SLR-J – 1

Seat No.	

M. Pharmacy (Sem. – I) Examination, 2015
PHARMACEUTICS
Advanced Pharmaceutical Analysis (CGPA/CBCS)

Day and Date : Monday, 7-12-2015 Total Marks : 70

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

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

1) Identify the molecule whose spectra are provided.

2) What is thermal analysis ? Give the applications of differential thermal analysis.

3) Name different immunochemical techniques. Explain radioimmuno assay technique and give its applications.

4) Write notes on X-ray diffraction and reference standard.

B. Answer **all** : **(2×20=40)**

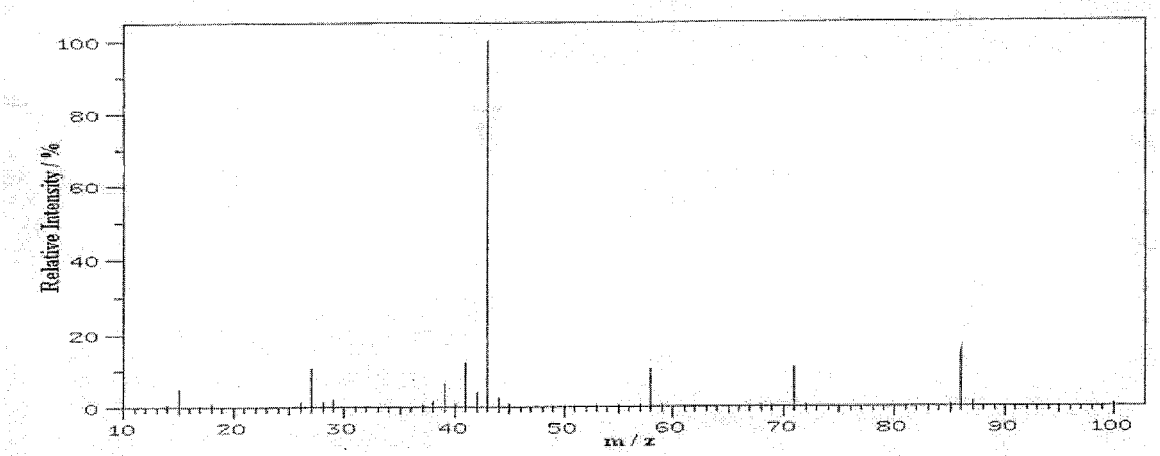
5) Discuss the theory of electronic spectroscopy. Explain the Woodward-Fieser Rules for Dienes for calculating absorption maxima. Calculate the λ_{max} for 1,3-cyclohexadiene.

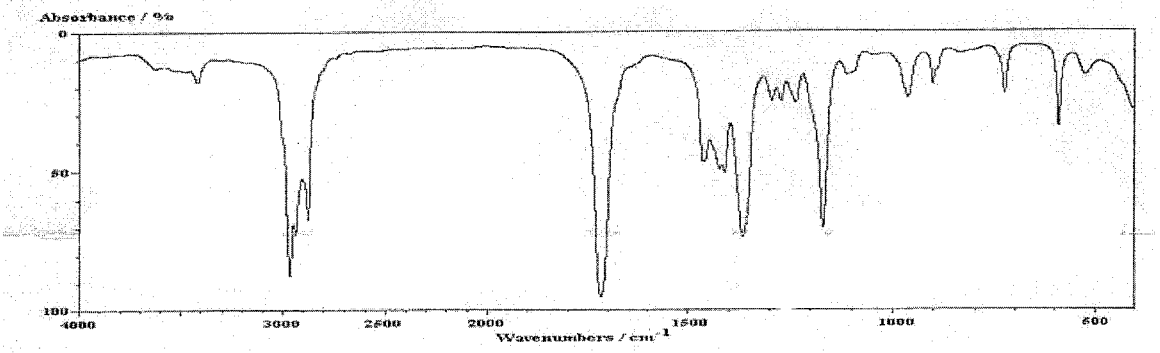
6) What is HPLC ? Name the different components of HPLC instrument and explain their role. Discuss detectors used in HPLC.

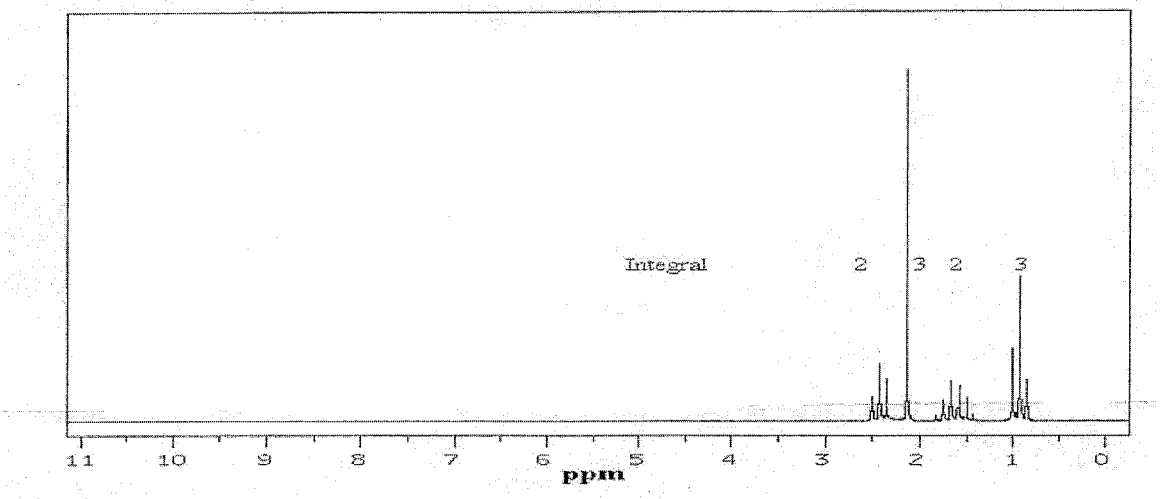
P.T.O.

SLR-J – 1

Spectra







SLR-J – 2

Seat No.	

M.Pharmacy (First Semester) Examination, 2015
Pharmaceutics (CGPA/CBCS)
ADVANCED PHARMACEUTICS – I

Day and Date : Wednesday, 9-12-2015 Max. Marks : 70

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

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

1) Explain the methods of polymerization. Write a note on characterization of polymers.

2) Explain in detail the characterization and applications of solid dispersion.

3) Describe the stability studies of tablets and suspensions. Add a note on shelf life determination.

4) Explain the importance of shape and surface area of solids. Add a note on characterization of granules.

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

5) Explain the term inclusion complex. Discuss the various methods by which cyclodextrin inclusion complex can be formed. Add a note on characterization of cyclodextrin inclusion complexes.

6) Describe the factors affecting dissolution rate. Explain the dissolution testing of uncoated, enteric coated and sustained release tablets.

SLR-J – 3

Seat No.	

M.Pharm. (Semester – I) (CGPA) (CBCS) Examination, 2015
PHARMACEUTICS
Biopharmaceutics and Pharmacokinetics (Elective)

Day and Date : Friday, 11-12-2015 Total Marks : 70

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

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

1) How would you estimate elimination rate constant, elimination half life and clearance of drug considering one compartment modeling for IV Bolus administration ? **10**

2) Describe in detail *In-Vitro-In-Vivo* Correlation. **10**

3) Discuss in detail various physicochemical properties of drug influencing on absorption. **10**

4) Describe the physiological barrier to distribution of drug. **10**

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

5) How nonlinear kinetics of a drug is detected ? Explain the causes of nonlinearity. Describe the Michaelis Menten Equation and determine K_m and V_{max}. **20**

6) Explain in detailed one compartment open model for Extra vascular administration. **20**

———————

SLR-J – 4

Seat No.	

M.Pharmacy (Semester – I) (CBCS/CGPA) Examination, 2015
PHARMACEUTICS
Advances in Drug Delivery System (Elective)

Day and Date : Friday, 11-12-2015 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Discuss the various methods for enhancement of dissolution characteristics evaluation thereof.
2) Explain the general methods of analysis of proteins and peptide drugs and their applications in drug delivery.
3) Write note on Medicated Intrauterine Drug Delivery System (MIUD).
4) Classify the Polymers. Discuss the applications of biodegradable polymers used in controlled drug delivery system.

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

5) Describe in details regulatory considerations in controlled drug release formulation in consideration of WHO and Indian condition.
6) Discuss technologies for development of Transdermal drug delivery system and evaluation thereof. Write a note on permeation enhancers used in TDDS.

———————

SLR-J – 5

Seat No.	

M.Pharm. (Semester – I) Examination, 2015
(CGPA/CBCS)
PHARMACEUTICS
Product Development (Elective)

Day and Date : Friday, 11-12-2015 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) a) Define Experiment, Independent variables, Dependent variables, Extraneous variables and Control. **5**

   b) What is experimental design ? Enlist various models for experimental design and describe any one. **5**

2) Define validation. What is need of validation ? Describe the types of validation in detail.

3) What are ideal characteristics of pharmaceutical packaging materials ? Write a note on packaging material for sterile dosage forms.

4) Discuss the concept of NDA and ANDA with the process of patent filing.

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

5) Write a detailed note on examples and roles of various components of immediate release tablet. Describe the process of compression of tablet.

6) Enlist various fundamental and derived properties of drug molecules. Add a detailed note on methods of particle size measurement.

SLR-J – 6

Seat No.	

M. Pharmacy (Sem. – I) Examination, 2015
QUALITY ASSURANCE
Advanced Pharmaceutical Analysis (CGPA/CBCS)

Day and Date : Monday, 7-12-2015 Total Marks : 70

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

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

1) Identify the molecule whose spectra are provided.

2) What is thermal analysis ? Give the applications of differential thermal analysis.

3) Name different immunochemical techniques. Explain radioimmuno assay technique and give its applications.

4) Write notes on X-ray diffraction and reference standard.

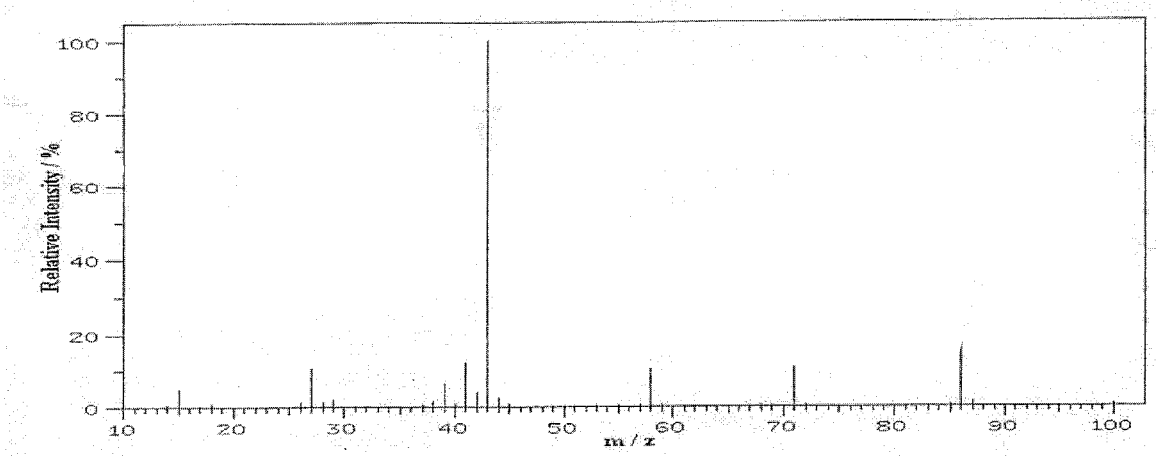
B. Answer **all** : **(2×20=40)**

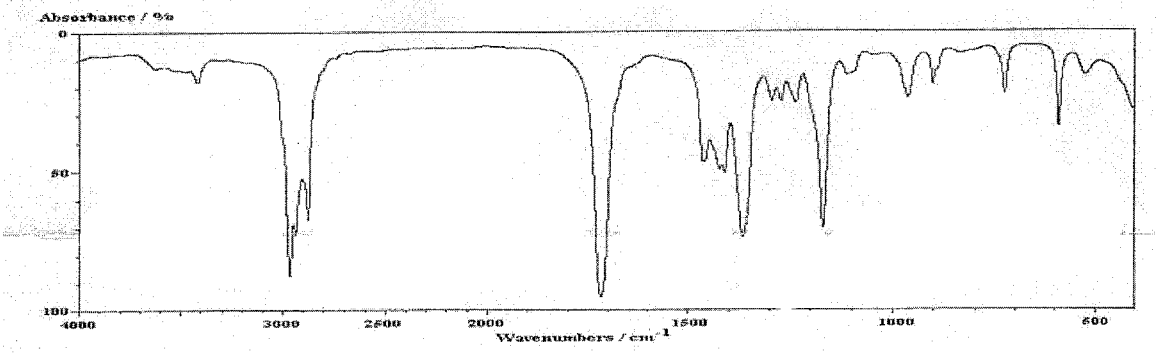
5) Discuss the theory of electronic spectroscopy. Explain the Woodward-Fieser Rules for Dienes for calculating absorption maxima. Calculate the λ_{max} for 1,3-cyclohexadiene.

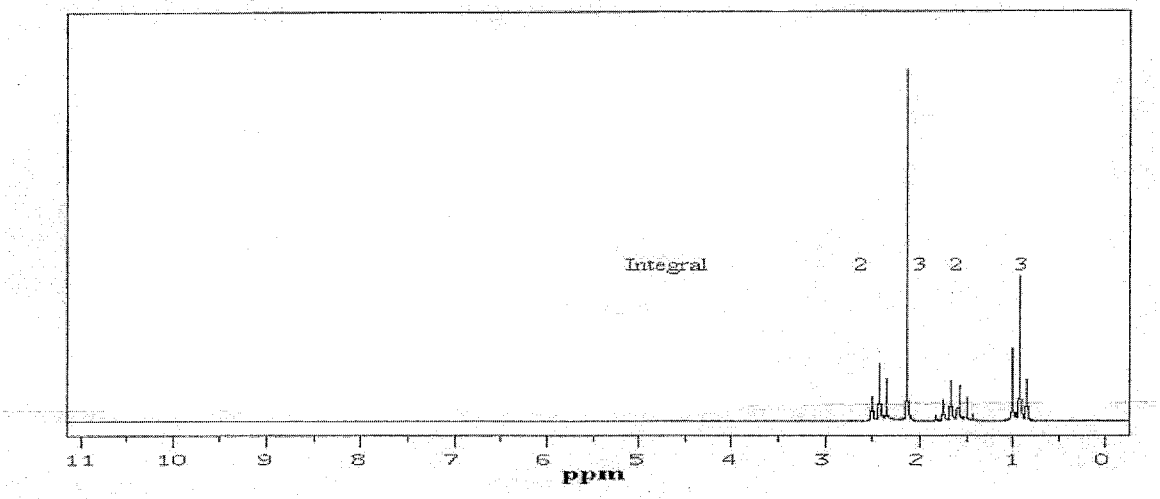
6) What is HPLC ? Name the different components of HPLC instrument and explain their role. Discuss detectors used in HPLC.

P.T.O.

Spectra


Relative Intensity / %
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
m / z


Absorbance / %
0
50
100
4000
3000
2500
2000
1500
1000
500
Wavenumbers / cm-1


Integral
2
3
2
3
11
10
9
8
7
6
5
4
3
2
1
0
ppm

SLR-J – 7

Seat No.	

M.Pharm. (Quality Assurance) (Semester – I) Examination, 2015
(CGPA/CBCS)
QUALITY ASSURANCE TECHNIQUES – I

Day and Date : Wednesday, 9-12-2015 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) Good Warehousing Practices
   ii) Batch release documents and finished product release protocol.
2) Give an account for quality system requirements for ISO 9001:2000 certification.
3) What is Investigational New Drug ? Explain the parts of the same giving suitable examples.
4) Describe Test for sterility as a tool for evaluation of effectiveness of antimicrobial preservatives.

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

5) i) Write a note on documentation related to product complaints and product recall.
   ii) Explain the concept of Quality assurance in pharma industry. Describe its organization and functions.
6) i) Write a note on applications of computers in Quality Assurance department for data handling.
   ii) Explain the role of a Quality Control Unit in pharma industry with reference to instruments, reagents and sampling plan.

SLR-J – 8

Seat No.	

M.Pharm. (Semester – I) Examination, 2015
(CGPA/CBCS)
QUALITY ASSURANCE (Elective)

Day and Date : Friday, 11-12-2015 Max. 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) Good warehousing practices
   ii) Applications of computers in Quality Assurance.
2) Describe the GMP aspects of Laboratory controls in pharma manufacturing.
3) Describe the Master Production and Control Documents in pharma manufacturing.
4) Write a note on management of returned products and product salvaging.

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

5) i) Describe the strategies of policy making and implementation of Total Quality Management in pharma industry.
   ii) Describe batch production records.
6) Giving relevant examples explain the steps of production planning. Briefly describe the tools used for production scheduling.

———————

SLR-J – 9

Seat No.	

M. Pharmacy (Sem. – I) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Analysis (CGPA/CBCS)

Day and Date : Monday, 7-12-2015 Total Marks : 70

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

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

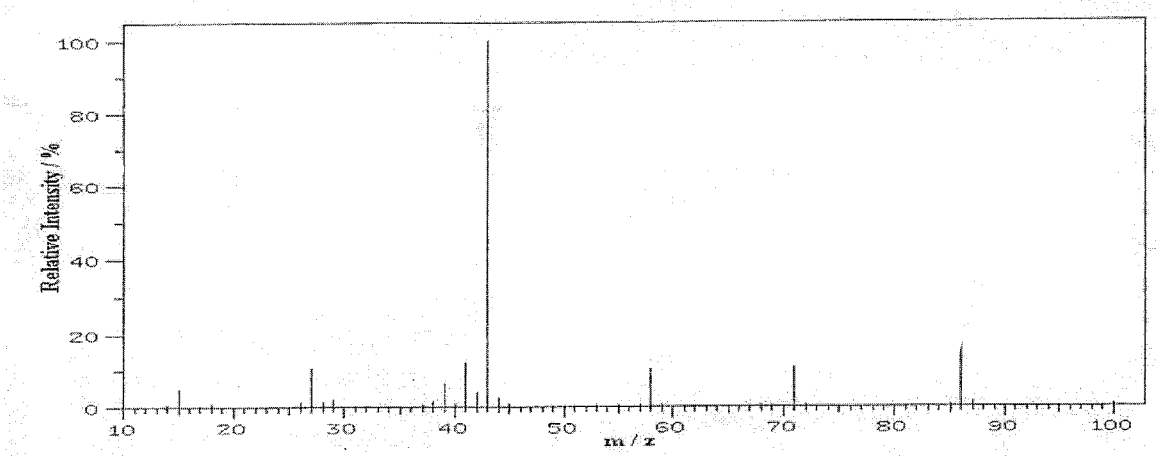
1) Identify the molecule whose spectra are provided.
2) What is thermal analysis ? Give the applications of differential thermal analysis.
3) Name different immunochemical techniques. Explain radioimmuno assay technique and give its applications.
4) Write notes on X-ray diffraction and reference standard.

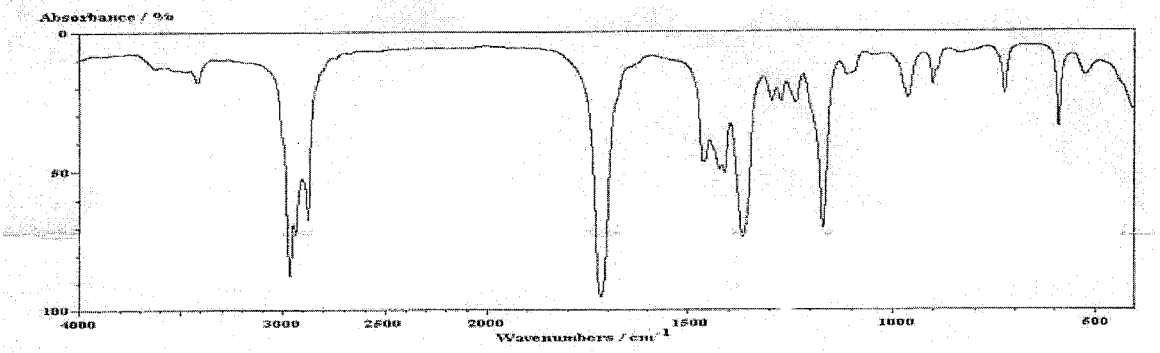
B. Answer **all** : **(2×20=40)**

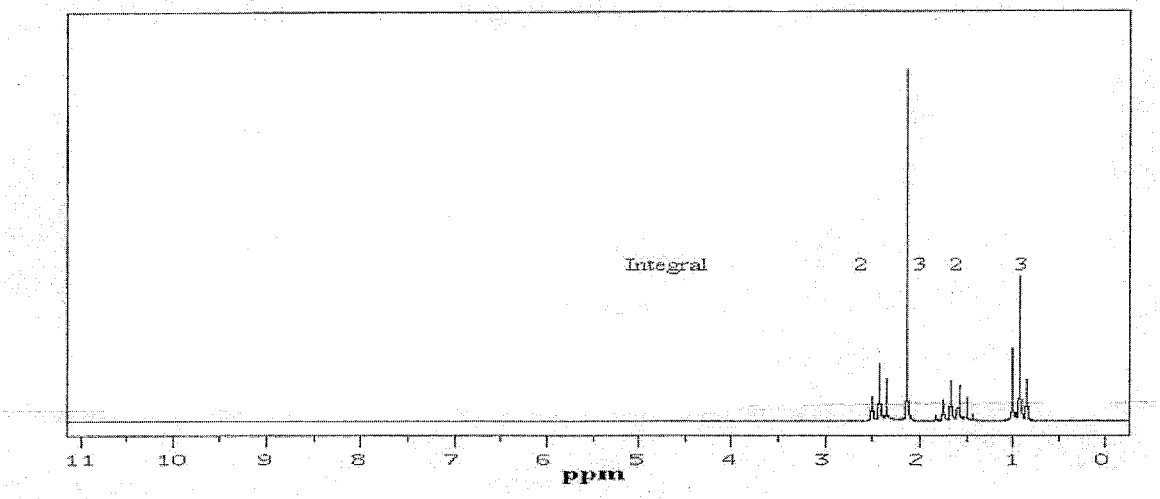
5) Discuss the theory of electronic spectroscopy. Explain the Woodward-Fieser Rules for Dienes for calculating absorption maxima. Calculate the λ_{max} for 1,3-cyclohexadiene.
6) What is HPLC ? Name the different components of HPLC instrument and explain their role. Discuss detectors used in HPLC.

P.T.O.

Spectra


Relative Intensity / %
100
80
60
40
20
0
10
20
30
40
50
60
70
80
90
100
m / z


Absorbance / %
0
50
100
4000
3000
2500
2000
1500
1000
500
Wavenumbers / cm-1


Integral
2
3
2
3
11
10
9
8
7
6
5
4
3
2
1
0
ppm

SLR-J – 10

Seat No.	

M.Pharmacy (Semester – I) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – I (CGPA/CBCS)

Day and Date : Wednesday, 9-12-2015 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 Histamine receptors.
2) In detail explain the role of aromatase in cancer progression and importance of aromatase inhibitors.
3) Define enzymes with examples. What is enzyme inhibition and explain in detail ?
4) Writer short notes on **any two** :
   a) Antibody Directed Enzyme Prodrug Therapy
   b) Role of HIV Protease
   c) Signal transduction.

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-J – 11

Seat No.	

M.Pharmacy (Semester – I) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Drug Design (CGPA/CBCS) (Elective)

Day and Date : Friday, 11-12-2015 Total Marks : 70

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

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

1) Explain in detail how next generation β-lactam antibiotics developed to counter the effects of β-lactamase and gastric acid.

2) How medicinal chemists will be assisted by rings and substituents in design of drugs for better interactions with the targets ?

3) What are angiotensin-II receptor and explain their antagonists along with their application in the treatment of hypertension related diseases ?

4) Write short notes on **any two** :
   a) Quantum mechanics
   b) H2 receptor antagonists
   c) Isosters in drug discovery.

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

5) A) What are the molecular mechanics based components of modern force fields ? **12**

   B) Elaborate in detail the method of receptor binding site. **8**

6) A) Systematically elaborate the design and development of angiotensin converting enzyme inhibitors. **12**

   B) Write a note on calcium channel blockers and their role usefulness in cardiovascular diseases. **8**

———————

SLR-J – 12

Seat No.	

M.Pharm. (Semester – II) (CGPA) Examination, 2015
Pharmaceutics
ADVANCED PHARMACEUTICS – II

Day and Date : Tuesday, 8-12-2015 Max. Marks : 70

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

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

1) Explain in detail pH and ion exchange controlled oral drug delivery system.

2) Describe in detail ocular inserts. Write a note on mucoadhesive polymers.

3) Explain floating pulsatile drug delivery system and add a note on disorders showing chronological varations.

4) Write a note on :
   A) Evalution of microspheres
   B) Implants and implantable devices.

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

1) What are different factors affecting colonic absorption ? Explain coating with pH dependent polymer system.

2) Describe structural complexity of protein and peptide drugs. Add a note on regulatory perspective for such drugs.

SLR-J – 13

Seat No.	

M.Pharm. (Pharmaceutics) (Semester – II) Examination, 2015
ADVANCED PHARMACEUTICS – III (CGPA)

Day and Date : Thursday, 10-12-2015 Max. Marks : 70

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

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

1) Justify - "Protein bound drug is Pharmacokinetically as well as Pharmacodynamically inert". Describe the effect of protein drug binding on Volume of distribution.

2) What is the need of individualization in drug therapy ? Write a note on does adjustments with renal failure.

3) Describe the physicochemical factors affecting renal excretion.

4) Discuss the study design protocol for BA-BE studies.

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

1) Write a note on passive diffusion. Describe the factors affecting passive diffusion with help of Fick's first law of diffusion.

2) What are the advantages of Pharmacokinetic Modeling ? Describe one compartment open model – IV infusion.

SLR-J – 14

Seat No.	

M.Pharmacy (Semester – II) Examination, 2015
Pharmaceutics (CGPA)
STERILE PRODUCT FORMULATION AND TECHNOLOGY

Day and Date : Saturday, 12-12-2015 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What are liposomes and niosomes ? Describe in detail components of liposomes.
2) Explain in detail about selection of packaging components in parenterals.
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 GMP guidelines for aseptic processing of parenteral formulations.
6) Discuss in detail preparation of various ophthalmic products.

SLR-J – 15

Seat No.	

M.Pharm. (Semester – II) (CGPA) Examination, 2015
PHARMACEUTICS
Cosmeticology

Day and Date : Saturday, 12-12-2015 Max. Marks : 70

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

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

1) Discuss regulatory requirement for sale and manufacture of cosmetics.

2) Explain evaluation of preservatives in cosmetics.

3) Describe about herbal cosmetics with examples.

4) Elaborate design and development of cosmetic packaging along with its evaluation.

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

1) Explain liposomes, multiple and microemulsions as advances in cosmetics.

2) Give formulation and evaluation of moisturizers, sunscreen and antiperspirants.

SLR-J – 16

Seat No.	

Master of Pharmacy (Quality Assurance) (CGPA) Semester – II Examination, 2015

QUALITY ASSURANCE TECHNIQUES – II

Day and Date : Tuesday, 8-12-2015 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

***Instruction** : Figures to the **right** indicate **full** marks.*

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

1) Give the Constitution and explain the objectives of Consumer Protection Councils.

2) How is computer system validation done ? What are benefits of the same ?

3) Write a note on water system validation.

4) Explain the differences and similarities between the terms calibration, qualification and validation.

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

5. i) Explain important laws and regulatory bodies governing manufacturing of drug products in India.

   ii) Write a note on vendor validation.

6. Giving suitable example explain the parameters used in analytical method validation.

SLR-J – 17

Seat No.	

M.Pharmacy (Semester – II) Examination, 2015
(CGPA)
QUALITY ASSURANCE
Quality Assurance Techniques – III

Day and Date : Thursday, 10-12-2015 Total Marks : 70

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

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

1) What is the importance of dissolution test ? Explain its operational qualifications.
2) What is biostatistics ? What is the regression analysis ? Explain parametric tests.
3) Name and define typical validation characteristics which should be considered for analytical method validation (ICH).
4) What is the goal of CPCSEA guidelines ? Give the guidelines for 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) Why HPLC performance is verified ? Discuss the performance verification of pump, injector and UV-visible detector modules in HPLC.

SLR-J – 18

Seat No.	

Master of Pharmacy (Quality Assurance) (Semester – II) (CGPA) Examination, 2015
QUALITY CONTROL

Day and Date : Saturday, 12-12-2015 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

***Instruction** : Figures to the **right** indicate **full** marks.*

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

1) Describe the role of QC in pharmaceutical product development.
2) Explain the principles of data management in the context of clinical research.
3) Explain the difference between QA and QC activities.
4) Discuss about the need and process of development of drug information leaflet.

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

5) Discuss steps involved in conduct and analysis of bioequivalence studies.
6) i) Explain the role of in-process quality control tests in pharmaceutical process development.
   ii) Describe process analytical technology as control strategy of quality by design.

SLR-J – 19

Seat No.	

M.Pharmacy (Semester – II) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – II (CGPA)

Day and Date : Tuesday, 8-12-2015 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What is high throughput screening ? List out the advantages and disadvantages of HTS. Explain the technique involved in HTS with examples.

2) Explain in detail, how prostaglandins are synthesized using microbial bioconversion.

3) Discuss the drugs used in the treatment of Parkinsonism.

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

   a) Targets of Alzheimer's disease drug discovery

   b) Enzyme immobilization

   c) Techniques of separation of racemic mixtures.

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

5) With neat figure explain the life cycle of HIV, classify anti-HIV drugs and explain HIV protease inhibitors. Add you understanding on resistance to HIV reverse transcriptase inhibitors.

6) Write in detail, the applications of chiral techniques involved in the synthesis of Naproxane, Propranolol and Atenolol.

SLR-J – 20

Seat No.	

M.Pharmacy (Semester – II) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – III (CGPA)

Day and Date : Thursday, 10-12-2015 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Describe with suitable examples the role of amine and amide groups in establishing binding with receptors.

2) Explain in detail, different ways of peptide synthesis with examples.

3) a) Role of relaxin

   b) 3D QSAR modeling.

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) What are force fields and systematically list out the components of molecular mechanics force fields ? With detail mathematical expressions describe the parameterization of force fields with examples.

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

SLR-J – 21

Seat No.	

Master of Pharmacy (Semester – II) (CGPA) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Quality Control

Day and Date : Saturday, 12-12-2015 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

***Instruction** : Figures to the **right** indicate **full** marks.*

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

1) Describe the role of QC in pharmaceutical product development.
2) Explain the principles of data management in the context of clinical research.
3) Explain the difference between QA and QC activities.
4) Discuss about the need and process of development of drug information leaflet.

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

5) Discuss steps involved in conduct and analysis of bioequivalence studies.
6) i) Explain the role of in-process quality control tests in pharmaceutical process development.
   ii) Describe process analytical technology as control strategy of quality by design.

SLR-J – 22

Seat No.	

M. Pharm. (Semester – II) Examination, 2015
PHARMACEUTICAL CHEMISTRY
Therapeutic Drug Monitoring (CGPA)

Day and Date : Saturday, 12-12-2015 Max. Marks : 70

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

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

1) Describe the principle and procedure of HPLC.

2) Why is TDM necessary ? Discuss criteria for valid TDM.

3) Explain importance of TDM in adverse drug reaction.

4) TDM of antitubercular drugs.

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

5) Write in details about TDM of Phenytoin. Add a note on dosing guidelines for Phenytoin.

6) Discuss the variation caused in estimation of clinical laboratory tests.
