SLR-GB-1

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Modern Pharmaceutical Analytical Techniques (8022101)

Day & Date: Thursday, 18-01-2024 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) Draw a neat labeled diagram of IR Spectrometer. Elaborate applications of it with suitable examples.
b) Give an account on principle & applications of Spectrofluorometer.
c) Write on fragmentation rule of Mass Spectrometry.
d) Discuss the principle and applications of Gel Electrophoresis
e) Write a note on Radio immune Assay.
f) Write in short on X-ray Crystallography.

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

a) Discuss instrumentation and Beers Lamberts Law of UV-Visible spectrophotometer.
b) Elaborate on instrumentation of Gas Chromatography. Enlist its applications.
c) Write principle, instrumentation and applications of Flame emission Spectrophotometer.
d) Describe factors affecting chemical shift. Discuss Stationary phases used in Thin Layer Chromatography.

Q.3 Discuss in detail on instrumentations Mass Spectrometer. Give Number of signals & multiplicity of peak for 1,2-dichloro propane. **20**

SLR-GB-2

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Drug Delivery System (8022102)

Day & Date: Saturday, 06-01-2024 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 Telepharmacy & personalized medicine.
b) Write a note on PH activated drug delivery system.
c) Explain the advantages, disadvantages & applications of biodegradable polymers.
d) Discuss the methods of enhancing transdermal permeation.
e) Write a short note on vaccine delivery systems.
f) Discuss the barriers to protein delivery.

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

a) With a neat labeled diagram explain the structure of skin. Add a note on the additives used in transdermal patch.
b) Explain the formulation & evaluation of Buccal patch.
c) Describe the formulation & evaluation of Ocular drug delivery system.
d) Discuss the formulation & evaluation of Osmotic drug delivery system.

Q.3 Explain the various approaches used to formulate Gastro-retentive drug delivery system. How are they evaluated? **20**

SLR-GB-3

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Modern Pharmaceutics (8022103)

Day & Date: Tuesday, 09-01-2024 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 stability testing in detail.
b) Give ICH guidelines for calibration and validation of equipments.
c) Discuss layout of manufacturing plant of pharmaceutical product as per CGMP.
d) Discuss linearity concept of significance.
e) Explain ANOVA test.
f) What do you mean by validation

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

a) Discuss theories of dispersion in detail
b) Describe the concept of total quality management.
c) Describe statistical designs with their significance.
d) Discuss Heckel and Higuchi and peppas plot. Describe chi-square test and student T-test.

Q.3 Discuss compression and compaction process of tablet manufacturing. **20**

SLR-GB-4

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Regulatory Affair (8022104)

Day & Date: Thursday, 11-01-2024 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) Describe various activities regulated by CDER.
b) What is DMF? Describe the types of DMF.
c) Explain the functional role of CDSCO.
d) Classify New Drug Applications.
e) Write a note on Post Marketing Surveillance.
f) Explain the various components of FDA.

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

a) Describe objectives, provisions and loopholes of the Hatch-Waxman Act.
b) Write a note on ANDA. Explain the concept of PARA I to IV filling.
c) Enumerate ICH quality guidelines. Explain ICH Q7 guidelines.
d) What is 21 CFR Part 211? Describe its salient features.

Q.3 Describe the procedure for New Drug approval from CDSCO in India. **20**

SLR-GB-5

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Modern Pharmaceutical Analytical Techniques (8023101)

Day & Date: Thursday, 18-01-2024 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. (5×5) **25**

a) Draw a neat labeled diagram of Flame emission Spectroscopy. Give its application.
b) Describe on instrumentation of NMR spectroscopy
c) Give principle of Gas Chromatography. Discuss Flame Ionization detector
d) Write on Principle and applications of Ion Exchange Chromatography.
e) Discuss any two detectors used in HPLC
f) Give principle and applications of Potentiometry

Q.2 Answer any three questions. (3×10) **30**

a) Discuss in detail Factors affecting vibrational frequencies and Applications of IR spectroscopy.
b) Write on Braggs law & applications of X-ray diffraction. Discuss in short on Gel Electrophoresis.
c) Draw a neat labeled diagram of double beam UV-Visible spectrophotometer. Elaborate on solvent effect and applications of UV-Visible spectrophotometer.
d) Write principle, instrumentation and applications of DSC.

Q.3 Discuss in detail on principle, instrumentation and any three ion sources and any one mass analyzer used in Mass Spectrometry. Give number of signals & multiplicity of peak for ethyl acetate & 1,2-dibromo propane. **20**

SLR-GB-6

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Quality Management System (8023102)

Day & Date: Saturday, 06-01-2024 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**

i) Define Quality. Explain the dimensions of quality.
ii) Explain the elements and requirements of quality.
iii) Write note on Quality by design approach of pharmaceuticals.
iv) Discuss in detail methods for assessment of risk management.
v) Give the advantages of benchmarking.
vi) Write the importance of Statistical Process Control. (SPC)

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

i) Define Quality? Explain in the different types of Customers?
ii) Write note on McKinsey 7s Model.
iii) Discuss in detail categories of cost of Quality.
iv) Discuss in detail ICH guidelines for stability testing of drug substances and drug products.

Q.3 Discuss in detail Total Quality Management and ICH guidelines for stability testing of drug substances and drug products. **20**

SLR-GB-7

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Quality Control and Quality Assurance (8023103)

Day & Date: Tuesday, 09-01-2023 Max. Marks: 75
Time: 2:30 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) Which are the drug manufactures covered under us fda GMP guidelines?
b) Give the scope of GLP.
c) Give QC tests for containers & closures.
d) What is pharmaceutical inspection convention? Give its objectives.
e) What is QC & QA?
f) What are theoretical yield, actual yield and percentage of theoretical yield?

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

a) Write note on release of finished product.
b) Write note on production & process control.
c) Explain the CDER & CBER.
d) Describe the sampling & testing of in-process materials & drug product.

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

SLR-GB-8

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Product Development and Technology Transfer (8023104)

Day & Date: Thursday, 11-01-2024 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 of following. **25**

a) Write a note on purpose, types and documentation in IND and NDA applications.
b) Enlist various methods of solubility enhancement. Describe any one method in detail.
c) Write a note on significant of pilot plant scale up. Add a note on opportunities and challenges in it.
d) Write a note on selection and evaluation of Pharmaceutical packaging materials.
e) Define technology transfer. Describe the documentation in technology transfer.
f) Write a note on product registration guidelines by CDSCO or USFDA.

Q.2 Answer ANY THREE of following. **30**

a) Describe various stages of Clinical trial process. Add a note on Pharmacovigilance.
b) Explain the concept of pilot plant scale up study. Describe a layout for pilot plant scale up study for solid dosage forms.
c) Classify packaging materials for pharmaceutical use. Describe the Quality control tests for containers, closures and secondary packing materials.
d) What are the different steps in technology transfer from R & D to production? Explain in detail.

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

Write a detailed note on Preformulation studies for pharmaceutical solid dosage forms. Add a note on Preformulation study protocol.

SLR-GB-9

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Molecular Pharmaceutics (Nano Tech and Targeted DDS) (8022201)

Day & Date: Friday, 05-01-2024 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 biological process involved in drug targeting.
b) Give preparation of Phytosomes.
c) Write a note on antisense molecules.
d) Discuss methods to target tumors.
e) Give a note on liposomes as a DDS.
f) Discuss use of propellant in intranasal DDS.

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

a) Write a note on preparation and application of Aquasomes.
b) Discuss preparation and evaluation of aersol as drug delivery system.
c) Elaborate Gene therapy.
d) Discuss brain specific drug delivery.

Q.3 Discuss introduction, preparation and evaluation of Nano Particles. **20**

SLR-GB-10

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Advanced Biopharmaceutics & Pharmacokinetics (8022202)

Day & Date: Monday, 08-01-2024 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) Give the significance of bioequivalence studies.
b) Differentiate between Plasma Protein binding and Tissue-Drug binding.
c) Write note on: Diffusion cell Method
d) What are the advantages of compartment modeling of drug?
e) What are the various pharmacodynamics parameters?
f) In compartment modelling, what does the term open mean?

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

a) Discuss in detail Mechanism of Drug Absorption.
b) Explain in detail pharmaceutical factors affecting on drug Absorption.
c) Discuss in detail theories of Drug Dissolution Process.
d) Define Bioavaibility. Explain in detail methods for assessment bioavailability

Q.3 Answer the following **20**

Define Pharmacokinetic Parameters? What are its various types? What are important considerations for parameters to be applicable in Pharmacokinetic Studies?

SLR-GB-11

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Computer Aided Drug Delivery System (8022203)

Day & Date Wednesday,10-01-2024 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 following. **25**

a) Describe the history of computers in pharmaceutical research and development.
b) Write a note on Clinical Data Collection and Management system.
c) Define- a) Solubility b) Permeability c) Absorption d) Distribution e) Elimination.
d) Explain the concept of ethics of computing in pharmaceutical research
e) Write a note on *in vivo-in vitro* correlation.
f) Describe the Concept of optimization. Add a note on Factorial design.

Q.2 Answer ANY THREE of following. **30**

a) Write in details about- Computational Modeling of Drug Disposition with suitable examples.
b) Describe the computer simulation in whole organism, isolated tissues, organs and genes.
c) Explain in detail about the Computer-aided biopharmaceutical characterization with the emphasis on various types of studies.
d) Write a note on Pharmaceutical applications of Al and robotics with its advantages and disadvantages. Add a note on future challenges.

Q.3 Answer the following.

Describe the concept of Quality-by-Design in Pharmaceutical Development. Add a note on scientifically based QbD with the suitable examples of application. **20**

SLR-GB-12

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICS
Cosmetic and Cosmeceuticals (8022204)

Day & Date: Friday, 12-01-2024 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 the following questions. (Any Five) **25**

a) Define cosmetics, cosmeceuticals. Classify cosmetics.
b) Enlist excipients used in cosmetics with examples, add note on emollients.
c) Write a note on common problems associated with skin.
d) Write note on Surfactants. Give its applications.
e) Define and classify perfume.
f) Explain the role of preservatives in cosmetics

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

a) Explain problems associated with teeth and gums.
b) Discuss designing of cosmeceutical products for sun protection.
c) Describe the principle, building blocks used in the formulation of oral care products.
d) Elaborate on Herbal ingredients used in Hair care and oral care.

Q.3 Write on building blocks of vanishing cream, cold cream and moisturizing creams. **20**

SLR-GB-13

Seat No.		Set	P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Hazards and Safety Management (8023201)

Day & Date: Friday, 05-01-2024 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 Critical hazard Management.
b) Write in brief on Factory act & rules.
c) Elaborate on Natural resources & its associated problems.
d) Describe Preliminary Hazard Analysis.
e) Write a note on Organic Solvent Hazards.
f) Write a note on Forest resources.

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

a) Discuss on Ecosystem: Concept, structure & functions.
b) Write on Air circulation maintenance industry for sterile and non sterile area.
c) Elaborate on fire prevention and types of fire extinguishers.
d) Explain Preventive and protective management from fire and explosion.

Q.3 Discuss the guidelines on risk assessment and risk management methods & tools. Write on Effluent treatment procedure. Write on sources of chemical hazards and discuss TLV concept. **20**

SLR-GB-14

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Pharmaceutical Validation (8023202)

Day & Date: Monday, 08-01-2024 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 validation? What are the types of validation?
b) What is change management?
c) Give the limit and range of air quality for parameters that are performed.
d) Differentiate between validation, qualification and calibration.
e) How is performance of disintegration tester verified?
f) What are the advantages of cleaning validation?

Q.2 Answer any three questions. (3×10) **30**

a) Explain the sampling techniques in Cleaning Validation.
b) Specify the important parameters for nitrogen gas quality.
c) Explain the parameters to be checked during qualification of IR spectrophotometer.
d) What is Intellectual Property Rights and explain different types.

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

SLR-GB-15

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Audits and Regulatory Compliance (8023203)

Day & Date: Wednesday, 10-01-2024 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) **25**

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

Q.2 Answer any three questions. (3×10=30) **30**

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

Q.3 Classify types of GMP audits in pharma industry. Explain the benefits of such audits. Describe the process of second party audit. **20**

SLR-GB-16

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination: Oct/Nov-2023
PHARMACEUTICAL QUALITY ASSURANCE
Pharmaceutical Manufacturing Technology (8023204)

Day & Date: Friday, 12-01-2024 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 evaluations tests for packaging materials.
b) Discuss Process Quality Control Tests for Ointment.
c) Give the Importance of Manufacturing Planning.
d) Discuss Approaches of QbD in tablet Coating Process.
e) Explain different types of granulators.
f) Distinguish between rapid mixer granulator and Rota Granulator.

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

a) Discuss plant layout of small volume parental.
b) Explain Process quality Control tests for Suspension and Emulsion.
c) Elaborate Mechanism of Pelletization Techniques.
d) Describe the elements of QbD.

Q.3 Discuss in detail Manufacturing flowcharts of tablet dosage form. **20**