SLR-FL-1

Seat No.	

Set P

M. Pharmacy (Semester –I) (CBCS) Examination Dec-2019
Pharmaceutics
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE

Day & Date: Thursday, 12-12-2019 Max. Marks: 75
Time:10:00 AM To 01:00 PM

Instructions:1) All questions are compulsory.
2) Figure to the right indicates full marks.

Q.1 Answer any FIVE of the following: **25**

a) How many different isomeric structures can be drawn for molecular formula C_4H_8O and assign their ^1H NMR peaks.
b) Describe Radio immuno assay.
c) Explain the principle X ray crystallography.
d) What is thin layer chromatography? Explain the steps involved in separation of compounds on TLC.
e) Write note of gel electrophoresis.
f) Write a note on chemical shift in NMR.

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

a) What is the principle involved in fluorescence? With neat labeled diagram explain different parts of modern fluorimeter. Highlight few application of Spectrofluorimeter.
b) Write the principle involved in High performance liquid chromatography. With neat diagram explain different parts of HPLC.
c) Draw labeled diagram of Mass spectrometry. Explain in detail at list two mass analyzers.
d) How concentration of sample is determined by UV-Visible spectroscopy. Describe any one method which determines the concentration of substances in two component mixture by UV Spectroscopic method

Q.3 Answer any two. **20**

a) Draw neat labeled diagram of double beam IR spectroscopy and explain different parts.
b) How inductive effect and hydrogen bonding affect the absorption of infra red frequencies.
c) List out the applications of IR spectroscopy.

SLR-FL-2

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination Dec -2019
Pharmaceutics
DRUG DELIVERY SYSTEM

Day & Date: Saturday, 14-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

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

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

a) Give an account on single shot vaccines.
b) Define CR, SR formulation. Classify polymers used in SR formulation with example.
c) What are barriers of drug permeation? Give methods to overcome barriers.
d) Discuss principles of muco adhesion.
e) Write a note on penetration enhancer.
f) Define and give examples of bioelectronic medicine and telepharmacy.

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

a) Write formulation and evaluation of floating tablets.
b) Discuss designing, principles of rate controlled drug delivery system.
c) Give detailed account on buccal drug delivery system.
d) Discuss formulation evaluation of protein delivery system.

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

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

SLR-FL-3

Seat No.	

Set P

M. Pharmacy (Semester – I) (CBCS) Examination Dec-2019
Pharmaceutics
MODERN PHARMACEUTICS

Day & Date: Tuesday, 17-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

Instructions: 1) All questions are compulsory.
2) Figure to the right indicates full marks.

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

a) Comment on: Total Quality Management System.
b) Describe the climatic zone for stability testing of drugs product.
c) Give the application of optimization process in formulations.
d) Elaborate Scheme to identify chemically compatible excipients.
e) Discuss the responsibility for scale forecasts.
f) Explain sampling statistics of APIs.

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

a) Define Preformulation. Give its significance.
b) Explain in detail design, layout of large volume parentals.
c) Discuss in detail validation of tablet Compression machine.
d) Define Equipment Qualification. Explain different types of Qualification.

Q.3 Explain different parameters studied in preformulation of a solid dosage form. Add a note on solid state characterization. **20**

SLR-FL-4

Seat No.	

Set P

M. Pharmacy (Semester – I) (CBCS) Examination Dec-2019
Pharmaceutics
REGULATORY AFFAIR

Day & Date: Thursday, 19-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

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

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

a) Enlist the responsibilities of regulatory affairs department.
b) Give the contents of registration dossier in India.
c) Write a note on CDSCO.
d) Interpret the regulations governing orphan drugs.
e) Describe the process of monitoring drug safety in clinical trials.
f) Explain the regulatory network in pharmaceutical industry in India.

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

a) Explain the role of laws and regulations that govern pharmaceutical industry in India.
b) What is 21 CFR Part 211? Describe its salient features.
c) Give the contents and regulatory requirements for submission of Abbreviated New Drug Application.
d) Describe the essential features of clinical trials.

Q.3 Describe in detail the drug approval process in India. **20**

SLR-FL-10

Seat No.	

Set P

M. Pharmacy (Semester – I) (CBCS) Examination Dec-2019
Pharmaceutical Quality Assurance
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day & Date: Thursday, 12-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

Instructions: 1) All questions are compulsory.
2) Figures to the right indicate full marks.
3) Assume suitable data if necessary.

Section – I

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

a) Draw the structures of isomeric nitro anilines and assign tentative NMR signals in DMSO D_6.
b) Explain the principle involved in potentiometry and briefly list out its applications.
c) Write a note on gel electrophoresis.
d) Explain the factors which influences absorption of infra radiations by compounds?
e) Derive Beer Lambert equation
f) What are the types of balances employed in TGA and explain any one? Write the applications of TGA.

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

a) Which are the factors which govern protons to resonate at different radio frequencies elaborate in detail?
b) Explain in detail Bragg's law and instrumentation of typical X ray crystallography.
c) Write a note on EI and CI ionization. What is HRMS?
d) Explain detail instrumentation of DSC and list of its applications.

Q.3 a) Define and classify chromatography with examples. With figure explain the instrumentation of GC. **10**
b) Mention the applications of TLC and HPLC **10**

SLR-FL-11

Seat No.	

Set P

M. Pharmacy (Semester - I) (CBCS) Examination Dec -2019
Pharmaceutical Quality Assurance
QUALITY MANAGEMENT SYSTEM

Day & Date: Saturday, 14-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

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

Q.1 Answer any five questions of the following. **25**

a) Discuss the role of QbD as a risk assessment tool.
b) Describe the process of 'vendor qualification' and its importance.
c) Discuss about batch review and batch release.
d) Discuss the salient features of ISO system in quality management.
e) How are causes of errors identified and managed?
f) Describe in brief bench marling.

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

a) What is SPC? Where is it useful? Discuss the role of SPC in managing quality.
b) Discuss briefly about IPQC and Batch review.
c) Elaborate the role of ICH Q9 in quality management.
d) What is McKinsey model of strategic development? Describe its usefulness.

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

Discuss the role of TQM in quality management as against quality control and quality assurance.

SLR-FL-12

Seat No.	

Set P

M. Pharmacy (Semester – I) (CBCS) Examination Dec-2019
Pharmaceutical Quality Assurance
QUALITY CONTROL AND QUALITY ASSURANCE

Day & Date: Tuesday, 17-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

Instructions: 1) All questions are compulsory.
2) Figure to the right indicates 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) What are non clinical laboratory study, testing facility & quality assurance unit?
d) What is pharmaceutical inspection convention? Give its objectives.
e) What are CDER & CBER?
f) Give overview of ICH guidelines.

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

a) What is the scope of QC & QA?
b) Write note on production & process control.
c) Give the IPQC & FPQC tests for parenteral & ointments.
d) Describe the sampling & testing of in-process materials & drug.

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

SLR-FL-13

Seat No.	

Set P

M. Pharmacy (Semester – I) (CBCS) Examination Dec-2019
Pharmaceutical Quality Assurance
PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Day & Date: Wednesday, 18-12-2019 Max. Marks: 75
Time: 02:00 PM To 05:00 PM

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

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

a) Give an account on USFDA guidelines for product registration.
b) Enlist pharmaceutical packaging materials and discuss briefly importance of glass as packaging material for pharmaceutical dosage forms.
c) Discuss preformulation protocol for new drugs.
d) Explain the phases of clinical research in drug development process.
e) Discuss evaluation tests of plastic containers used in packaging of pharmaceutical preparations.
f) Write in detail account on qualitative technology transfer models.

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

a) Explain in detail physicochemical properties of API analyzed during preformulation studies.
b) Explain the steps in investigational new drugs application during drug development.
c) Discuss in detail various techniques to study crystal properties and polymorphism of API.
d) Explain pilot plant scale up for parenteral dosage forms.

Q.3 Discuss the importance of techniques of solubility improvement of API during preformulation studies. **20**

SLR-FL-20

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination Dec- 2019
Pharmaceutics
MOLECULAR PHARMACEUTICS (NANO TECH AND TARGETED DDS)

Day & Date: Wednesday, 11-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 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 brief application of niosomes.
b) Discuss about preparation of Phytosomes.
c) Write the evaluation tests of aerosoles.
d) Write a note on Active and Passive targeting.
e) Write the applications of Aptamers.
f) Write a note on monoclonal antibodies in drug targeting.

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

a) Discuss the role of propellants in aerosols.
b) Write a note on preparation and evaluation of microspheres.
c) Discuss - Biodistribution and Pharmacokinetics.
d) What do you understand by the term Gene Therapy? Add a note on gene expression systems.

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

SLR-FL-21

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination Dec- 2019
Pharmaceutics
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Day & Date: Friday, 13-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 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) Discuss the effects of dosage forms on bioavailability.
b) Write a note on in vitro-in vivo correlation
c) With the help of Michaelis- Menten equation, describe the concept of non-linear pharmacokinetics.
d) Write a note on Biopharmaceutical Classification System.
e) Write a note on proteins and peptides in targeted drug delivery.
f) Describe the effect of protein binding interactions on pharmacokinetics with suitable examples.

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

a) Describe the mechanism of passive diffusion and carrier mediated transport.
b) Write a note on methods for dissolution testing.
c) Explain the One compartment open model-IV bolus in detail.
d) Give a detailed account of objectives, method and design of bioequivalence study.

Q.3 Answer the following questions.

Describe the physicochemical factors affecting absorption in detail with special emphasis on pH-partition hypothesis. **20**

SLR-FL-22

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination Dec -2019
Pharmaceutics
COMPUTER AIDED DRUG DELIVERY SYSTEM

Day & Date: Monday, 16-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

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

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

a) Name and explain the functions of drug transporters.
b) Enlist advantages and disadvantages of pharmaceutical automation.
c) Mention the important biowaiver considerations in solid dosage forms.
d) Explain the role of computers in factorial design.
e) Differentiate between descriptive and mechanistic modelling.
f) Write a note on Monte Carlo simulation.

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

a) Write in detail about computational modelling techniques used in drug absorption in body.
b) Explain the role of computers in IVIVC.
c) Outline the quality by design concept in product development with respect to ICH guidelines.
d) Describe the role of computers in formulation development of emulsions by using simulation technique.

Q.3 Explain in detail the different physiochemical parameters that affect biological activity. **20**

SLR-FL-23

Seat No.	

Set P

M. Pharmacy (Semester – II) (CBCS) Examination Dec-2019
Pharmaceutics
COSMETIC AND COSMECEUTICALS

Day & Date: Wednesday, 18-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

Instructions: 1) All questions are compulsory.
2) Figure to the right indicates full marks.

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

a) Describe formulation and evaluation of sunscreen cream.
b) Discuss cleansing care needs for face and under-arm.
c) Define cosmetics, cosmeceuticals. Classify cosmetics.
d) Write a note on formulation of soap.
e) Describe formulation and evaluation of moisturizing cream.
f) What are the general requirements for the factory premises for manufacturing of cream?

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

a) Write formulation and evaluation of vanishing cream.
b) Discuss challenges in formulating herbal cosmetics.
c) Define and classify perfume. Add a note on perfume ingredients listed as allergens in EU regulation.
d) Discuss merits and demerits of preservative used in cosmetics.

Q.3 Give detailed account on herbal ingredients used in hair, skin and oral care. **20**

SLR-FL-28

Seat No.	

Set P

M. Pharmacy (Semester – II) (CBCS) Examination Dec-2019
Pharmaceutical Quality Assurance
HAZARDS AND SAFETY MANAGEMENT

Day & Date: Wednesday, 11-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

Instructions: 1) All questions are compulsory.
2) Figure to the right indicates full marks.

Q.1 Answer any five of the following questions. **25**

a) Write in brief about hazards associated with radioactive resources.
b) Write in brief how energy resources can be ensured in a sustainable way.
c) Discuss about personal protective equipments commonly used in a chemical industry.
d) What types of hazards are associated with organic synthetic processes? Explain.
e) Comment on OSHA guidelines on hazard management.
f) Describe methods used for effluent evaluation.

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

a) Write a note on organizations making regulations on hazards and safety in industries.
b) Discuss the nature and importance of emergency services in a chemical industry.
c) Elaborate the role of Preliminary Hazard Analysis of a process in a pharma industry.
d) Describe the methodology of treatment of effluent of a chemical process industry.

Q.3 Discuss the causes of fire hazard in a chemical industry. Explain the approaches available to overcome it. **20**

SLR-FL-29

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination Dec- 2019
Pharmaceutical Quality Assurance
PHARMACEUTICAL VALIDATION

Day & Date: Friday, 13-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

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

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

a) List the documents associated with qualification and validation.
b) Name wide variety of procedures, processes, and activities need to be validated.
c) Name laboratory and manufacturing equipment used in tableting.
d) What is cleaning validation?
e) What is requalification?
f) What is Intellectual Property Rights?

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

a) Explain the types of validation.
b) Discuss the qualification of autoclave.
c) Discuss the qualification of UV-Vis spectrophotometer.
d) Write about pharmaceutical patent.

Q.3 Define process validation and describe the stages of process validation. **20**

SLR-FL-30

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination Dec-2019
Pharmaceutical Quality Assurance
AUDITS AND REGULATORY COMPLIANCE

Day & Date: Monday, 16-12-2019 Max. Marks: 75
Time:10:00 AM To 01:00 PM

Instructions: 1) All questions are compulsory.
2) Figure to the right indicates full marks.

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

a) Explain the process of auditing the packaging department.
b) What are the objectives of quality auditing in a pharmaceutical industry?
c) Describe the process of auditing a warehouse.
d) Give the pre-requisites attributes and qualification of a quality auditor.
e) Enlist the guidelines for good documentation practices in audits
f) Explain with example the method of loan license auditing.

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

a) Classify and describe the possible compliance outcome of a regulatory audit.
b) What are the objectives of performing a first party audit? Describe the usefulness of performing such audits.
c) Define an internal audit. Explain the important outcomes of such audits.
d) Explain GMP audit checklist for the drug manufacturer with reference to manufacturing plant related parameters.

Q.3 What different types of audits are done in pharmaceutical industry? Elaborate on the same. Describe the scope of second party audit. **20**

SLR-FL-31

Seat No.	

Set P

M. Pharmacy (Semester - II) (CBCS) Examination Dec- 2019
Pharmaceutical Quality Assurance
PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Day & Date: Wednesday, 18-12-2019 Max. Marks: 75
Time: 10:00 AM To 01:00 PM

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

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

a) Describe the elements of Manufacturing Planning Systems.
b) Discuss about Critical Quality Attributes.
c) Explain stability Aspects of packaging.
d) Explain Quality Control tests for Tablets.
e) Explain evaluations tests for packaging materials.
f) Discuss Approaches of QbD in tablet Coating Process.

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

a) Discuss in detail principle, process equipment for Lyophilization Technology.
b) Explain in detail plant layout for SVPs.
c) Haw to calculate standard cost in pharmaceutical industry.
d) Discuss in detail Quality Control test for Suspension.

Q.3 Discuss the design, Operational facilities for Pelletization Techniques. **20**