Seat No.	

Set **P**

M. Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: March/April - 2025
Modern Pharmaceutical Analytical Techniques (8022101)

Day & Date: Wednesday, 29-10-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

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

a) Elaborate applications of UV-Visible Spectrophotometer with suitable examples.

b) Discuss instrumentation of Flame Emission Spectrophotometer.

c) Write in short Ion Exchange Chromatography.

d) Discuss in brief Gel Electrophoresis.

e) Write a note on ELIZA.

f) Write principle & applications of X-ray Crystallography.

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

a) Discuss instrumentation of IR spectrophotometer.

b) Elaborate on Detectors of Gas Chromatography.

c) Write in detail on instrumentation of HPLC.

d) Elaborate with suitable examples on Spin-Spin Coupling.

Q.3 Discuss in detail on Ion sources of Mass Spectrometer. Give applications of Mass Spectrometer. Give Number of signals & multiplicity of peak for Benzyl alcohol and Benzoic acid by Proton NMR. **20**

Seat No.	

Set **P**

M.Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: March/April - 2025
Drug Delivery System (8022102)

Day & Date: Friday, 31-10-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

Q.1 Solve the questions: (Any Five) **25**

a) Give an account on osmotic activated drug delivery system.
b) Define vaccines and sera. Classify vaccines with examples.
c) What are barriers of drug permeation? Give methods to overcome barriers.
d) Explain 5 evaluation tests for buccal drug delivery system.
e) Explain 5 evaluation tests for ocular drug delivery system.
f) Write a note on penetration enhancer.

Q.2 Solve the questions. (Any Three) **30**

a) Define intracellular DDS, intercellular DDS, and transappendageal DDS. Write in detail on evaluation of TDDS.
b) Write formulation and evaluation of floating tablets.
c) Discuss formulation evaluation of protein delivery system.
d) Write a note on pH activated drug delivery system.

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

Give detailed account on formulation and evaluation of CR and SR tablets. Add a note on merits and demerits of CR and SR formulation.

SLR-JB-3

Seat No.	

Set P

M. Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: March/April - 2025
Modern Pharmaceutics (8022103)

Day & Date: Monday, 03-11-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

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

a) Discuss theories of pharmaceutical Dispersion.
b) Explain Chi square test, students T-test.
c) Give the objectives and policies of cGMPs.
d) Discuss inventory control.
e) Discuss ICH guidelines for validation of Master plan.
f) Write note on budget and cost control.

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

a) Explain the concepts of total quality Management and discuss validation of pharmaceutical process.
b) Explain in detail Higuchi Model and Korsmeyer-peppas model for drug release.
c) Elaborate stability testing of pharmaceuticals.
d) Discuss about ideal layout of pharmaceutical industry.

Q.3 What is Preformulation? Give its significance and discuss physics of tablet compression. **20**

Seat No.	

Set **P**

M.Pharmacy (Pharmaceutics) (Semester - I) (CBCS) Examination: March/April - 2025
Regulatory Affair (8022104)

Day & Date: Thursday, 06-11-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

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

a) Explain the concept of six sigma.
b) Explain the functional role of CDSCO.
c) Define CTD & eCTD. Explain modules of CTD.
d) Explain in detail how regulatory affairs department helps the pharma industry.
e) Describe various activities regulated by CDER.
f) What is Post Marketing Surveillance? Give its importance in clinical trials.

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

a) State the responsibilities of CDSCO. Write a brief note on the concept of Quality by Design.
b) What is CFR Title21? Describe its salient features.
c) Describe the process of approval of new drug in India.
d) Explain the ANDA regulatory approval process.

Q.3 Elaborate in details the current scenario of regulatory process of drug approval in India. **20**

Seat No.	

Set P

M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS) Examination: March/April - 2025
Modern Pharmaceutical Analytical Techniques (8023101)

Day & Date: Wednesday, 29-10-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

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

a) Draw a neat labeled diagram of IR instrument. Elaborate its application.

b) What is Fluorescence? Discuss factors affecting Fluorescence.

c) Write on types of ions produced in Mass Spectrometry.

d) Discuss the principle and applications of Capillary Electrophoresis.

e) Write Principle of NMR spectroscopy. Draw a neat labeled diagram of NMR instrument.

f) Describe in short on instrumentation of High-Performance Thin Layer Chromatography.

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

a) Discuss with suitable examples factors affecting Chemical Shift.

b) Elaborate on instrumentation of HPLC. Enlist its applications.

c) Write principle and instrumentation of Thermo Gravimetric Analysis.

d) Describe any three ion sources used in Mass Spectrometry.

Q.3 Discuss instrumentation of UV-Visible spectrophotometer. Elaborate on principle & detectors used in Gas Chromatography. Give Number of signals & multiplicity for butanoic acid & ethyl acetate. **20**

SLR-JB-6

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS) Examination: March/April - 2025
Quality Management System (8023102)

Day & Date: Friday, 31-10-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

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

a) Explain in detail dimensions of quality.
b) Write note: Control Chart Analysis.
c) Define Statistical Process Control. Give its Importance.
d) Discuss in detail Batch Review and Batch Release process.
e) What are the different preventive measures of cost of quality?
f) How to determine root cause, corrective & preventive actions in quality system.

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

a) Discuss in detail mission and vision statement for quality policy.
b) Explain in detail Six-sigma concept for quality management system.
c) Discuss in detail ICH Q8 and ICH Q9 guidelines for stability of pharmaceutical products.
d) Define customer. Give the requirements and types of customers.

Q.3 Define benchmarking. Give its reasons for benchmarking. Discuss in detail types and process of benchmarking. **20**

Seat No.	

Set P

M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS) Examination: March/April - 2025
Quality Control and Quality Assurance (8023103)

Day & Date: Monday, 03-11-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 PM

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

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

a) Which are the drug manufactures covered under the us fda GMP guidelines?
b) Give QC tests for containers & closures.
c) What is QC & QA?
d) What are theoretical yield, actual yield and percentage of theoretical yield?
e) How is waste and scrap disposal handled?
f) What are CDER, CBER, EMA, IPR and Drug product?

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

a) Write note on release of finished product.
b) Describe the sampling & testing of in-process materials & drug product.
c) What are non-clinical laboratory study, testing facility & quality assurance unit?
d) What is pharmaceutical inspection convention? Give its objectives.

Q.3 What is common technical documentation? Give details of Drug Master Formula. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I) (CBCS) Examination: March/April - 2025
Product Development and Technology Transfer (8023104)

Day & Date: Thursday, 06-11-2025 Max. Marks: 75
Time: 02:30 PM To 05:30 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 Post marketing surveillance of product.
b) Describe the scale-up process of tablet granulation.
c) Compare between Phase-I and Phase-ll clinical trials.
d) What is Preformulation? What is the need and applications of preformulation?
e) Describe the concept of process optimization during technology transfer.
f) Give SUPAC guidelines applicable in case of major changes.

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

a) Write a short note on quality control tests for glass containers.
b) What is the importance of solubility in formulation development? Describe methods of increasing solubility.
c) Describe the process of New Drug Application (ANDA).
d) What is meant by pilot plant scale up? Describe in detail the steps involved in scale-up of tablet dosage form.

Q.3 Elaborate in details the current scenario of regulatory process of drug approval in India. **20**

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: March/April - 2025
Molecular Pharmaceutics (Nano Tech and Targeted DDS) (8022201)

Day & Date: Tuesday, 28-10-2025 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) Discuss in detail about preparation of microcapsules. Enlist its applications.
b) What is Aquasome? Write down the composition and properties of Aquasomes.
c) Enlisting the applications, describe the preparation of monoclonal antibodies.
d) Enlist types of nanoparticles. Write a note on solid lipid nanoparticles.
e) Write a note on Aptamers.
f) Discuss the preparation of Electrosomes. Enlist its applications.

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

a) Elaborately discuss Aerosol drug delivery systems including their formulation, quality control tests and evaluations.
b) Discuss the different types of active drug targeting.
c) Describe preparation and evaluation methods of Microspheres.
d) Discuss medical devices for delivery of aerosols to lungs.

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

a) Discuss in short viral and non-viral modes of gene delivery.
b) Elaborate pharmacokinetic and biodistribution aspects of interfering RNAs.

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: March/April - 2025
Advanced Biopharmaceutics & Pharmacokinetics (8022202)

Day & Date: Thursday, 30-10-2025 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 Solve the following questions. (Any Five) **25**

a) Explain Michaelis-Menten equation in determination nonlinearity.
b) Write a note on pH partition theory.
c) Give detailed account on BCS and its significance in designing of dosage form.
d) Write a note on monoclonal antibodies.
e) Explain factors affecting dissolution rate.
f) Write a note on modified release drug product.

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

a) Explain relative and absolute bioavailability. Add note on methods for assessing bioavailability.
b) Write note on correlation of in-vivo in-vitro dissolution data.
c) Discuss clinical significance of bioequivalence study.
d) Write a note on drug interaction.

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

What is compartment? Classify the pharmacokinetic compartment models. Give schematic representation of the same.

Seat No.	

Set **P**

M.Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: March/April - 2025
Computer Aided Drug Delivery System (8022203)

Day & Date: Saturday, 01-11-2025 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 questions. (Any Five) **25**

a) Write a note on computational modeling of intestinal permeability.
b) Describe the historical events in development of computers in pharmacy field.
c) Explain the importance of *in vitro* dissolution studies in pharmaceutical product development.
d) Explain the computers in market analysis.
e) Write a note on various statistical parameters used in pharmaceutical research.
f) Write a note on development of pharmaceutical emulsions.

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

a) Describe the concept of scientifically based QbD in pharmaceutical development with examples of application.
b) Write a note on active transport system. Describe the role of following in computational modeling- BBB-Choline Transporter, ASBT, hPEPTl, OCT, OATP.
c) Explain the Concept of optimization. Describe various Optimization parameters. Add a note on Factorial design.
d) Give the pharmaceutical applications of Artificial Intelligence and Robotics. Add a note on their advantages, disadvantages, current challenges and future scope.

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

Describe the Computer-aided biopharmaceutical characterization with suitable examples. Explain the applications of computers in clinical development.

Seat No.	

Set **P**

M. Pharmacy (Pharmaceutics) (Semester - II) (CBCS) Examination: March/April - 2025
Cosmetic and Cosmeceuticals (8022204)

Day & Date: Tuesday, 04-11-2025 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**

a) Highlight the herbal ingredients used in hair care and oral care cosmetics.
b) Write a note on challenges in formulating Herbal cosmetics.
c) Define the terms misbranded cosmetic and spurious cosmetic.
d) Discuss anti microbial agents used as preservatives in cosmetics.
e) Explain the formulation of cosmetics for dental cavities and bleeding gums.
f) Highlight the anti dandruff agents used in shampoos.

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

a) Discuss the cleansing and care needs of neck, body and under arm.
b) Define and classify surfactants. Explain the role of surfactants in various cosmetics.
c) Discuss the formulation of sun protection cosmetics in detail.
d) Describe the structure of hair and hair growth cycle.

Q.3 Explain the Indian regulatory provisions relating to import and manufacture of cosmetics. Add a note on the regulator requirements for labeling of cosmetics. **20**

Seat No.	

Set P

M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS) Examination: March/April - 2025
Hazards and Safety Management (8023201)

Day & Date: Tuesday, 28-10-2025 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) Discuss on Mineral resources.
b) Write a note on BOD.
c) Discuss on Hazards of organic synthesis.
d) Write a note on sources of chemical hazards.
e) Describe in short on Industrial Process Hazards.
f) Write on Effluent Treatment Procedure.

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

a) Discuss on Factory act and rules. Elaborate on Preliminary Hazard Analysis.
b) Write a note on Ecosystem. Discuss on Fire extinguishers.
c) Elaborate on control measures for Chemical Hazards.
d) Discuss in detail on Preventive and Protective Management from Fire and explosion.

Q.3 Elaborate on ICH guidelines on risk assessment and risk management methods and tools. Discuss on air circulation maintenance industry for sterile area and non-sterile area. **20**

Seat No.	

Set **P**

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS) Examination: March/April - 2025
Pharmaceutical Validation (8023202)

Day & Date: Thursday, 30-10-2025 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**

a) What is qualification? Which are the stages of qualification?
b) What is FAT and SAT?
c) Write about selection of analytical method in cleaning validation.
d) Name analytical method validation characteristics.
e) What is Intellectual Property Rights?
f) Name laboratory and manufacturing equipment used in tablet unit.

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

a) Name utility systems. Give validation of one system.
b) Explain the performance qualification of UV-Vis spectrophotometer.
c) Write about pharmaceutical patent.
d) Give the qualification of Dry Powder Mixer.

Q.3 What is process validation? Discuss the approach to process validation as per fda. **20**

SLR-JB-15

Seat No.	

Set P

M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS) Examination: March/April - 2025
Audits and Regulatory Compliance (8023203)

Day & Date: Saturday, 01-11-2025 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 questions. (Any Five) **25**

a) Describe the responsibilities of quality auditors.
b) Elaborate on audit questionnaire and checklists.
c) Explain the evaluation activities of QMS.
d) Give the objectives of quality auditing in the pharma industry.
e) Describe process for auditing of sterile production.
f) Describe with examples the different types of deficiencies in audit process.

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

a) Enlist the Quality system elements in as per cGMP regulations related to
1) Management responsibilities.
2) Resources.
3) Manufacturing process.
b) Explain the process of auditing the warehouse.
c) Describe the process of grading and approval of vendors.
d) Enumerate the important aspects of the auditing microbiology laboratory and discuss any four.

Q.3 Describe in detail the GMP audit of manufacturing process and facility. **20**

Seat No.	

Set P

M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - II) (CBCS) Examination: March/April - 2025
Pharmaceutical Manufacturing Technology (8023204)

Day & Date: Tuesday, 04-11-2025 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) Discuss in detail Quality control test for Suspension.
b) Explain in detail Fill Seal Technology.
c) Explain in detail manufacturing layout of tablet production process.
d) What are the different factors affecting plant layout?
e) Write note on: Process Analytical Technology (PAT).
f) Discuss in detail legal requirements for API industry.

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

a) Discuss in detail techniques of Pelletization.
b) Explain in detail dispatching records and Production Controls.
c) Explain in detail principle and process of Lyophilization techniques.
d) Describe the elements of QbD.

Q.3 Discuss in detail containers and closures used in pharmaceutical packaging materials. **20**