SLR-JB-1

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April-2024
PHARMACEUTICS
Modern Pharmaceutical Analytical Techniques (8022101)

Day & Date: Wednesday, 22-05-2024 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 on instrumentation and applications of Fluorescence.
b) Discuss theory and Beers Lamberts law of UV-Visible spectroscopy.
c) Elaborate on Radioimmunoassay (RIA).
d) What is X-ray diffraction? Give its applications.
e) Write in short on capillary electrophoresis.
f) Explain instrumentation of Atomic absorption spectroscopy.

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

a) Discuss in detail on chromatographic parameters. Write in brief on stationary phase used in TLC.
b) Describe Spin-Spin coupling with suitable examples. Give different chemical shift values for different functional groups containing proton.
c) Elaborate on any three detectors used in Gas chromatography.
d) Discuss Instrumentation and applications of HPLC.

Q.3 What is Mass Spectrometry? Give its application. Write on any two Ion sources & mass analyzers. Discuss types of ions produced in Mass. **20**

SLR-JB-2

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April-2024
PHARMACEUTICS
Drug Delivery System (8022102)

Day & Date: Saturday, 25-05-2024 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) Define Polymers. Discuss various applications of the polymers in formulation of CRDDS.
b) Distinguish between SR and CR formulations. Discuss advantages and disadvantages of it.
c) Discuss the principle involved in osmotically activated gastro-retentive drug delivery systems.
d) Write a note on Telepharmacy.
e) Discuss protein drug delivery system.
f) Explain the various components of transdermal drug delivery system.

Q.2 Answer Any Three Questions. **30**

a) What are the vaccines? Give a detailed note on uptake of antigens.
b) Explain various formulation strategies to overcome the barriers of ocular drug permeation.
c) Discuss osmotically activated drug delivery system.
d) Discuss various formulation approaches for designing Controlled drug delivery system.

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

Discuss theories of muco-adhesion, polymers used and various approaches of muco-adhesive drug delivery systems.

SLR-JB-3

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April - 2024
PHARMACEUTICS
Modern Pharmaceutics (8022103)

Day & Date: Tuesday, 28-05-2024 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) Discuss Higuchi and Peppas plot.
b) Give the objectives of Current Good Manufacturing Practices in pharmaceuticals.
c) Explain different Dissolution Parameters.
d) Write a note on Inventory Management and its majors of Controls.
e) Write note on: Budget and Cost Control.
f) What do you mean by Pharmaceutical Validation? Give its scope and merits of Validation.

Q.2 Answer Any Three Questions. **30**

a) Write on students T-test and ANOVA test.
b) Explain in detail about Validation of Master Plan.
c) What do you mean by Total Quality Management?
d) Discuss in detail Sales Forecasting.

Q.3 Discuss Tablet Compression and Consolidation. **20**

SLR-JB-4

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April-2024
PHARMACEUTICS
Regulatory Affair (8022104)

Day & Date: Thursday, 30-05-2024 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) Give a comparative review of CMC and CTD.
b) Explain the role of institutional ethics committee in clinical trials.
c) What is drug master file? Give the regulatory basis of DMF.
d) Write a note on national and global regulatory control in pharmaceutical industry.
e) Write a note on pre-requisites for a regulatory affair professional.
f) What is the use of Orange Book? Give its contents.

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

a) Describe the factors responsible for the rapid development of pharma industry in India.
b) Describe in detail phase-I and phase-II study during development of a new drug.
c) Explain guidelines applicable on documentation as per USFDA CFR.
d) Discuss in detail the process of ANDA filing in USA.

Q.3 Describe the global scenario of drug regulatory bodies. Explain the role, constitution, responsibilities and statutory functions of regulatory bodies in India. **20**

SLR-JB-5

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Modern Pharmaceutical Analytical Techniques (8023101)

Day & Date: Wednesday, 22-05-2024 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 Gel electrophoresis.
b) Discuss on different stationary phases used in TLC.
c) Discuss principle and applications of Flame emission Spectroscopy.
d) Draw and discuss Instrumentation of UV spectroscopy.
e) Discuss on types of crystals & applications of X-Ray Crystallography.
f) Write number of signals & its multiplicity for Isopropyl alcohol & ethyl acetate molecule.

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

a) Elaborate on Instrumentation & applications of Gas Chromatography.
b) Discuss with suitable examples Spin Spin coupling. Write on theory of Fluorescence.
c) Discuss different modes of molecular vibrations & sample handling system. Write on IR peak range for the organic compounds containing carbonyl group.
d) Discuss Instrumentation & applications of DTA.

Q.3 Discuss on Ion sources used in Mass spectrometry. Write on general rules of fragmentation pattern and enlist applications of Mass spectrometry. **20**

SLR-JB-6

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Quality Management System (8023102)

Day & Date: Saturday, 25-05-2024 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) What are the different benefits of quality management systems?
b) Define Quality. Give its importance.
c) Explain in detail Objectives of Quality.
d) Discuss in detail Models for cost of quality.
e) Define ISO. Give its advantages.
f) Write note on IPQC tests.

Q.2 Answer Any Three Questions. **30**

a) Discuss in detail concept Total Quality Management.
b) Describe in detail principles of Quality Management.
c) Discuss in detail Quality by Design for tablets.
d) Explain in detail methods for management of Risk.

Q.3 Define Benchmarking. Discuss in detail benchmarking process and its types. **20**

SLR-JB-7

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April - 2024
PHARMACEUTICAL QUALITY ASSURANCE
Quality Control and Quality Assurance (8023103)

Day & Date: Tuesday, 28-05-2024 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 documentation in Pharmaceutical Industry.
b) Give the IPQC & FPQC tests for Ophthalmic Products.
c) What is Pharmaceutical Inspection Convention? Give its objectives.
d) What is quality assurance, quality control, and drug discovery and development process?
e) Give the content of BMR for the operation process of Tablet Manufacturing.
f) When are GLP, GCP, GMP followed in the stages of the development and lifecycle of a drug product?

Q.2 Answer Any Three Questions. **30**

a) Give overview of ICH guidelines-QSEM.
b) Explain the GMP guidelines for drug industry location, construction, and plant lay out.
c) Define control article & test article. How is non clinical laboratory study result prepared & stored?
d) Write note on production & process control.

Q.3 What are cGMPs? Why are cGMPs so important? Explain the GMP guidelines for sterile area, sanitation, and warehousing. **20**

SLR-JB-8

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Product Development and Technology Transfer (8023104)

Day & Date: Thursday, 30-05-2024 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) What is Preformulation? What are objectives and principle of preformulation?
c) Discuss documentation in technology transfer for tablet dosage form.
d) Write a short note on quality control tests for plastic packaging material.
e) Describe various factors that affect the design of a pharmaceutical pilot plant facility.
f) Discuss the pilot plant scale-up points to be considered for liquid dosage form.

Q.2 Answer any three of following. **30**

a) Describe the process of New Drug Application (NDA).
b) Give detail note on quality control test for containers and closures.
c) Describe various steps involved in technology transfer. Elaborate on documentation in technology transfer.
d) Write a note on product registration guidelines in USFDA.

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

Describe SUPAC guidelines in details.

SLR-JB-9

Seat No.	

Set P

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

Day & Date: Friday, 24-05-2024 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 the phase separation coacervation technique of preparation of microspheres.
b) What are the different types of drug delivery systems for intranasal drug delivery?
c) Explain in brief about electrosomes.
d) Describe the liquid nasal formulation along with their merits and demerits.
e) What are aerosols? Discuss its evaluation tests.
f) Discuss - Bio distribution and Pharmacokinetics.

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

a) Explain the concepts of drug targeting? Classify and describe the various carrier system used for targeted drug delivery.
b) What do you understand by Gene Therapy? Add a short note on antisense molecules
c) What are Aquasomes? How do they differ from liposomes? Describe the principle involved in their method of preparation.
d) Explain in brief the different techniques of gene transfer.

Q.3 Describe the methods of active and passive targeting using particulate carriers. Describe the use of liposomes for drug targeting. **20**

SLR-JB-10

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICS
Advanced Biopharmaceutics & Pharmacokinetics (8022202)

Day & Date: Monday, 27-05-2024 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) Define Bioavailability. Explain in detail factors affecting on drug Bioavailability.
b) Write note on: pH-partition Hypothesis theory of drug absorption.
c) Discuss in detail Biopharmaceutical Classification of Drug.
d) What are the Clinical Significance of Bioequivalence studies?
e) Explain in detail *In-vitroln-vivo* correlation.
f) What is the process for Drug Review?

Q.2 Answer Any Three Questions. **30**

a) Discuss in detail factors affecting on the Drug Dissolution Rate.
b) Explain in detail official test for drug dissolution testing as per IP.
c) Explain in detail pharmacokinetic Application in Targeted Drug Delivery System.
d) Discuss in detail one compartment model with IV infusion Model with its equation.

Q.3 Define Drug Absorption. Explain in detail mechanism of Drug Absorption. Discuss in detail factors affecting on Drug Absorption. **20**

SLR-JB-11

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICS
Computer Aided Drug Delivery System (8022203)

Day & Date Wednesday, 29-05-2024 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 of the following Questions. **25**

a) Write in brief about history of computers in Pharmaceutical Research and Development.
b) Comment on the challenges and future directions of Artificial Intelligence in pharmaceutical sector.
c) Describe the development of Pharmaceutical Emulsions.
d) How the computers are applicable in Clinical Development?
e) What is in vitro-in vivo correlation?
f) Write a note on statistical modeling in pharmaceutical research and development.

Q.2 Answer Any Three of following. **30**

a) Write in details about- ICH Q8 guideline and Scientifically based QbD.
b) Describe the applications of computer in pharmaceutical research with some examples. What are the provisions for legal protection of innovative uses of computers in R&D?
c) Write a note on pharmaceutical applications of AI, computational fluid dynamics and robotics with its advantages and disadvantages.
d) Explain the process of computer simulation in whole organism, isolated tissues, organs and genes.

Q.3 Answer the following Question.

Write in details about- computational modeling of drug disposition with suitable examples of modeling techniques used in Solubility, Permeation, Absorption, Distribution and Excretion of drug. **20**

SLR-JB-12

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICS
Cosmetic and Cosmeceuticals (8022204)

Day & Date: Friday, 31-05-2024 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) Define and classify perfumes.
b) Write a note on conditions for obtaining license for manufacturing of cosmetics
c) Explain Common problems associated with oral cavity.
d) Write a brief note on surfactants used in cosmetics.
e) Define SPF and classify sunscreens.
f) Write on Structure of hair and add a note on hair growth cycle.

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

a) Explain preservatives, write their merits and demerits.
b) Define cosmetics, write on regulatory provisions relating to import of cosmetics.
c) Write on building blocks of vanishing cream, cold cream and moisturizing creams.
d) Write a note on herbal ingredients used in haircare products.

Q.3 Draw Structure of skin & elaborate on skin related problems like dry skin, acne, pigmentation, prickly heat, wrinkles. **20**

SLR-JB-13

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Hazards and Safety Management (8023201)

Day & Date: Friday, 24-05-2024 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 Water Resources.
b) Write a note on COD.
c) Discuss Fire Protection System.
d) Write a note on sources of Chemical Hazards.
e) Describe in short on TLV concept.
f) Write on Effluent Treatment Procedure.

Q.2 Answer Any Three Questions. **30**

a) Discuss on Ecosystem.
b) Write a note on Industrial process Hazards. Discuss Preventive and protective management from fire and explosion.
c) Elaborate on control measures for Chemical Hazards.
d) Discuss in detail on risk assessment and risk management methods.

Q.3 Elaborate on Air based Hazards. Discuss air circulation maintenance industry for sterile and non sterile area. Write on Preliminary Hazard Analysis. **20**

SLR-JB-14

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Pharmaceutical Validation (8023202)

Day & Date: Monday, 27-05-2024 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) What is the Factory Acceptance Test and Site Acceptance Test?
b) What are the advantages of Validation?
c) Name Utility Systems. Give the tests for Compressed Air.
d) How is pure Steam collected for analysis? List tests for Steam.
e) Give the process validation activities stages as per fda.
f) How is performance of disintegration tester verified?

Q.2 Answer Any Three Questions. (3×10) **30**

a) Explain the basic cleaning mechanism to remove residues from equipment.
b) Explain the parameters to be checked during qualification of IR spectrophotometer.
c) Give the steps involved in analytical method validation.
d) Define and give mechanism for protection of patent, copyright and trademark.

Q.3 Discuss the process validation of mixing or blending needed to manufacture the tablet dosage form. **20**

SLR-JB-15

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Audits and Regulatory Compliance (8023203)

Day & Date: Wednesday, 29-05-2024 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) Define audit, auditee and regulatory compliance. Differentiate between Internal Audit and External Audit.
b) Explain in brief about auditing of Capsule Manufacturing Department.
c) Describe Qualification and Attributes of Auditor in detail.
d) Write note on auditing of Manufacturing Process.
e) Discuss the role of quality system approach in Pharmaceutical Industries.
f) Explain parameters for auditing of Packaging Materials.

Q.2 Answer Any Three Questions. **30**

a) Explain different types of deficiencies observed in an Audit.
b) Explain in brief about auditing of Sterile Manufacturing Department.
c) Discuss designing and implementation for Internal Audit System.
d) How is quality measured in Manufacturing Operations? Comment on 'Quality culture'.

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

Describe the process of Management and Conduct of a Regulatory Audit.

SLR-JB-16

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: March/April-2024
PHARMACEUTICAL QUALITY ASSURANCE
Pharmaceutical Manufacturing Technology (8023204)

Day & Date: Friday, 31-05-2024 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 process layout of sterile products.
b) Discuss in detail about Critical Quality Attributes.
c) Explain different types of closures and closure liners.
d) Describe the elements of Manufacturing Planning Systems.
e) Give the Fundamental Process Lyophilization Technology.
f) Explain stability Aspects of packaging.

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

a) Define Palletizations. Explain different methods used to preparation of pellet.
b) Discuss legal requirements and Licenses for API and Formulation Industry.
c) Discuss in detail process flow chart for Small volume Parenterals (SVPs) manufacturing process.
d) Explain principle and mechanism of extruders.

Q.3 What is meant by QbD? Mention its advantages and limitations. Discuss the process for applying QbD for designing drug products. **20**