Education & Research, Mysuru

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I Semester M. Pharm Examination- June 2026

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 various methods of isolation, cultivation and preservation of pure culture.
2. Discuss in detail about the protein synthesis process in cells.
3. Describe the various steps involved in cell cycle process.
4. Discuss in detail the suitable physical and chemical environment for microbial growth.

Section B

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

5. Write a note on the cultivation of virus in laboratory.
6. Explain the methods of reproduction in fungi.
7. Explain the structure of DNA.
8. Write note on the types of mutants.
9. Explain apoptosis.
10. Write a note on carcinogens.
11. Write about the nutrient composition used for the animal cell culture.
12. Discuss in short on method of enumeration of animal cells.
13. Write about the mechanism of action of antimicrobial agents.
14. Discuss the multiplication of HIV in the host and its identification test.
15. Write in detail treatment regimen used for any one viral disease.
16. Write a note on the basic features of pathogenic bacteria and virus.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Quality Assurance

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

1. Discuss the importance, scope and frequency of calibration and validation.
2. Design an operational qualification protocol for low pressure quaternary gradient HPLC system.
3. Design an operational qualification protocol for pharmaceutical compressed air systems.
4. Explain the stages of process validation of hard gelatin capsules.

Section B

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

5. Explain the advantages of calibration.
6. Discuss the scope of validation master plan.
7. Design the operational qualification protocol for Differential Scanning Calorimetry.
8. Design the performance qualification of tray dryers.
9. Design the operation qualification protocol for the friability test apparatus.
10. Design the operational qualification protocol for disintegration test apparatus.
11. Explain revalidation and its criteria with suitable examples.
12. How will you perform process validation of aerosols? Explain with examples.
13. Explain the importance of GAMP guidelines.
14. Discuss the scope of electronic records and digital signatures.
15. Discuss IPP with suitable examples.
16. Discuss the significance of transfer technology.

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutics

Subject: Advanced Biopharmaceutics & Pharmacokinetics

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

1. Explain the physicochemical factors affecting drug absorption.
2. Describe different levels of *in vitro-in vivo* correlation.
3. Explain one compartment model for intravenous (IV) infusion and equation for calculating the loading dose.
4. Describe the methods used for assessing bioavailability.

Section B

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

5. Explain the role of excipients in the absorption of drugs from gastrointestinal tract.
6. Write a note on importance of Tight-Junction Complex.
7. Write a note on methods for dissolution profile comparisons.
8. Explain the rate-limiting steps in drug absorption.
9. Describe the causes for non-linearity in pharmacokinetics.
10. Explain cytochrome p450-based drug interactions.
11. Explain the crossover study designs.
12. Write on clinical significance of bioequivalence studies.
13. Explain the pharmacokinetics and pharmacodynamics of proteins and peptides.
14. Explain the pharmacokinetics of targeted drug delivery systems.
15. Explain the pharmacokinetics and pharmacodynamics of oligonucleotides.
16. Explain the pharmacokinetics and pharmacodynamics of vaccines.

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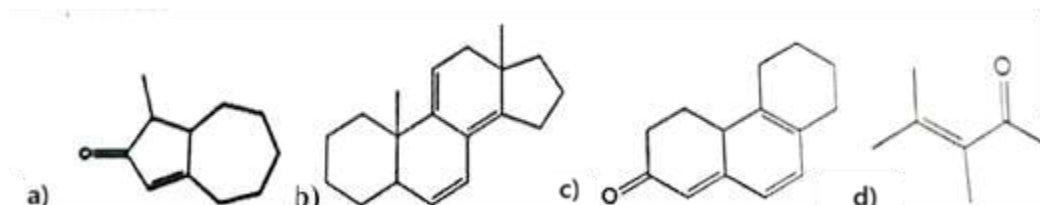
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Second Semester M. Pharm Examination - June 2026**Branch: Pharmaceutical Chemistry****Subject: Advanced Spectral Analysis**

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

1. Explain Woodward-Fieser Rule and assign the wavelength for following compounds:



2. Explain NOESY, COSY and INADEQUATE techniques in Nuclear Magnetic Resonance spectroscopy with examples.
3. Explain mass fragmentation rules with suitable examples for alcohols, amine, carbonyl groups and alkanes.
4. Explain principle, instrumentation and applications of Ion chromatography and Ion exclusion chromatography.

Section B**II. SHORT NOTES (Answer any NINE questions)****9x5=45 Marks**

5. Give principle and advantages of ATR-IR technique.
6. Give the scheme for identification and confirmation of alcohols, aldehydes and ketones from IR data.
7. Explain principles and applications of 1-D NMR.
8. Predict the multiplicity and chemical shift value for protons in the following compounds:
- a) $\text{CH}_3\text{CH}_2\text{CH}_2\text{OCH}_3$
- b) $(\text{CH}_3)_2\text{CHOCH}(\text{CH}_3)_2$
9. Give importance of Mc Lafferty rearrangement.
10. Describe the different ions produced in mass spectrometry with examples.
11. Explain the working and different types of HPTLC.
12. Explain mechanism of supercritical fluid chromatography.
13. Write the principle and applications of differential thermal analysis.
14. Explain Raman spectroscopy with example.
15. Write the principle and importance of ELISA.
16. Explain RIA of insulin.

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Second Semester M. Pharm Examination - June 2026

Branch: Pharmaceutical Regulatory Affairs

Subject: Regulatory Aspects of Food & Nutraceuticals

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

1. Discuss scope and opportunities of nutraceutical market and add a note on history of food and nutraceutical regulations.
2. Describe the WHO guidelines on nutrition in detail.
3. Explain regulations for import, manufacture and sale of nutraceutical products in India.
4. Describe the labelling requirements and label claims for dietary supplements. Add a note on Dietary Supplement Health and Education Act.

Section B

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

5. Write a note on functional foods and medical foods.
6. Mention difference between nutraceuticals and novel food. Add a add note on various schedules as per FSSAI.
7. Discuss good manufacturing practices for nutraceuticals.
8. Explain role of NSF International in dietary supplements and nutraceuticals.
9. Describe the organizational structure and functions of Food Safety and Standards Authority of India.
10. Write a note on classification and sale of nutraceutical products in India.
11. Describe the US regulations for manufacturing and sale of nutraceuticals.
12. Write a note on the importance of labelling requirements and label claims for dietary supplements.
13. Describe the organization structure and functions of European Food Safety Authority.
14. Write a note on EU directives for manufacturing and sale of dietary supplements in EU.
15. Explain European regulation on novel foods.
16. Discuss nutrition labelling of dietary supplements as per EFSA.

JSS Academy of Higher Education & Research, Mysuru

(Deemed to be University)

Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Regulatory Affairs

Subject: Regulatory Aspects of Medical Devices

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

1. What is the concept and significance of risk-based classification in the regulatory framework for medical devices and in vitro diagnostics (IVDs)? Additionally, what are the essential principles that govern the design and manufacturing of medical devices and IVDs?
2. What are the key components and significance of the ISO 14155:2011 standard, which outlines the principles of Good Clinical Practice (GCP) for conducting clinical investigations of medical devices?
3. What are the different classifications of medical devices in the United States, and what are the regulatory approval processes, including the 510(k) Premarket Notification and Pre-Market Approval (PMA), for these medical devices?
4. What is the regulatory approval process for medical devices in the European Union, including the classification system?

Section B

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

5. What are the stages in the product lifecycle of medical devices, and how does the classification of medical devices work?
6. Write a note on Global Medical Device Nomenclature (GMDN).
7. Write a note on Quality Risk Management of medical devices.
8. Write a note on Adverse Event Reporting of medical device.
9. Write a note on post marketing surveillance of medical devices and Unique Device Identification (UDI).
10. What are the key aspects of the classification system and approval process for *in vitro* diagnostics (IVDs) in the United States?
11. What is the process for obtaining CE certification for medical devices in the European Union?
12. What is the Active Implantable Medical Device Directive, and what are its key requirements and implications for manufacturers and users of active implantable medical devices?
13. What are the regulatory registration procedures for medical devices and *in vitro* diagnostics (IVDs) in Thailand?
14. What are the regulatory registration procedures for medical devices and *in vitro* diagnostics (IVDs) in China?
15. What are the regulatory registration procedures for medical devices and *in vitro* diagnostics (IVDs) in Japan?
16. What are the study groups within the International Medical Device Regulators Forum (IMDRF), and what are some key guidance documents developed by IMDRF?

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Regulatory Affairs

Subject: Regulatory Aspects of Herbal & Biologicals

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

1. Explain the data requirements and pharmacovigilance aspects for similar biologics in India.
2. Discuss in detail the biologics regulations as per USFDA.
3. Discuss the EU regulations for the development and regulatory approval of biologics.
4. Write the Indian regulatory requirements for the blood and related products.

Section B

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

5. Enlist the data requirements of biologics for preclinical studies in India.
6. Write a note on GDP aspects in India.
7. Enumerate the BLA requirements for biologics in USA.
8. Differentiate between generic drugs and biologics
9. Write a note on comparability and bio-similarity assessment as per EMA regulations.
10. Discuss about stability, safety and labeling aspects of biologics in EU.
11. Discuss the vaccine regulations in India.
12. Explain about blood regulations in European Union.
13. Discuss the safety guidelines related to EU herbal drug products.
14. Write about the safety guidelines of herbal products as per Indian legislation.
15. Give an overview of quality regulations of herbal products in USA
16. Discuss the regulatory approval of herbal drug products in EU.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Regulatory Affairs

Subject: Regulatory Aspects of Drugs & Cosmetics

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

1. Explain regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA.
2. Explain the regulatory requirements for approval of drug application as per European Medicines Agency (EMA).
3. Discuss organization, types of registration applications and DMF system in Japan.
4. Explain various committees across the globe like ASEAN, APEC, EAC, GCC, PANDRH and SADC.

Section B

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

5. Discuss regulatory requirements for orphan drugs in USA.
6. Brief on regulatory aspects of combination products in USA.
7. Write a note on variations and extensions in EU.
8. Discuss roles and responsibilities of Qualified Person (QP) in EU.
9. Discuss post marketing surveillance in Japan.
10. Write a note on approval of cosmetics in Japan.
11. Explain WHO good manufacturing practice (GMP) guidelines.
12. Discuss Certificate of Pharmaceutical product.
13. Discuss regulatory considerations for post approval requirements in Saudi Arabia and UAE.
14. Write a note on marketing authorization procedure in South Korea.
15. Discuss regulatory considerations for cosmetics in Brazil.
16. Explain marketing authorization procedure in Russia.

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Second Semester M. Pharm Examination - June 2026

Branch: Pharmaceutical Quality Assurance

Subject: Pharmaceutical Manufacturing 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Explain the legal requirements and licensing procedure for new formulation industry.
2. Explain the manufacturing flow chart and in-process quality control tests for suspensions.
3. Explain the in-process quality control test for tablets.
4. Classify the types of primary packing materials for pharmaceuticals. Explain the different types of plastics used.

Section B

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

5. Write a note on loading and scheduling in production planning.
6. Write the basic requirement for sterile layout.
7. Explain in-process quality controls for ointments.
8. Explain the principle, process and equipment in lyophilization technology.
9. Explain the in process quality control tests for soft gelatin capsules.
10. Write a note on pelletization equipments.
11. Classify different types of closures. Enlist their merits and demerits.
12. Write the overview of stability aspects of packaging.
13. Briefly explain the Design of Experiment (DOE) approaches and significance in the formulation developments.
14. Explain the elements of QbD
15. Write a note on QTPP, CMA, and CQA.
16. Explain FDA initiatives on process analytical technology.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Quality Assurance

Subject: Audits and Regulatory Compliance

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

1. Discuss in detail about planning process for management of an audit as an auditee and auditor.
2. Design a detailed audit check list for drug industries.
3. Prepare a detailed audit checklist for dry production facilities manufacturing sterile powder.
4. Prepare an audit checklist for microbiology laboratory of a non-sterile manufacturing unit.

Section B

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

5. Explain the importance of information gathering.
6. Explain the impact of critical deficiencies with the help of case study.
7. Write a note on quality assurance functions during an audit.
8. How do you control non-conformance by adhering to current GMP guidelines?
9. Discuss any five critical deficiencies to be listed out in a sterile production.
10. Discuss points to be considered during preparation of an audit check list for tablet production facility.
11. Write a note on auditing microbiology laboratory.
12. Discuss about testing of samples in microbiology lab as per the regulatory
13. Explain the parameters to be checked in auditing HVAC.
14. Discuss the importance of ETP in pharmaceutical industry.
15. Write a note on impact of qualification of HVAC unit and mandatory test to be conducted for effective functioning of HVAC.
16. Critical auditing points to be considered for water for injection systems.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Quality Assurance

Subject: Hazards & Safety Management

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

1. Discuss in detail about natural resources and associated problems.
2. Discuss in detail about fire extinguishers and critical hazard management system.
3. Explain in detail about management of over exposure to chemicals and TLV concept.
4. Discuss in detail about safety and hazards regulations.

Section B

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

5. Structure and function of ecosystem.
6. Water resources and associated problems.
7. Role of HVAC system in non-sterile manufacturing facility and its importance in preventing air-based hazards.
8. Fire protection system.
9. Organic solvent hazard and its prevention.
10. Sulphonating hazard and its prevention.
11. Hazards associated with electrical and mechanical process.
12. Preventive management from fire and explosion.
13. Design an installation protocol for a reactor considering ICH Q9 guidelines.
14. Draft a SOP on self-protective measuring techniques for an API industry.
15. Importance of safety programme and its training in a pharmaceutical facility.
16. Overall function of ETP set up in the bulk drug industry.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacy Practice

Subject: Pharmacoepidemiology & Pharmacoeconomics

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

1. Define pharmacoepidemiology. Explain its scope and applications. Write note on prevalence and incidence. (1+7+2)
2. Define drug utilization evaluation and explain the steps involved. What are various types of drug utilization evaluation? (1+6+3)
3. Explain the following terms in detail a) Clinical outcome, b) Economic outcomes. (5+5)
4. Explain quality adjusted life years along with the steps involved in calculating.

Section B

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

5. Explain diagnosis and therapy surveys.
6. Write note on attributable risk and relative risk.
7. What are record linkage systems? Explain.
8. Write in detail about case reports and case series.
9. Enumerate on need of pharmacoeconomic studies in Indian healthcare system.
10. Explain the concept of Willingness to Pay.
11. Write in brief on cost consequence analysis.
12. What are the applications of pharmaco-economic evaluations?
13. Write short note on HRQOL
14. What is sensitivity analysis? Write its applications.
15. Enlist five different softwares used in:
 - a) Pharmacoeconomics
 - b) Meta analysis
16. Write note on decision tree.

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Second Semester M. Pharm Examination - June 2026

Branch: Pharmacy Practice

Subject: Clinical Pharmacokinetics and Therapeutic Drug Monitoring

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

1. Define clinical pharmacokinetic and explain plasma drug concentration-time profile. (2+8)
2. Explain the various pharmacokinetic drug interactions with suitable examples. (10)
3. Define nonlinear mixed effects modelling (NONMEM). What is inter-individual variability and how is it incorporated into population PK models using random effects? (2+8)
4. Explain in detail the general approaches for dosage adjustment in renal diseases. (10)

Section B

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

5. Explain the different methods of conversion of intravenous to per oral dosing.
6. What are nomograms? Explain their applications in pharmacokinetic studies with examples.
7. Describe the role of cytochrome P-450 enzymes in drug interactions and explain with suitable example.
8. Discuss the role and clinical significance of genetic polymorphism in drug transports and drug targets with suitable examples.
9. Write a stepwise process for building a population pharmacokinetic model.
10. What are the most commonly used estimation methods in population PK modeling and how do they differ?
11. Explain the various pharmacokinetic changes observed in the renal impaired patients.
12. Explain drug dosing in hepatic failure.
13. Write the therapeutic drug monitoring of digoxin.
14. Define TDM. Discuss the indications for TDM of drugs.
15. Explain effect of age and bodyweight in individualization of drug dosage regimen.
16. Write the therapeutic drug monitoring of Cyclosporine.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacy Practice

Subject: Pharmacotherapeutics - II

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

1. What is Parkinson's disease? Explain the pharmacological management of Parkinson's disease. (1+9)
2. Write the clinical presentation and management for schizophrenia. (3+7)
3. Explain the pharmacological management of tuberculosis and septicemia. (5+5)
4. What are opportunistic infections? Explain its management. (2+8)

Section B

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

5. Define and classify neuralgia. Write a note on trigeminal neuralgia.
6. Explain pain pathways and enlist the drugs used in pain management.
7. What are the clinical features of depression? Write its management.
8. Enlist drug induced renal disease. Briefly explain any one of them.
9. Write the clinical features, risk factors and pharmacological management of urinary tract infection.
10. What is bacterial endocarditis? Explain its management.
11. Write the clinical features and pharmacological management of rheumatic fever.
12. Write the patient counselling points for HIV and H1N1.
13. Write a note on general principles of cancer chemotherapy.
14. Explain the pharmacological management of breast cancer.
15. Write the supportive care required and drugs used in head and neck cancer.
16. Write a note on hematological malignancies.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacy Practice

Subject: Principles of Quality Use of Medicines

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

1. Define quality use of medicines and explain principles of quality use of medicines.
2. Define evidence based medicine and explain approach and practice of evidence based medicine in clinical settings with suitable example.
3. Explain prescribing in pregnancy and lactating women.
4. Explain the role of industry in quality use of medicines in medicine development.

Section B

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

5. Role of communication in quality use of medicines.
6. Aims and desirable attributes of six building blocks in quality use of medicines.
7. Need and concept of rational drug use.
8. Essential drugs.
9. Impact of quality use of medicines on E-Health.
10. Prescribing in immune compromised patients.
11. Role of Central Drugs Standard Control Organization and Good Manufacturing Practices in quality use of medicines in India.
12. Schedules of drugs in India.
13. Mechanism of Type B adverse drug reactions.
14. Different types of medication errors with suitable examples.
15. World Health Organization (WHO) causality assessment of adverse drug reactions.
16. Define Pharmacovigilance and Adverse Drug Reactions as per World Health Organization.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacology

Subject: Clinical Research and Pharmacovigilance

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

1. Describe the origin and principles of International Conference on Harmonization (ICH). Write a note on ethical committee and Institutional Review Board (IRB). (4+3+3)
2. Explain contract research organization along with its management. Differentiate various aspects of RCTs and non RCTs. (6+4)
3. Describe the types, methods of detection and reporting, and severity and seriousness assessment of adverse drug reactions.
4. Explain the basic aspects and functions of pharmacovigilance. Add a note on evaluation of medication safety.

Section B

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

5. Write a note on Good Clinical Practice (ICH-GCP) guidelines.
6. Write in detail about ethical principles governing informed consent process.
7. Explain the different observational study in detail.
8. What are the roles and responsibilities of clinical study investigator?
9. Describe the guidelines involved in the preparation of protocol.
10. Explain the safety monitoring in clinical trials.
11. Enumerate the roles and responsibilities of pharmacovigilance in health care system.
12. Write in detail about industry and national programmes related to pharmacovigilance.
13. Write a note on statistical methods for evaluating medication safety data.
14. What is spontaneous reporting? Explain.
15. Explain the International classification of diseases.
16. What is pharmacoeconomics and what is its role in health care?

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026**Branch: Pharmacology****Subject: Principles of Drug Discovery**

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

1. Enumerate on various strategies of lead identification and add a note on economy of drug discovery process. (7+3)
2. a) Explain the process of combinatorial chemistry and its applications on drug discovery process. (3+2+2+3)
b) Describe the principles and applications of High Throughput screening and NMR in drug discovery process
3. a) Define and make a relevance of pharmacophore in docking process. (2+3+3+2)
b) Explain the process of virtual screening and add a note on its limitations.
4. Enumerate on various methods of *de novo* synthesis.

Section B**II. SHORT NOTES (Answer any NINE questions) 9x5=45 Marks**

5. Describe proteomics and its application relevant to drug discovery process.
6. Describe antisense technology and add a note on its application and limitations.
7. Describe various levels of protein structure and make a relevance on various types of chemical bonding.
8. What is homology model of protein? How is it useful in drug discovery process?
9. Compare the traditional Vs rational drug design methods.
10. Explain the pharmacophore mapping process.
11. Explain the concept and limitations of Hammett substituent constant.
12. Compare hydrophobicity and substituent hydrophobicity constant.
13. Explain COMFA and its limitations.
14. Explain the application of prodrug concept towards improving target specificity and delivery with suitable examples.
15. What is PLS and how is applicable in validation of QSAR?
16. Explain the application of prodrug concept towards improving patient acceptability with suitable examples.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacology

Subject: Pharmacological and Toxicological Screening Methods- II

*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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks**
1. Discuss the history, principles and basic concepts of Good Laboratory Practices. (2+3+5)
 2. What are OECD guidelines? Define the principle, methodology and observations of dermal irritation test in detail. (2+8)
 3. Classify reproductive toxicity studies. Elaborate on teratogenicity studies. (2+8)
 4. Write the importance of safety pharmacology studies. Explain in detail the safety pharmacology core battery test for the central nervous system. (2+8)

Section B

- II. SHORT NOTES (Answer any NINE questions) 9x5=45 Marks**
5. Explain the types of toxicology testing.
 6. Explain OECD guidelines for repeated dose 28 days toxicity study.
 7. Explain the principle and procedure for OECD 425 test guidelines.
 8. Write in brief about OECD 403 test guidelines.
 9. What is genotoxicity? Write the principle of micronucleus chromosomal aberrations study.
 10. Write a brief note on male reproductive toxicity studies.
 11. Define IND. Explain the list of studies and their importance in drug discovery process.
 12. Write a brief note on CVS safety pharmacology.
 13. Define toxicokinetics. Elaborate principles and parameters of toxicokinetics.
 14. Explain the alternative methods of animal toxicity testing.
 15. Write the applications of toxicokinetics.
 16. What is saturation kinetics? Explain its importance and applications in toxicology studies.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacology

Subject: Advanced Pharmacology - II

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

1. Discuss the mode of action, pharmacological actions, adverse drug reactions and uses of insulin.
2. Write the molecular mechanisms of action of beta lactum antibiotics and add note on its ADR.
3. Explain the role of cellular and biochemical mediators involved in inflammation and immune responses.
4. Define and classify anti-ulcer drugs. Write the mechanism of action and adverse reactions of H2 blockers and proton pump inhibitors.

Section B

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

5. Write the molecular and cellular mechanism of action of estrogen.
6. Outline the pharmacological agents used to treat prolactinomas and their mechanism of action.
7. Write the mechanism of action of azithromycin and give its uses.
8. Explain the mechanisms of development of microbial resistance to antibiotics.
9. Write the mode of action of any two drugs used in helminthiasis.
10. Write the classification of anticancer drugs with specific examples
11. What is chronopharmacology? Write its principles and concepts.
12. Classify antiemetic drugs with examples. Write the mechanism of action of any one class.
13. Write a brief note on recent advances in the treatment of Alzheimer's disease.
14. Explain the role of free radicals in etiopathology of diabetes.
15. Outline the protective roles of important antioxidants in combating oxidative stress.
16. Describe the process of free radical generation and its impact on cellular structures.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacognosy

Subject: Herbal Cosmetics

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

1. Explain in detail about GMP related to manufacture of cosmetics.
2. Describe pre-formulation and compatibility studies involved in cosmetic formulations.
3. Explain the physiology and chemistry of lips and nail.
4. Explain the methods of preparation and standardization of herbal fairness formulations.

Section B

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

5. Classification of herbal cosmetics.
6. Offences and penalties as per Drugs and Cosmetics Act.
7. Surfactants and humectants used in herbal cosmetics.
8. Discuss ideal requirements of preservatives used in cosmetics. Mention various preservatives recommended for cosmetics.
9. Preparation and standardization of Bleaches.
10. Parameters involved in the standardization of mouth washes.
11. Method of preparation of deodorants.
12. Method of preparation of conditioners.
13. Toxicity studies as per Drugs and Cosmetics Act.
14. Protocol for stability testing of herbal cosmetics.
15. General methods of analysis of skin care products by BIS standards.
16. Protocol for testing skin irritation and allergic reactions for hair dyes.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacognosy

Subject: Indian Systems of Medicine

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

1. Discuss in detail on different dosage forms of the Indian Systems of Medicine.
2. Write a detail note on yoga, asana, pranayama, meditation and relaxation techniques.
3. Explain the method of preparation and standardization of any two formulations as per Siddha pharmacopoeia.
4. Elaborate on preparation of documents for new drug applications and export registration of Indian system of medicine.

Section B

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

5. Purification process (Suddhi) in Siddha system of medicine.
6. Fundamental concepts of Homeopathy system of medicine.
7. Discuss the benefits of aroma oils for common problems and enlist the role of carrier oils in the preparation.
8. Write the treatment modalities of naturopathy.
9. Explain the stability studies of ISM formulations.
10. Describe the formulation development of Unani and Homeopathy system of medicine.
11. Good Agricultural Practice of Indian system of medicine.
12. Regulation challenges in monitoring the safety of herbal medicine.
13. Geographical indication bill.
14. Central council for research in ayurveda science.
15. Write a brief note on traditional knowledge digital library and highlight its objectives and recent development.
16. Enlist the roles and responsibilities of central council for research in Siddha.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacognosy

Subject: Advanced Pharmacognosy - II

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

1. Give an account on pharmacodynamics and pharmacokinetics issues in herbal drug remedies.
2. Discuss in detail about adulteration and deterioration of herbal drugs.
3. Explain the role of ethno botany in traditional medicine and new development of herbals.
4. Write the analytical profile of *Andrographis paniculata*.

Section B

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

5. Write a note on herbals Vs conventional drugs.
6. Add a note on validation of herbal therapies.
7. Write a note on detection of pesticidal residues in herbal drugs and formulations.
8. Write the method of determination of foreign matter in herbal drugs.
9. What are Bio-prospecting tools for drug discovery?
10. Discuss the role of bio-adversity in herbal drug development.
11. Write the analytical profile of *Coleus forskholii*.
12. Write the analytical profile of *Psoralea corylifolia*.
13. Explain the significance of phytopharmacological screening of natural products.
14. In-vivo evaluation technique for anti-ulcer activity.
15. Explain the pharmacological screening of natural products for anticancer activity.
16. Write the method of evaluation of antimicrobial activity of an extract *in vitro*.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmacognosy

Subject: Medicinal Plant 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Describe the structure and complicity of genome in DNA recombinant technology.
2. Explain the method of initiations of hairy root and multiple shoot culture and their applications.
3. Explain immobilization techniques of plant cell and its application on secondary metabolite production.
4. Explain in detail the factors influencing biotransformation and transgenesis.

Section B

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

5. Write a note on cell signaling.
6. Define genetic code and write its characteristic features.
7. Write a note on synthesis seeds.
8. Write the applications of gene transfer in plant cells.
9. Write the advantages and disadvantages of plant cell cloning.
10. Write the applications of protoplast culture.
11. Write the methods used in sequencing of genes.
12. Write the applications of PCR in plant genome analysis.
13. Explain the production of ergot alkaloids using fermentation technology.
14. Write the method of amylase production.
15. Write the sources, therapeutic use and method of production of asparaginase.
16. Give the list of microorganisms used for single cell proteins (SCP) production.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutics

Subject: Cosmetics and Cosmeceuticals

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

1. Explain the Indian regulatory provision relating to import, manufacture and labeling of cosmetics.
2. Describe the structure and growth cycle of hair with a neat diagram.
3. Discuss in detail about the building blocks used in the formulation of a tooth paste.
4. Describe a brief note on the design of cosmeceutical products – acne, pigmentation, and body odour.

Section B

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

5. Differentiate misbranded and spurious drug cosmetics.
6. Define loan license under Drugs & Cosmetics Act. Explain offences and penalties related to misuse of loan license.
7. Discuss cleansing and care needs for lips and eyelid.
8. Illustrate and discuss the structure of skin.
9. Enumerate the evaluation of shampoo.
10. List out the formulation requirements for vanishing and cold cream.
11. Describe in brief sunscreens.
12. Summarize the common problems associated with oral cavity.
13. List out the herbal ingredients used in hair care.
14. Discuss shortly about herbal formulation of face cream.
15. Describe the guidelines for herbal cosmetics by COSMOS.
16. Discuss shortly about rheological modifiers.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutics

Subject: Computer Aided Drug 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. SHORT ESSAY (Answer any THREE questions)

3x10=30 Marks

1. Describe the history of computers in pharmaceutical research and development.
2. Discuss modeling techniques in drug absorption and intestinal permeation.
3. Explain different screening designs in pharmaceutical development.
4. Describe gastrointestinal absorption simulation in detail.

Section B

II. SHORT NOTES (Answer any NINE questions)

9x5=45 Marks

5. Explain sensitivity analysis.
6. Differentiate descriptive versus mechanistic modeling.
7. Write a note on BBB-Choline transporter.
8. Discuss BCRP and Nucleoside transporters.
9. Discuss the ethics of computing in pharmaceutical research.
10. Explain the legal protection of innovative uses of computers in R&D.
11. Briefly discuss biowaiver considerations.
12. Write a note on modeling fed vs fasted state.
13. Write a note on computational fluid dynamics.
14. Explain the current challenges and future directions of robotics.
15. Write a note on Artificial Intelligence (AI).
16. Discuss the pharmaceutical applications, advantages and disadvantages of pharmaceutical automation.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutics

Subject: Molecular 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Explain the basic concept of target-oriented drug delivery system. Write note on tumour targeting.
2. Explain the principle and techniques of formulating nanoparticles.
3. What are niosomes? Explain any five methods of preparation of niosomes.
4. Discuss the types, preparation, problems and evaluation of pulmonary drug delivery systems.

Section B

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

5. Why targeting is required? Explain active targeting in detail.
6. Explain different barriers for drug delivery to brain. Suggest ways to overcome them.
7. Write a note on lipids used for liposome preparation.
8. What are the different types of nanoparticles? Discuss SCF methods for preparing nanoparticles.
9. Discuss method of preparing monoclonal antibodies.
10. Describe applications of aquasomes as targeted drug delivery system.
11. What is the role of propellant in aerosols? Discuss about types of propellants.
12. Describe the formulation of nasal sprays. How is it evaluated?
13. Explain in detail liposomal gene drug delivery system.
14. Write a note on antisense molecules.
15. Define gene therapy. Describe *ex vivo* and *in vivo* gene therapy.
16. Explain therapeutic applications of aptamers as drugs of future.

JSS Academy of Higher Education & Research, Mysuru

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Chemistry

Subject: Pharmaceutical Process 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Explain the stages in scaling up a chemical synthesis process from bench to large-scale production.
2. Explain the principle of crystallization and explain the factors affecting crystallization and nucleation. (5+5)
3. Explain the types of oxidative reactions. Give the mechanisms, advantages, and limitations of sodium hypochlorite. (4+6)
4. Explain the types and mechanisms of reduction reactions.

Section B

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

5. In-process quality control of APIs during the large-scale manufacturing.
6. Types and sources of impurities in APIs.
7. Concept of liquid equilibria and describe any one method of extraction.
8. Principle of filtration and describe vacuum filtration.
9. Types of halogenations.
10. Kinetics and mechanism of aromatic nitration.
11. Heterogeneous and homogeneous catalysts.
12. Aerobic and anaerobic fermentation process.
13. Types and purposes of PPE.
14. Hazard labels for chemicals.
15. Occupational Health & Safety Assessment Series 1800.
16. Fire Hazards.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Chemistry

Subject: Computer Aided Drug Design

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

1. Describe the historical developments of Quantitative Structure Activity Relationships (QSAR). Explain how physicochemical parameters contribute to QSAR models. (4+6)
2. Compare Hansch analysis and Free Wilson analysis in QSAR and highlight their advantages & disadvantages.
3. Explain the significance of energy minimization methods in identifying global minimum conformation and bioactive conformation in drug design.
4. Explain the importance of predicting and analyzing ADMET properties in drug design. Describe any one computational tool used for ADMET prediction. (6+4)

Section B

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

5. Explain the importance of statistical validation in QSAR modeling.
6. Explain the importance of electronic parameters.
7. Derive a simple 2D-QSAR equation and explain the variables and constants.
8. Outline the procedures involved in generating and interpreting contour maps in 3D QSAR.
9. Discuss the application of energy minimization in protein-ligand docking.
10. Describe the flexible docking in detail.
11. Discuss about De novo drug design.
12. Explain the concept of homology modeling and its significance in protein structure prediction.
13. Explain the concept of pharmacophore mapping.
14. Outline the steps involved in pharmacophore-based virtual screening.
15. Describe the importance of protein-ligand interactions in structure-based virtual screening.
16. Explain similarity based and pharmacophore based screening.

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Second Semester M. Pharm Examination – June 2026**Branch: Pharmaceutical Chemistry****Subject: Advanced Organic Chemistry – II**

*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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks**
1. Explain the effects of solvents in microwave assisted synthesis. Write the merits and demerits of microwave assisted organic synthesis. (4+6)
 2. What are pericyclic reactions and its principle? Explain cycloaddition and electrocyclic reactions. (6+4)
 3. Explain t-Boc & Fmoc in peptide synthesis. Write a note on coupling agents with suitable examples. (5+5)
 4. Explain the significance of catalysis in organic synthesis. Write a note on Phase transfer catalysis - theory and applications. (3+7)

Section B

- II. SHORT NOTES (Answer any NINE questions) 9x5=45 Marks**
5. Classify sonochemical reactions with examples.
 6. Explain principle and working of continuous flow reactors.
 7. Explain ultrasound assisted reactions and its synthetic applications.
 8. Explain possible scheme to synthesis tripeptide using glycine alanine and phenylalanine.
 9. Explain segment and sequential strategies for solution phase peptide synthesis with any one case study.
 10. Describe sigma trophic rearrangement reactions with examples.
 11. Describe electrocyclic reaction with examples.
 12. Explain the homogenous catalysis with examples. Write their advantages and disadvantages.
 13. Explain the heterogeneous catalysis with examples. Add a note on their advantages and disadvantages.
 14. Explain optical activity and specific rotation in stereochemistry.
 15. Explain the rules of naming E and Z notation using (CIP) sequence rule.
 16. Write a note on chiral auxiliaries and catalyst used in asymmetric synthesis.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Biotechnology

Subject: Biological Evaluation of Drug Therapy

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

1. What is a bioassay? What are the indications of bioassay? Outline the principles and classification of bioassays. Explain quantal types of bioassay with a specific example.
2. Discuss the principle, protocol and interpretation of results of microbiological assay of antibiotics by turbidimetric method.
3. Citing a suitable example, explain how the therapeutic hormones can be produced using recombinant DNA technology. Give details of cloning strategies employed.
4. Give an account on regulatory consideration for pre-clinical testing and clinical testing of drugs.

Section B

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

5. Enlist types of studies involved in preclinical evaluation of drugs.
6. How to determine the therapeutic index of a drug? Explain its significance.
7. What are the advantages and disadvantages of using cell line studies in drug development?
8. Briefly outline the principle and protocol for test for pyrogens as per Indian Pharmacopoeia.
9. What are the challenges associated with delivering therapeutic genes to target cells. Write a note on the advantages and disadvantages of these delivery methods.
10. Describe the principle and application of CRISPER-CAS9 as an effective way of gene editing.
11. Explain the role of regulatory agencies in ensuring the quality and safety of biopharmaceuticals.
12. What are the post-approval requirements for new drugs, including phase IV clinical trials, risk management plans, and adverse event reporting?
13. What is bioequivalence, and why is it important for ensuring the therapeutic efficacy and safety of generic drugs?
14. How can pharmacokinetic modeling be used to predict the optimal dosage regimen and dosing interval for biopharmaceuticals?
15. Outline the different methods used to measure bioavailability, including *in vivo* and *in vitro* techniques.
16. Discuss the role of pharmacokinetic modeling in optimizing drug formulations, predicting drug interactions, and assessing the safety and efficacy of new drug candidates.

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Second Semester M. Pharm Examination – June 2026

Branch: Pharmaceutical Biotechnology

Subject: Bioinformatics and Computational 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. SHORT ESSAY (Answer any THREE questions) 3x10=30 Marks

1. Discuss the history of bioinformatics and its development over time. Explain the applications of bioinformatics in research. (5+5)
2. Describe the different types of sequence alignment techniques in bioinformatics. Compare and contrast pairwise alignment with multiple sequence alignment.
3. List two early and two modern prediction methods for protein structure. How has accuracy improved and why is it useful for biotech?
4. Discuss the differences between prokaryotic and eukaryotic gene families. Explain how genome analysis contributes to understanding the evolution of these gene families.

Section B

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

5. Define data mining and explain its importance in bioinformatics.
6. Describe nucleic acid databases. How are these databases important for storing and retrieving biological data?
7. Explain the use of the CLUSTAL W and CLUSTAL X programs in multiple sequence alignment. Why are these tools important for sequence analysis?
8. Explain the differences between global and local sequence alignment.
9. Write a note on alignment correction and its importance in homology modeling.
10. Explain the role of loop searching and loop generating methods in protein structure prediction. Why are loops significant in predicting protein folding?
11. What is genome annotation, and why is it important in genome analysis?
12. Explain the significance of completed genomes, such as those of bacterium, nematode, plant, and human.
13. Explain the process of target identification and target validation in the early drug discovery process.
14. What is *in-silico* gene expression microarray analysis, and how is it used in target identification?
15. Describe the parameters to predict the drug quality.
16. Explain the importance of target modulations.
