Seat No.	

Set **P**

M.Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: Oct/Nov - 2024
Modern Pharmaceutical Analytical Techniques
(8022101)

Day & Date: Wednesday, 30-April-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions **25**

a) Write Principle, Instrumentation and Applications of Flame photometry.
b) Describe applications of NMR spectroscopy.
c) Draw a neat labeled diagram of UV-Visible Spectrophotometer. Give its application.
d) Describe MALDI with suitable diagram.
e) Write a note on column chromatography.
f) What is fluorescence? Write factor affecting on fluorescence.

Q.2 Answer any three questions **30**

a) Explain Principle, instrumentation and application of IR.
b) Explain columns used in GC with suitable diagram.
c) Write a note on ELIZA. Discuss on Gel Electrophoresis
d) Write Principle, Instrumentation and applications of HPLC.

Q.3 Discuss Principle, Instrumentation and application of Mass Spectroscopy. Write a note on factors affecting chemical shift with suitable examples. **20**

Seat No.	

Set **P**

M.Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: Oct/Nov - 2024
Drug Delivery System (8022102)

Day & Date: Friday, 02-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any FIVE questions. **25**

a) Write a note on osmotic activated drug delivery system.
b) Define, explain and give examples of bioelectronic medicine and telepharmacy.
c) What are barriers of drug permeation? Give methods to overcome barriers.
d) Explain 5 evaluation tests for buccal drug delivery system.
e) Write a note on vaccine drug delivery system.
f) Give an account on penetration enhancer.

Q.2 Answer any THREE questions. **30**

a) Give detailed account on formulation and evaluation of SR and CR tablets.
b) Write formulation and evaluation of muco adhesive tablet.
c) Discuss formulation and evaluation of protein delivery system.
d) Write a note on pH activated drug delivery system.

Q.3 Answer the following question. **20**

Give detailed account on TDDS. Add a note on factors affecting drug absorption.

SLR-SB-3

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: Oct/Nov - 2024
Modern Pharmaceutics (8022103)

Day & Date: Monday, 05-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions **25**

a) What is cGMPs? Give its Significance.

b) Discuss inventory management and its importance.

c) Discuss contour designs and their importance.

d) Discuss types of validation.

e) Describe similarity factors f2 and f1.

f) Elaborate Higuchi and Peppas model.

Q.2 Answer any three questions **30**

a) Discuss physics of tablet compression.

b) Discuss WHO guidelines for calibration and validation of equipment's.

c) Discuss sales forecasting, budget and cost control in detail.

d) Discuss pupariation and stability of large and small volume parenteral.

Q.3 Discuss preformulation with details description on its various parameters. **20**

SLR-SB-4

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: Oct/Nov - 2024
Regulatory Affair (8022104)

Day & Date: Wednesday, 07-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer the following questions (Any Five) **25**

1) What is orange book? Explain the important features of orange book.

2) Describe the regulatory functions of CDSCO.

3) What is drug master file? Give the regulatory basis of DMF.

4) Write a note on ideal requirements for a regulatory affair professional.

5) Explain the components of registration dossier in India.

6) Describe the role of documents in developing clinical trials protocols.

Q.2 Answer the following questions (Any Three) **30**

1) Explain the comparative review on drug regulating authorities in different countries in the development of new drug.

2) What is CFR Title21? Describe its salient features.

3) Describe the role of pharmacovigilance in drug development.

4) Describe the process of regulatory approval of new drugs in India.

Q.3 Describe in detail the process of NDA filing to USFDA. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS)
Examination: Oct/Nov - 2024
Modern Pharmaceutical Analytical Techniques (8023101)

Day & Date: Wednesday, 30-April-2025 Max. Marks: 80
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions **25**

a) Draw a neat labeled diagram of Flame emission Spectroscopy. Give its principle.
b) Draw a neat labeled diagram of Mass Spectrometer. Discuss Time of Flight Mass Analyzer.
c) Write different modes of Molecular Vibrations of IR spectroscopy.
d) Write on Principle and applications of Ion Exchange Chromatography.
e) Discuss columns used in HPLC.
f) Give principle and applications of Potentiometry.

Q.2 Answer any three questions **30**

a) What is Chemical Shift? Discuss with suitable examples Spin-Spin Coupling.
b) Discuss on X-ray Crystallography. Give its applications.
c) Elaborate on UV-Visible spectrophotometer in connection to Principle, Woodward-Fieser rule & solvent effect.
d) Write principle, instrumentation of DSC.

Q.3 Elaborate on Principle & general rules of fragmentation of Mass Spectrometer. Discuss in short on Gel Electrophoresis & instrumentation of Gas chromatography. **20**

SLR-SB-6

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS)
Examination: Oct/Nov - 2024
Quality Management System (8023102)

Day & Date: Friday, 02-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any FIVE questions. **25**

a) Write note on NABL certification.
b) Discuss about Statistical control charts.
c) What are the Limitations of benchmarking?
d) Explain in detail different types of customers.
e) Define Quality Management System. Give its advantages.
f) Discuss in detail different policies for Quality Management System.

Q.2 Answer any THREE questions. **30**

a) Define Cost of quality. Explain in details Models of cost of quality.
b) Write in detail about principles of Six Sigma concept.
c) Define Benchmarking. Discuss in details types of Benchmarking.
d) Explain in detail process of Area clearance and Line clearance.

Q.3 Define customer and customer focus. Give its classification of customers, Explain in detail about Customer focus, Customer perception of quality. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS)
Examination: Oct/Nov - 2024
Quality Control and Quality Assurance (8023103)

Day & Date: Monday, 05-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions **25**

a) What are change control & calculation of yield?

b) Brief the analysis of raw materials.

c) Explain the activities of CDER and PIC/S.

d) Which are studies covered under GLP in pharmaceuticals development?

e) Give the overview of QSEM.

f) Write the GLP principles according to OECD.

Q.2 Answer any three questions **30**

a) Explain the documentation in pharmaceutical industry and its types.

b) Give details the batch formula record.

c) Give the location and surroundings of factory building and warehousing area in the factory.

d) What is Intellectual Property Rights? Give the types of IPR.

Q.3 Discuss the finish product quality test for tablets. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS)
Examination: Oct/Nov - 2024
Product Development and Technology Transfer (8023104)

Day & Date: Wednesday, 07-05-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions. (5x5=25) **25**

1) Write importance of ADME study in drug discovery.
2) What is IND? Enlist the different reasons for IND application.
3) Write a note on role of active surveillance in ADR reporting.
4) Explain method of selection and evaluation of pharmaceutical packaging materials.
5) Compare between Phase-ll & Phase-III clinical trials.
6) Elaborate on Supplemental New Drug Application (SNDA).

Q.2 Answer any three questions. (3x10=30) **30**

1) Describe SUPAC guidelines for semisolid dosage forms.
2) Explain the product registration guidelines as per USFDA.
3) What is technology transfer? Discuss steps involved in technology transfer process.
4) What is the importance of solubility in formulation development? Describe methods of increasing solubility.

Q.3 Describe the steps undertaken for pilot plant scale-up of uncoated tablets prepared by wet-granulation method. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: Oct/Nov - 2024
Molecular Pharmaceutics (Nano Tech and Targeted DDS) (8022201)

Day & Date: Saturday, 03-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any FIVE questions. **5 × 5 = 25**

a) Discuss the therapeutic applications of microcapsules.

b) Define aerosols. Describe different types of containers used for packing and storage of aerosols along with their merits and demerits.

c) Write in brief about the need and different advantages of gene therapy.

d) What are the different types of drug delivery systems for intranasal drug delivery?

e) Explain the different techniques of its preparation of microspheres.

f) Explain in brief about Electrosomes.

Q.2 Answer any THREE questions. **3 × 10 = 30**

a) Differentiate between nanoparticles and liposomes. Describe all the evaluation parameters for liposomes.

b) What are the different techniques available for pulmonary drug delivery? Explain the preparation and evaluation of dry powder for inhalation.

c) Explain the barriers for brain targeting. How could one achieve brain targeting?

d) What are monoclonal antibodies? Describe the technology used for their production.

Q.3 Explain the term targeted drug delivery system. Add a note on the different concepts used in drug targeting. **20**

Seat No.	

Set P

M. Pharmacy (Pharmaceutical) (Semester - II) (CBCS) Examination: Oct/Nov - 2024
Advanced Biopharmaceutics & Pharmacokinetics (8022202)

Day & Date: Tuesday, 06-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions: (5x5=25) **25**

1) Explain in detail plasma Drug concentration Time profile.
2) Explain in detail bio pharmaceutics classification system.
3) Add a Note on: Monoclonal antibodies.
4) Discuss in detail modified release drug delivery system.
5) Explain in detail Basic considerations for pharmacokinetic models.
6) Write a note on: IVIVC (*In-vivo In-Vitro* Correlation)

Q.2 Answer any three questions: (3x10=30) **30**

1) Describe in detail rate-limiting steps in drug absorption.
2) State the pH-partition hypothesis briefly. On what assumption this statement based?
3) Describe the drug interactions involved in cytochrome P-450.
4) Explain the Michaelis - Menten equation for Non liner pharmacokinetics.

Q.3 Define bioavailability of Drug. Explain in detail methods used for assessment of Bioavailability of Drug. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: Oct/Nov - 2024
Computer Aided Drug Delivery System (8022203)

Day & Date: Thursday, 08-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions. (5x5=25) **25**

1) Define –
a) Solubility b) Permeability c) Absorption d) Distribution e) Elimination
2) Write in brief about history of computers in pharmaceutical research and development.
3) Explain the computer aided simulation experiments for estimation of drug absorption.
4) Write a note on statistical modeling in pharmaceutical research and development.
5) Explain the concept of ethics of computing in pharmaceutical research.
6) Write a note on current challenges and future directions of Artificial Intelligence in pharma industry.

Q.2 Answer any three questions. (3x10=30) **30**

1) Describe the concept of Quality-by-Design in pharmaceutical development.
2) Write a note on pharmaceutical applications of Al and robotics with its advantages and disadvantages.
3) Write in details about- computational modeling of drug disposition with suitable examples.
4) Describe the uses of computers in clinical development. Add a note on regulation of computer systems.

Q.3 Answer the following. **20**

Write in details about- Application of computers in pharmaceutical formulation and development process with suitable examples. Add a note on Optimization technology & screening design.

SLR-SB-12

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: Oct/Nov - 2024
Cosmetic and Cosmeceuticals (8022204)

Day & Date: Saturday, 10-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions. **25**

a) List out various cosmetic excipients. Discuss emollients.

b) Write on Soaps and syndet bars.

c) Define and classify perfumes.

d) Define preservatives, write their merits and demerits.

e) Explain any 4 problems associated with teeth and gums.

f) Write formulation and evaluation of cold cream.

Q.2 Answer any three questions. **30**

a) Write on Structure of hair and hair growth cycle.

b) Elaborate on vanishing cream, and moisturizing creams.

c) Define cosmetics, cosmeceuticals. Classify cosmetics with example.

d) Classify rheology modifiers and humectants used in cosmetics. Write its applications.

Q.3 Give detailed account structure of skin and problems related to skin. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS)
Examination: Oct/Nov - 2024
Hazards and Safety Management (8023201)

Day & Date: Saturday, 03-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any FIVE questions. **5 × 5 = 25**

a) Write a note on Ecosystem.

b) Discuss Relief systems.

c) Elaborate on types of Fire Extinguishers.

d) Describe TLV Concept.

e) Write a note on BOD.

f) Discuss on Energy resources.

Q.2 Answer any THREE questions. **3 × 10 = 30**

a) Elaborate on sources of chemical hazards & its control measures.

b) Explain ICH guidelines of different tools & methods used for risk assessment and risk management.

c) Elaborate on preventive and protective management from fire and explosion.

d) Discuss on air circulation maintenance in industry for sterile and non-sterile area.

Q.3 Write in detail on Industrial process Hazards. Write on Preliminary Hazard Analysis and Effluent treatment procedure. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS)
Examination: Oct/Nov - 2024
Pharmaceutical Validation (8023202)

Day & Date: Tuesday, 06-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions: (5x5=25) **25**

1) What are validation, qualification and calibration?

2) What is change management?

3) Give the limit and range of air quality for parameters that are performed.

4) What is electronic record (21 CFR Part 11)?

5) How is performance of dissolution apparatus verified?

6) Give the process validation activities stages as per fda.

Q.2 Answer any three questions: (3x10=30) **30**

1) Explain the sampling techniques in Cleaning Validation.

2) Specify the important parameters for nitrogen gas quality.

3) How is the performance qualification of HPLC verified?

4) What is Intellectual Property Rights and explain different types.

Q.3 Discuss the validation of analytical method as per ICH guidelines. **20**

Seat No.	

Set P

M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS)
Examination: Oct/Nov - 2024
Audits and Regulatory Compliance (8023203)

Day & Date: Thursday, 08-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions. (5x5=25) **25**

a) Explain different types of deficiencies observed in an audit.
b) Explain the auditing procedure of holding and release of finished products.
c) Write in detail about objectives and management of audits.
d) Write about responsibilities, information gathering and administration of an audit.
e) Discuss auditing process of quality assurance and engineering department.
f) Describe in detail the responsibilities and role of audit compliance.

Q.2 Answer any three questions. (3x10=30) **30**

a) Write the process and steps for auditing the microbiological laboratory.
b) Describe the process of grading and approval of vendors.
c) What are the objectives of performing an internal audit? Describe the usefulness of performing such audits.
d) Explain different QMS regulations and guidelines applicable to pharmaceutical industry.

Q.3 Describe the role of quality audit in pharma industry. Classify types of GMP audits in pharma industry. Describe the process of second party audit. **20**

SLR-SB-16

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS)
Examination: Oct/Nov - 2024
Pharmaceutical Manufacturing Technology (8023204)

Day & Date: Saturday, 10-May-2025 Max. Marks: 75
Time: 10:30 AM To 01:30 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer any five questions. **25**

a) Explain in detail different factors influencing on plant location.

b) Discuss in detail general principle of production planning.

c) Write note on Cleaning in Space (CIP).

d) Give the importance of Manufacturing Planning.

e) Define Quality by design. Give its Importance.

f) What are the advantages of pelletization process?

Q.2 Answer any three questions. **30**

a) Define Pelletization. Explain in detail techniques used in pelletization.

b) Describe the in-process quality control tests for ointments.

c) Discuss in detail principle and working of lyophillizer.

d) Write a note on spheronization and its applications.

Q.3 Explain in detail legal requirements and licenses for API and Formulation Industry. **20**