SLR-TE – 1

Seat No.	

Set P

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2018
Pharmaceutics
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day and Date : Thursday, 3-5-2018 Total Marks : 75
Time : 10.30 a.m. to 1.30 p.m

I. Answer **any five** questions : **(5×5=25)**

1) What are the factors which the fluorescence ?
2) Explain different rules involved in predicting fragmentation in electron impact Mass spectrometer.
3) With neat figure, explain different types of paper chromatograph.
4) Write with portrays different types of Infra Red vibration modes.
5) Applications of X-ray crystallography.
6) Write note of gel electrophoresis.

II. Answer **any three** questions : **(3×10=30)**

1) What do you mean by radio immuno assays and explain different types of RIA ?
2) What are the different ionization techniques in Mass spectrometer ? Explain FAB and MALDI.
3) With neat labeled diagram explain instrumentation of Gas chromatography.
4) With examples explain different electronic transitions involved in UV-Visible spectroscopy and how do you select solvent for estimation of compounds by UV-Visible spectrocopy.

III. Answer **any two** questions : **20**

a) Explain the principle involved in nuclear magnetic resonance.

b) With neat diagram explain the instrumentation of NMR.

c) What do you mean by chemical shift and which are the factor which effect the chemical shift ?

SLR-TE – 2

Seat No.	

Set P

M.Pharm. (Pharmaceutics) (Semester – I) Examination, 2018
DRUG DELIVERY SYSTEM
(New CBCS)

Day and Date : Saturday, 5-5-2018 Max. Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

1. Answer **any five** of following : **(5×5=25)**

   A) Describe different approaches of gastro-retention.

   B) Write a note on formulation of delivery systems of proteins and peptides.

   C) What is personalized medicine ? What are the categories of patients for personalized medicines ?

   D) Write a short note on vaccine delivery systems.

   E) Describe the mechanisms of drug release from osmotic drug delivery devices.

   F) Explain various mechanism of absorption of drug from transdermal route.

2. Answer **any three** of following : **(10×3=30)**

   A) Write a note on mechanically and pH triggered drug delivery systems.

   B) Describe the barriers to drug permeation in ocular drug delivery system. What are the methods to overcome ?

   C) Write a note on composition and preparation of Transdermal patch.

   D) What are different mechanisms of mucoadhesion ? Give the advantages and disadvantages of GRDDS.

3. Answer the following : **(1×20=20)**

   Write a note on basic concepts in SR/CR formulations, their merits, demerits and factors influencing their design. Add a note on mechanisms of drug release from SR/CR formulations.

SLR-TE – 3

Seat No.	

Set P

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2018
PHARMACEUTICS
Modern Pharmaceutics

Day and Date : Tuesday, 8-5-2018 Max. Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

1. Solve **any five** : **(5×5=25)**
   1) Discuss stability testing of pharmaceuticals.
   2) Add a note on large volume parenteral formulations.
   3) Discuss factorial designs of optimization.
   4) What do you mean by pharmaceutical validation ? Give its scope and merits of validation.
   5) Give the objectives of current good manufacturing practices in pharmaceuticals.
   6) Discuss Higuchi and Peppas plot.

2. Solve **any three** : **(3×10=30)**
   1) What do you mean by total quality management ?
   2) Give the quality control tools of parenteral formulations.
   3) Discuss different factors affecting tablet compression.
   4) Add a note on inventory management and its majors of controls.

3. Solve **any one** : **(1×20=20)**
   1) Give the ICH & WHO guidelines for calibration and validation of equipments.
   2) Discuss tablet compression and consolidation.

SLR-TE – 4

Seat No.	

Set **P**

Master of Pharmacy (Semester – I) (New CBCS)
Examination, 2018
(Pharmaceutics)
REGULATORY AFFAIRS

Day and Date : Saturday, 12-5-2018 Max. Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions. **(5×5=25)**

1) Write a note on QSEM guidelines.
2) Describe the modules used for CTD for marketing authorization.
3) Explain the importance of documentation in manufacturing.
4) What are the differences in regulatory environment of regulated countries and rest of the world ?
5) Explain basic ethical principles and ethical issues in clinical trials.
6) What are orphan drugs ? Explain the regulations governing orphan drugs.

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

1) Explain the important routine terminologies used in clinical trials. Add a note on types of clinical research.
2) Describe the process of approval of new drug in India.
3) Explain in detail Phase – I and Phase – II study Indian regulatory authority.
4) Give organization structure, activities and responsibilities of drug regulatory agency of India.

III. Describe in detail various stages of drug discovery to development. **20**

Seat No.	

SLR-TE – 5

Set P

M. Pharmacy (Sem. – I) (CGPA/CBCS) Examination, 2018
PHARMACEUTICS
Advanced Pharmaceutical Analysis (Old)

Day and Date : Thursday, 3-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) What is ELISA ? Explain with its types. Give its applications.
2) Explain the IR, NMR and mass spectral data for $CH_3 – CO – CH_3$.
3) Write note on X-ray diffraction and reference standard.
4) What is thermal analytical technique ? Give its types. Explain the theory involved in thermogravimetry analysis.

B. Answer **all** : **(2×20=40)**

5) Explain the partition chromatography with normal and reverse phase. Discuss the theory and applications of GLC.
6) Derive simultaneous equation for sample containing two UV absorbing drugs each of which absorb at the λ_{max} of the other. Discuss the various techniques employed for placing the sample in the path of infrared radiations.

SLR-TE – 6

Seat No.	

Set P

M. Pharmacy (Semester – I) (CBCS/CGPA Pattern) Examination, 2018
PHARMACEUTICS
ADVANCED PHARMACEUTICS – I (Old)

Day and Date : Saturday, 5-5-2018 Max. Marks : 70

Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three**. **(10×3=30)**

1) Explain the characterization of particles by size and shape. Add a note on handling of solids.

2) Discuss the factors affecting dissolution rate. How do you perform the dissolution testing of enteric coated tablets ?

3) Discuss the polymer properties that influence the design of dosage form.

4) Enumerate the reasons for preparing solid dispersion. Explain the factors influencing selection of carriers for solid dispersion. How are the solid dispersions evaluated ?

B. Answer the following. **(20×2=40)**

1) How are cyclodextrin complexes prepared ? Enlist the advantages, disadvantages and applications of cyclodextrin complexes. Add a note on the characterization of cyclodextrin complexes.

2) Justify the need for performing accelerated stability studies. How is it performed for uncoated tablets ? Add a note on shelf-life calculations.

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SLR-TE – 7

Seat No.	

Set **P**

M.Pharmacy (Semester – I) (CBCS/CGPA) Examination, 2018
PHARMACEUTICS (BIOPHARMACEUTICS AND PHARMACOKINETICS (Old) (Elective)

Day and Date : Tuesday, 8-5-2018 Max. Marks : 70

Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(10×3=30)**

1) Define Renal clearance. Discuss in detail factor affecting renal excretion.
2) Describe the mechanism of drug absorption. Write in detail on carrier-mediated transport.
3) Discuss various dissolution testing models available for solid dosage form.
4) Explain the two-compartment open modeling for intravenous bolus administration and intravenous infusion.

B. Answer the following : **(20×2=40)**

5) What are the objectives of bioavailability ? Describe the method for measurement of bioavailability. **20**
6) Write a note on the following :
   a) Michaelis Menten equation. **10**
   b) *In-Vitro In-Vivo* Correlation. **10**

SLR-TE – 8

Seat No.	

Set P

M.Pharmacy (Semester – I) (CBCS/CGPA) Examination, 2018
PHARMACEUTICS (Elective)
Advances in Drug Delivery (Old)

Day and Date : Tuesday, 8-5-2018 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(10×3=30)**

1) Write in detail hand shaking and non-hand shaking method of preparation of liposomes.
2) Explain the technologies used to design buccal tablet and give its advantages.
3) Classify the polymers. Write on applications of biodegradable polymers used in controlled drug delivery system.
4) Discuss the various methods for enhancement of dissolution characteristics evaluation thereof.

B. Answer the following : **(20×2=40)**

5) Describe barrier to transport of protein and peptide drugs and formulation considerations for their delivery.
6) Discuss technologies for developing transdermal drug delivery system and evaluation thereof.

SLR-TE – 9

Seat No.	

Set P

M. Pharm. (Semester – I) (CGPA/CBCS) Examination, 2018
PHARMACEUTICS
Product Development (Elective) (Old)

Day and Date : Tuesday, 8-5-2018 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(10×3=30)**

1) Explain the concept of validation. Write a note on process validation.
2) Explain the concept of NDA and ANDA with the process of patent filing.
3) Classify the pharmaceutical packaging materials. Write a note on packaging materials for sterile dosage forms.
4) Classify various techniques of design of experiments. Write a detailed note on factorial design with suitable example.

B. Answer the following questions : **(20×2=40)**

5) Write in detail on various types of emulsion. Give detailed account of formulation of Self emulsifying drug delivery system.
6) What is the need of Preformulation ? Describe the Preformulation process for pharmaceutical dosage forms.

SLR-TE – 10

Seat No.	

Set **P**

Master of Pharmacy (Semester – I) (New-CBCS) Examination, 2018
(Pharmaceutical Quality Assurance)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day and Date : Thursday, 3-5-2018 Total Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions. **(5×5=25)**

1) What do you mean by fluorescence and explain instrumentation of fluorimeter ?
2) Explain different rules involved in predicting fragmentation in electron impact Mass spectrometer.
3) What are the different types of TLC, how do you select the stationary and mobile phases ?
4) How hydrogen bonding influences IR absorption ?
5) Explain in detail Braggs law in X ray diffraction.
6) Write note on gel electrophoresis.

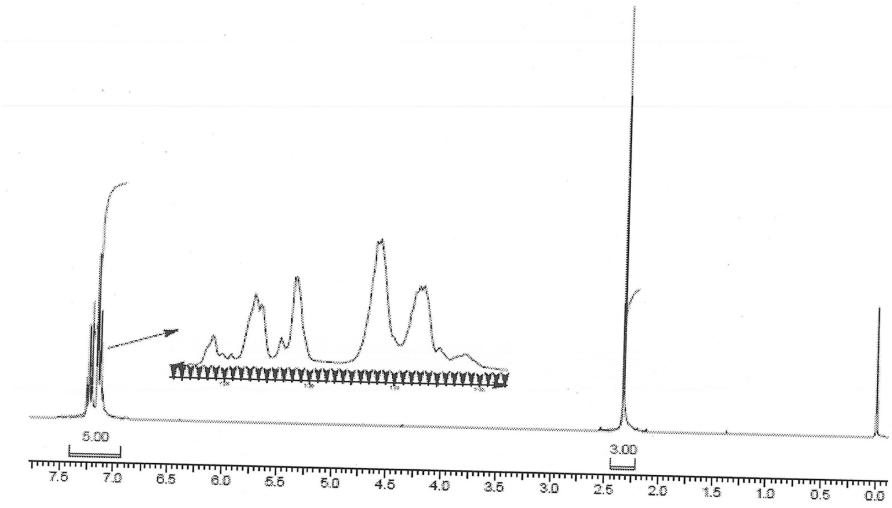
II. Answer **any three** questions : **(3×10=30)**

1) An aromatic compound with molecular formula C_7H_8 shows ^1H NMR, EI Mass and IR as depicted in the below figures, identify the compound.
2) Explain the rules to predict the fragmentation in Mass and also McLafforty rearrangement.
3) Describe the instrumentation and applications of DSC.
4) With neat labeled diagram explain instrumentation of NMR.
5) Explain in detail different electron transitions in UV-visible spectroscopy and how solvent influences the absorption of UV rays.

III. a) With neat diagram explain different parts of HPLC. **20**

b) With suitable diagram elaborate the working of detectors of gas chromatography.

P.T.O.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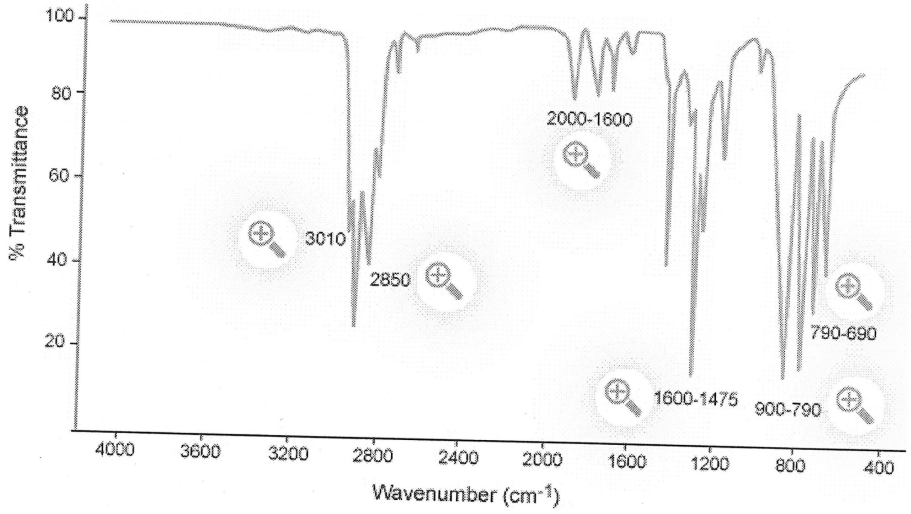
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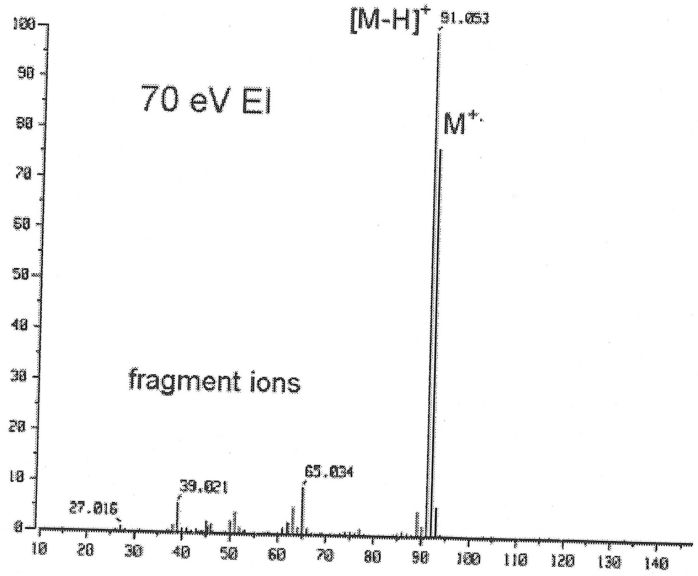
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39.021
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SLR-TE – 11

Seat No.	

Set **P**

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Quality Management System

Day and Date : Saturday, 5-5-2018 Total Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions : **(5×5=25)**

1) What are the quality systems standards ?
2) Explain in brief ISO 9001:2008.
3) Explain in brief out of specification (OOS) and out of trend (OOT).
4) Give detail focus on principles of six sigma.
5) Write an account on McKinsey 7S model.
6) Write a note on strategic planning and implementation for quality.

II. Answer **any three** questions : **(3×10=30)**

1) Give detail account on total quality management.
2) Explain in detail customer perception of quality and factors affecting customer perception.
3) Give a detail note on categories and models of cost quality.
4) Explain in detail statistical process control charts and control chart analysis.

III. Give detail focus on WHO-GMP requirement for pharmaceutical quality management. **20**

SLR-TE – 12

Seat No.	

Set **P**

Master of Pharmacy (Semester – I) (New – CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Quality Control and Quality Assurance

Day and Date : Tuesday, 8-5-2018 Max. Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions. **(5×5=25)**

1) What are quality, quality control and quality assurance ?

2) Give the IPQC and FPQC tests for capsules.

3) What are distribution records ?

4) What is aseptic process control ?

5) What are CDER and CBER ?

6) Give overview of ICH guidelines.

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

1) Define control article and test article. How is non clinical laboratory study result prepared and stored ?

2) Discuss the analysis of raw materials, finished product.

3) What is the format of SOP ? Explain with example.

4) Write note on production and process control.

III. What are cGMPs ? Why are cGMPs so important ? Explain the GMP guidelines for design, construction and sanitation of building. **20**

SLR-TE – 13

Seat No.	

Set P

M.Pharmacy (Semester – I) (New CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Product Development and Technology Transfer

Day and Date : Saturday, 12-5-2018 Total Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

1. Answer **any five** questions : **(5×5=25)**
   1) Discuss the technology transfer documentation.
   2) Write note on Aseptic packaging systems.
   3) Distinguish between thermoplastic and thermosetting materials.
   4) Explain the Investigational New Drugs Application (IND).
   5) Describe different packaging materials used for primary packing.
   6) Discuss the importance of particle size, shape and surface area in formulation design.

2. Answer **any three** questions. **(3×10=30)**
   1) Discuss in detail about the problems during the technology transfer from R and D to plant scale of novel drug delivery systems.
   2) Discuss in detail about different types of Pharmaceutical containers and closures including their merits and demerits.
   3) Describe various approaches of “pilot plant scale up techniques”. Explain its significance with reference to pharmaceutical industries.
   4) Explain the role of various Physico-Chemical characteristics of a new drug molecule in preformulation studies.

3. Discuss the evaluation of glass containers used in packaging of pharmaceutical preparation. **20**

SLR-TE – 14

Seat No.	

Set **P**

M. Pharmacy (Sem. – I) (CGPA/CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Advanced Pharmaceutical Analysis (Old)

Day and Date : Thursday, 3-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) What is ELISA ? Explain with its types. Give its applications.
2) Explain the IR, NMR and mass spectral data for $CH_3 – CO – CH_3$.
3) Write note on X-ray diffraction and reference standard.
4) What is thermal analytical technique ? Give its types. Explain the theory involved in thermogravimetry analysis.

B. Answer **all** : **(2×20=40)**

5) Explain the partition chromatography with normal and reverse phase. Discuss the theory and applications of GLC.
6) Derive simultaneous equation for sample containing two UV absorbing drugs each of which absorb at the λ_{max} of the other. Discuss the various techniques employed for placing the sample in the path of infrared radiations.

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SLR-TE – 15

Seat No.	

Set P

M.Pharm. (Semester – I) (CBCS/CGPA) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE (Old)
Quality Assurance Techniques – I

Day and Date : Saturday, 5-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Solve **any three** : **(3×10)**

1) Explain objectives, management and role of quality assurance in pharmaceutical industries.
2) Write a note on ICH guideline for stability of pharmaceuticals.
3) What is product recall ? Write a detail account on product recall.
4) Explain the BMR of tablet with example.

B. Solve both : **(2×20)**

5) Write a note on procedure for new drug application.
6) Write an account on LD50, ED 50 determination and explain its importance in pharmaceutical industry.

SLR-TE – 16

Seat No.	

Set P

M. Pharm. (Semester – I) (CBCS/CGPA) Examination, 2018
Pharmaceutical Quality Assurance (Elective) (Old)
QUALITY ASSURANCE

Day and Date : Tuesday, 8-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

***Instruction** : **All** questions are **compulsory**.*

A. Answer **any three** : **(10×3=30)**

1) Write notes on the following :
   i) Complaint handling.
   ii) Applications of computers in GMPs.
2) Giving relevant examples, give the details regarding the components and management of Batch Manufacturing Records.
3) Describe the GMP aspects of Laboratory controls in Pharma manufacturing.
4) Give an account of handling of returned and salvaged products.

B. Answer the following : **(20×2=40)**

5) What are the requirements of management systems to meet the demand of Corrective and Preventive Actions ? Discuss in detail.
6) Explain the ways to avoid making the common GMP errors. Describe the role of documentation for compliance to the GMP requirements.

SLR-TE – 17

Seat No.	

Set **P**

M. Pharmacy (Sem. – I) (CGPA/CBCS) Examination, 2018
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Analysis (Old)

Day and Date : Thursday, 3-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) What is ELISA ? Explain with its types. Give its applications.
2) Explain the IR, NMR and mass spectral data for $CH_3 – CO – CH_3$.
3) Write note on X-ray diffraction and reference standard.
4) What is thermal analytical technique ? Give its types. Explain the theory involved in thermogravimetry analysis.

B. Answer **all** : **(2×20=40)**

5) Explain the partition chromatography with normal and reverse phase. Discuss the theory and applications of GLC.
6) Derive simultaneous equation for sample containing two UV absorbing drugs each of which absorb at the λ_{max} of the other. Discuss the various techniques employed for placing the sample in the path of infrared radiations.

SLR-TE – 18

Seat No.	

Set **P**

M. Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2018
Pharmaceutical Chemistry
ADVANCED PHARMACEUTICAL CHEMISTRY – I (Old)

Day and Date : Saturday, 5-5-2018 Total Marks : 70

Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three**. **(10×3=30)**

1) Describe the design of antagonist of adrenergic receptors.

2) How amine and hydroxyl functional groups can be modified in prodrug approach with suitable examples.

3) Define enzymes with examples. What is enzyme inhibition and explain in detail.

4) Write short notes on **any two** :

   a) Plan out the synthetic scheme of propanolol using synthon approach.

   b) Inhibitors for DHFR.

   c) Antibody Directed Enzyme Prodrug Therapy.

B. Answer the following. **(20×2=40)**

5) Define and classify receptors with examples. Explain in detail any receptor theories to explain the ligand receptor interactions.

6) Define the terminologies a) Disconnection b) Functional group interconversion. How the disconnection approach contribute towards the synthesis of drugs explain along with the rules and examples.

SLR-TE – 19

Seat No.	

Set P

M. Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2018
PHARMACEUTICAL CHEMISTRY
Drug Design (Elective) (Old)

Day and Date : Tuesday, 8-5-2018 Total Marks : 70

Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) Write a note on chemical subtypes of Ca-channel antagonists.
2) Give a brief account with examples of drug design based on antagonism.
3) Write a note on design of cholesterol lowering drugs on the basis of biochemical and physiological information.
4) Explain with examples the concept of isosterism and bioisosterism.

B. Answer **all** : **(2×20=40)**

5) Give a detailed account of possible therapeutic targets and development of antineoplastic and antimicrobial drugs.
6) Describe the various approaches employed for molecular modelling. Give applications of different classes of enzyme inhibitors in drug design.

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SLR-TE – 20

Seat No.	

Set P

Master of Pharmacy (Semester – II) (New CBCS) Examination, 2018
PHARMACEUTICS
Molecular Pharmaceutics (Nano Tech and Targeted DDS)

Day and Date : Friday, 4-5-2018 Total Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

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

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

   1) What are microspheres ? Explain the different applications of microspheres.

   2) Write a brief note on preparation of monoclonal antibodies.

   3) What are Aptamers ? Add a brief note on its preparation.

   4) Write in short about therapeutic anti-sense molecules.

   5) What are aerosols ? Explain the evaluation tests for aerosols.

   6) Write in brief about nanoparticulate drug delivery system.

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

   1) Explain in brief preparation and evaluation of niosomes.

   2) What are the barriers for brain drug delivery ? Explain the different approaches for brain targeting.

   3) Explain in brief the different techniques for preparation of micropheres.

   4) Explain the need for pulmonary drug delivery system. Add a note on different approaches for pulmonary drug delivery.

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

SLR-TE – 21

Seat No.	

Set P

M.Pharm. (Semester – II, New CBCS) Examination, 2018
PHARMACEUTICS
Advanced Biopharmaceutics and Pharmacokinetics

Day and Date : Monday, 7-5-2018 Total Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

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

I. Answer **any five** the following. **(5×5=25)**

1) Describe about Wagner-Nelson method for estimation of Ka.
2) Enlist phase I reactions and explain Drug Metabolizing Enzymes.
3) What is Biopharmaceutics classification system ? Explain with example.
4) Elaborate Application of Pharmacokinetics in immunotherapy.
5) Discuss about biologics and biosimilar drug.
6) What is non-linear pharmacokinetics ? Give cause of non-linearity.

II. Answer **any three** of the following. **(3×10=30)**

1) Explain in detail mechanism of absorption.
2) Describe in detail compendial methods of dissolution.
3) Describe in brief Tight-Junction Complex of GIT.
4) Explain in brief one compartment Model-IV bolus administration.

III. Answer the following. **(1×20=20)**

1) Explain formulation and physicochemical factors affecting drug dissolution.

SLR-TE – 22

Seat No.	

Set **P**

Master of Pharmacy (Semester – II) (New CBCS) Examination, 2018
(Pharmaceutics)

COMPUTER AIDED DRUG DELIVERY SYSTEM

Day and Date : Friday, 11-5-2018 Max. Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions : **(5×5=25)**

1) Enumerate the statistical modeling in pharmaceutical research and development.
2) Discuss computer aided biopharmaceutical characterization at fed vs fasted state.
3) Add a note on ethics of computing in pharmaceutical research.
4) Discuss pharmaceutical automation and its application in drug development.
5) Give an account of sensitivity analysis.
6) Explain legal protection of innovative uses of computers in R and D.

II. Answer **any three** questions : **(3×10=30)**

1) Explain computer simulation in PK/PD usingcell and gene.
2) Explain in brief the steps involved in Quality by Design.
3) With suitable example explain the role of different transporters in intestinal drug permeation.
4) Elaborate the concept of Clinical Data Collection and Management.

III. Discuss in detail optimization technology and screening designs used in pharmaceutical formulation development. **20**

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SLR-TE – 23

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester – II) (New CBCS) Examination, 2018
COSMETICS AND COSMECEUTICALS

Day and Date : Monday, 14-5-2018 Total Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

I. Solve **any five** questions : **(5×5=25)**

1) Write formulation and evaluation of cold cream.
2) Define cosmetics, cosmeceuticals. Classify cosmetics.
3) What is meant by spurious and misbranded cosmetics ?
4) Discuss cleansing care needs for hands and feet.
5) Write a note on formulation of soap.
6) Highlight building blocks of formulation of moisturizing cream.

II. Solve **any three** questions : **(3×10=30)**

1) Write formulation and evaluation of herbal tooth paste.
2) Discuss designing of cosmeceutical products for sun protection.
3) Define and classify perfume. Add a note on perfume ingredients listed as allergens in EU regulation.
4) Discuss merits and demerits of preservative used in cosmetics.

III. Solve the following question : **(1×20=20)**

Give detailed account on herbal ingredients used in hair, skin and oral care. Add a note on challenges in formulating herbal cosmetics.

SLR-TE – 24

Seat No.	

Set P

M.Pharm. (Semester – II) (Old CBCS/CGPA) Examination, 2018
Pharmaceutics
ADVANCED PHARMACEUTICS – II

Day and Date : Friday, 4-5-2018 Max. Marks :70
Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any three** of the following : **(10×3=30)**

1) Explain briefly ion exchange and gel diffusion controlled.
2) Describe in detail biocompatibility and performance evaluation of implants.
3) Discuss about evaluation of colon specific drug delivery devices.
4) Add note on immunogenicity and stability of insulin.

II. Answer the following : **(20×2=40)**

1) Explain approaches and technologies for TDDS. Add a note on evaluation of TDDS.
2) Write an account on :
   A) Modulation of gastrointestinal transit time
   B) Hydrodynamically balanced system

SLR-TE – 25

Seat No.	

Set P

M. Pharmacy (Semester – II) (CBCS CGPA) Examination, 2018
PHARMACEUTICS
Advanced Pharmaceutics – III (Old)

Day and Date : Monday, 7-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three**. **(3×10=30)**

1) Discuss the significance of Pharmacokinetics in new drug development.
2) Explain the factors affecting drug metabolism.
3) Discuss the adjustment of dosage for patients with renal failure.
4) Describe Non-linear pharmacokinetics.

B. Answer **all**. **(2×20=40)**

5) Discuss in detail the biological and pharmaceutical factors affecting drug absorption. Add a note on pH partition hypothesis.
6) Explain the factors affecting drug distribution and add a note on significance of protein binding.

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Seat No.	

Set **P**

M. Pharmacy (Semester – II) (CBCS/CGPA) Examination, 2018
PHARMACEUTICS (Elective) (Old)
Sterile Product Formulation and Technology

Day and Date : Friday, 11-5-2018 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(10×3=30)**

1) Explain in detail temperature and humidity control parameters in manufacturing of parenterals.

2) Explain physicochemical properties of materials used in formulation of liposomes and liposmes.

3) What is industrial sterilization ? Explain specifications and process of selection in large scale sterilization.

4) What is importance of preformulation in drug delivery system ? Describe in detail preformulation aspects of developing parenteral products.

B. Answer the following : **(20×2=40)**

5) Explain in detail sterile diagnostics and radiopharmaceuticals.

6) Discuss in detail preparation of various ophthalmic products.

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Seat No.	

Set P

M.Pharm. (Semester – II) (Old CBCS-CGPA) Examination, 2018
Pharmaceutics
COSMETICOLOGY (Elective)

Day and Date : Friday, 11-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

I. Answer the following **(any three)** : **(10×3=30)**

1) Explain advances in toothpastes and hair waving cosmetics.
2) Write a note on :
   A) Contact lenses.
   B) Hair planting.
3) Describe physiological considerations in relation to hair and nail.
4) Explain about clinical safety testing of irritation and sensitization.

II. Answer the following: **(20×2=40)**

1) What are cosmetics ? Explain manufacturing techniques foam and aerosol cosmetics.
2) Write a note on :
   A) Deodorant
   B) Creams
   C) Herbal cosmetics
   D) Hair products.

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Seat No.	

Set **P**

M.Pharm. (Semester – II) (New CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Hazards and Safety Management

Day and Date : Friday, 4-5-2018 Max. Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions of the following : **(5×5=25)**

1) Write in brief about hazards associated with land resources.
2) How can accidents be prevented in an industry ? Elaborate.
3) Discuss about fire-fighting equipments.
4) What types of hazards are associated with sulfonation process ? Explain.
5) OSHA guidelines on hazard identification – comment.
6) Elaborate importance of “emergency services” in hazard management.

II. Answer **any three** questions of the following : **(3×10=30)**

1) What are the causative factors for a fire hazard in a pharma industry ? Discuss.
2) How natural resources like air and water might bring about hazards in a chemical process industry ? Discuss remedies for the same.
3) What is preliminary hazard analysis ? How this can be used in preventing a fire hazard ?
4) Write the significance of evaluation of physiochemical parameters, BOD and COD of effluents.

III. Elaborate on ICH guidelines on risk assessment and risk management in a pharmaceutical industry. **(1×20=20)**

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Seat No.	

Set **P**

Master of Pharmacy (Semester – II) (New CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Pharmaceutical Validation

Day and Date : Monday, 7-5-2018 Max. Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions : **(5×5=25)**

1) Explain the stages of validation of equipment.
2) Write a note on validation documentation.
3) Explain the method of calibration of volumetric flask and burette.
4) Elaborate on usefulness of operational qualification of equipments.
5) Explain the critical attributes of water system to be met during its validation.
6) Write a note on TRIPS Agreement and its impact on Indian Pharma Industry.

II. Answer **any three** questions : **(3×10=30)**

1) Describe the method of validation of UV-Visible spectrophotometer.
2) Explain the important considerations in validation of cleaning.
3) Describe the steps involved in the development of analytical method.
4) Explain the media fill validation method for aseptic filling.

III. Explain in detail types of process validation. Add a note on change control. **20**

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Seat No.	

Set P

Master of Pharmacy (Semester – II) (New CBCS) Examination, 2018
PHARMACEUTICAL QUALITY ASSURANCE
Audits and Regulatory Compliance

Day and Date : Friday, 11-5-2018 Max. Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions : **(5×5=25)**

1) Describe the role of regulatory audits in pharmaceutical industry.
2) Enlist the guidelines for good documentation practices in audits.
3) Explain the method of loan license auditing.
4) What are the administrative responsibilities with respect to quality audits ?
5) Explain basic principles of internal audits.
6) Explain the process of auditing packaging department.

II. Answer **any three** questions : **(3×10=30)**

1) Enlist and describe the parameters used by the manufacturer in the form of checklist for employee training and audit.
2) Explain the process of auditing a microbiology lab.
3) What are the protocols to be followed in selecting vendors ? Add a note on purchase, storage and release of raw materials.
4) What are the objectives of performing a third party audit ? Describe the usefulness of performing such audits.

III. What are the different types of audits ? Explain in detail audit methods and techniques involved in it. **20**

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Seat No.	

Set **P**

Master of Pharmacy (Semester – II) (New CBCS) Examination, 2018
Pharmaceutical Quality Assurance

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Day and Date : Monday, 14-5-2018 Total Marks : 75

Time : 10.30 a.m. to 1.30 p.m.

I. Answer **any five** questions : **(5×5=25)**

1) Explain process layout of sterile products.
2) Discuss about critical quality attributes.
3) Explain different types of closures and closure liners.
4) Describe the elements of Manufacturing Planning Systems.
5) Give the Fundamental Process Lyophilization Technology.
6) Explain stability aspects of packaging.

II. Answer **any three** questions : **(3×10=30)**

1) Define pelletization. Explain different methods used to preparation of pellet.
2) Discuss legal requirements and Licenses for API and Formulation Industry.
3) Discuss in detail process flow chart for tablet manufacturing process.
4) Explain principle and mechanism of extruders.

III. How do you apply Quality by Design (QbD) and Process Analytical Technology (PAT) in Novel drug delivery systems ? **20**

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Seat No.	

Set P

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2018
Pharmaceutical Quality Assurance
QUALITY ASSURANCE TECHNIQUES – II (Old)

Day and Date : Friday, 4-5-2018 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) Name different methods for the validation of services. Write a note on checkers checking.

2) What is software validation ? Give its importance.

3) What is patent ? Give general precautions for applicant. Give a note on patentable and non patentable inventions.

4) What are the drawbacks of improper cleaning ? What is validation of effective cleaning ?

B. Answer **all** : **(2×20=40)**

5) What do you mean by validation of water process system ? Explain the method of cleaning process for water process system.

6) Why validation of membrane filter is essential ? Where it is used in pharmaceutical industry ? Write a note in validation of membrane filter.

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Seat No.	

Set **P**

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2018
Pharmaceutical Quality Assurance (Old)
QUALITY ASSURANCE TECHNIQUES – III

Day and Date : Monday, 7-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) What is CFR ? Why HPLC performance is verified ?

2) What is biostatics ? What is the regression analysis ? Explain parametric tests ?

3) Give guidelines for statistical analysis given in the FDA/Method validation.

4) Give the guidelines for functional area, anaesthesia and euthanasia as per CPCSEA.

B. Answer **all** : **(2×20=40)**

5) Why are cGMPs so important ? Give guideline for drug product containers and closures (subpart-E) and warehousing procedures (subpart-H).

6) Discuss the performance validation of UV-VIS spectrophotometer.

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Seat No.	

Set P

M. Pharmacy (Sem. – II) (CGPA/CBCS) Examination, 2018
Pharmaceutical Quality Assurance
QUALITY CONTROL (Old)

Day and Date : Friday, 11-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) Define pharmaceutical standard and reference standard ? How are these fixed ? Add a note on contents of an ideal monograph as per current USP.

2) What is bioavailability and bioequivalence ? Explain the need of bioequivalence studies.

3) Write a brief note on principles of quality risk management.

4) What do you understand by the term Quality by design ? Explain the steps involved therein.

B. Answer **all** : **(2×20=40)**

5) What is shelf life ? Explain in brief real time and accelerated stability testing.

6) Write a brief note on :

a) In-process quality control

b) Phases of clinical trials.

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Seat No.	

Set P

M.Pharmacy (Semester – II) (CBCS/CGPA) Examination, 2018
PHARMACEUTICAL CHEMISTRY (Old)
Advanced Pharmaceutical Chemistry – II

Day and Date : Friday, 4-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(10×3=30)**

1) Explain the bioconversions of NSAID's using esterases.
2) Describe in detail screening of libraries using HTS technology.
3) Write a note on enzyme immobilization and its applications.
4) Write short notes on **any two** :
   a) Resistance of anti HIV drugs.
   b) HIV reverse transcriptase inhibitors.
   c) HIV fusion inhibitors.

B. Answer the following : **(20×2=40)**

5) What is combinatorial chemistry approach ? With suitable examples, describe in detail the techniques of combinatorial library synthesis.
6) Write the elaborate chiral synthetic methods for Diltiazem and Propranolol.

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Seat No.	

Set P

M. Pharmacy (Semester – II) Examination, 2018
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – III (Old) (CGPA/CBCS)

Day and Date : Monday, 7-5-2018 Total Marks : 70

Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(10×3=30)**

1) What are the three different types of components in molecular mechanics force fields ? Give mathematical approach to quantify bond stretching and bending in force fields.

2) Explain in detail how crystal structure of target is helpful in drug design with example.

3) Explain the chemistry and vital role played by insulin and interferon.

4) Write short notes on **any two** :
   a) Explain primary and secondary structure of proteins.
   b) Molecular dynamics simulations.
   c) Bioinformatics.

B. Answer the following : **(20×2=40)**

5) List out the different properties that are included in QSAR study. Discuss any two such properties in detail with examples.

6) What are the different stages of drug discovery processes and explain in detail lead identification process and clinical trials.

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Set P

M. Pharmacy (Sem. – II) (CGPA/CBCS) Examination, 2018
Pharmaceutical Chemistry
Elective : QUALITY CONTROL (Old)

Day and Date : Friday, 11-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Answer **any three** : **(3×10=30)**

1) Define pharmaceutical standard and reference standard ? How are these fixed ? Add a note on contents of an ideal monograph as per current USP.

2) What is bioavailability and bioequivalence ? Explain the need of bioequivalence studies.

3) Write a brief note on principles of quality risk management.

4) What do you understand by the term Quality by design ? Explain the steps involved therein.

B. Answer **all** : **(2×20=40)**

5) What is shelf life ? Explain in brief real time and accelerated stability testing.

6) Write a brief note on :

a) In-process quality control

b) Phases of clinical trials.

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Seat No.	

Set **P**

M.Pharm. (Semester – II) (CGPA/CBCS) Examination, 2018
Pharmaceutical Chemistry
THERAPEUTIC DRUG MONITORING (Old) (Elective)

Day and Date : Friday, 11-5-2018 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

A. Solve **any three** : **(10×3=30)**

1) Describe the principle and procedure of HPTLC.
2) How will you monitor the patient in cardio-pulmonary dysfunction ?
3) Discuss the general guidelines for TDM.
4) Explain the role of clinical pharmacist in TDM.

B. Answer the following : **(20×2=40)**

5) Discuss the monitoring of patient, precautions to be taken and therapeutics in the management of Diabetes Mellitus.
6) Write in details about TDM of Gentamicin. Add a note on dosing guidelines for Gentamicin.
