SLR-U – 1

Seat No.	

M. Pharmacy (Sem. – I) Examination, 2014
PHARMACEUTICS
Advanced Pharmaceutical Analysis (New)

Day and Date : Friday, 12-12-2014 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 analytical technique ? Give its types. Explain the theory involved in thermogravimetry analysis.
3) Name different immunochemical techniques. Explain one technique and give its applications.
4) Write notes on X-ray diffraction and process validation.

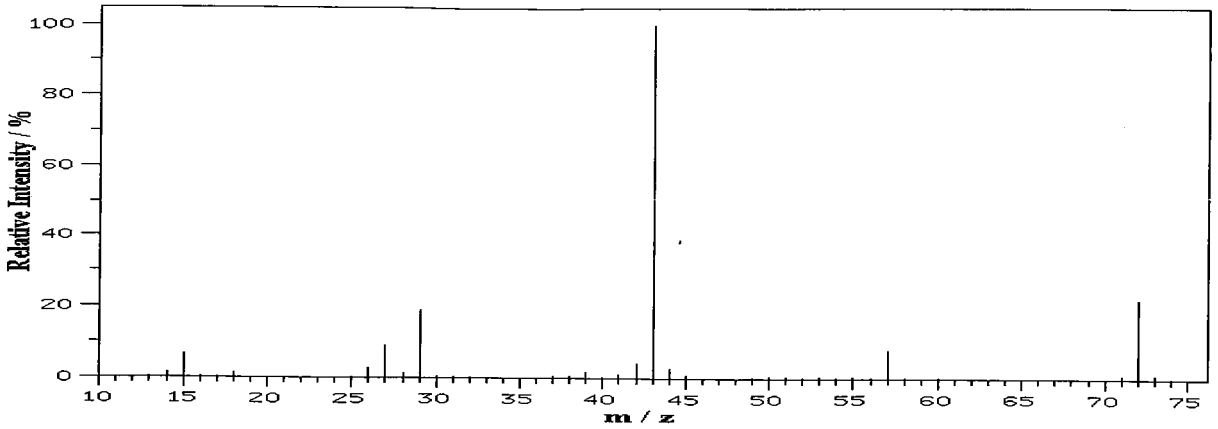
B. Answer **all** : **(2×20=40)**

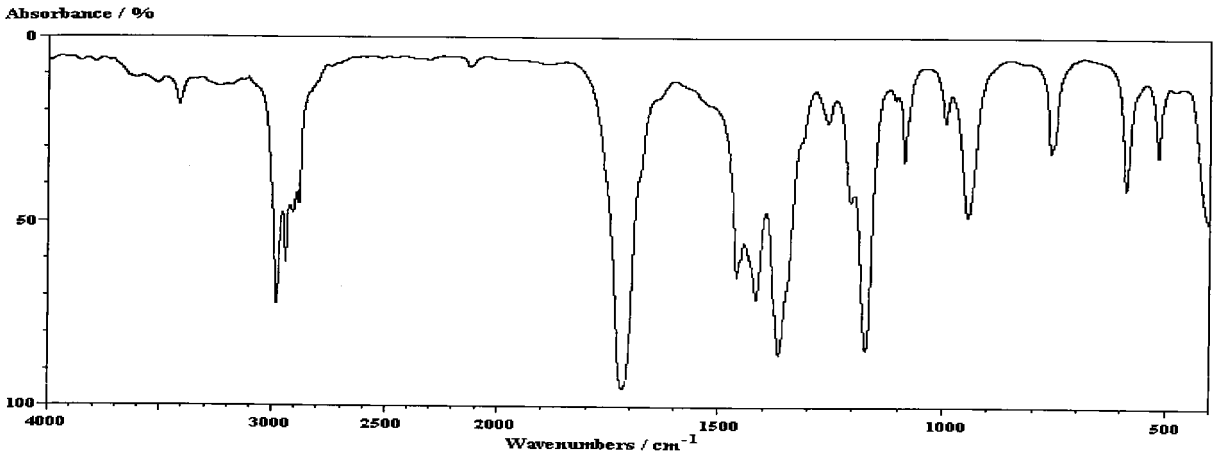
5) Derive simultaneous equation for sample containing two UV absorbing drugs, each of which absorb at the λ_{max} of the other. Discuss the chemical derivatisation in indirect UV-V is spectrophotometric assays.
6) Classify liquid chromatography by separation mechanism. What is the scope of HPLC ? Name the different components of GC instrument and explain their role.

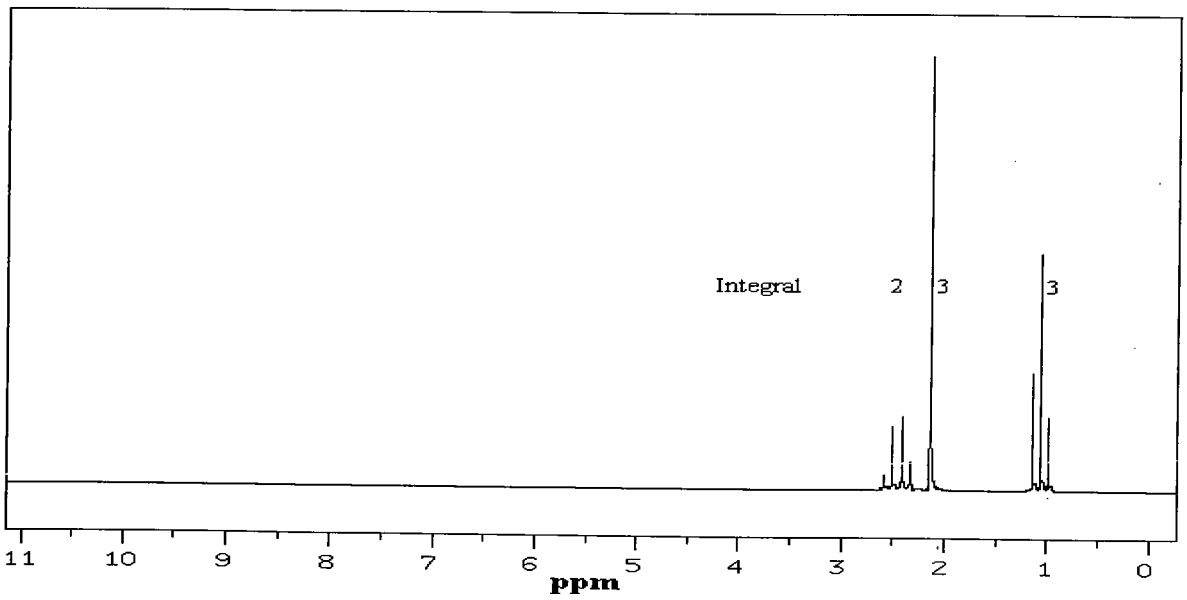
P.T.O.

SLR-U – 1

Spectra







SLR-U – 10

Seat No.	

M.Pharmacy (Semester – I) Examination, 2014
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – I (New)

Day and Date : Monday, 15-12-2014 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Describe the synthon approach towards the synthesis of Ibuprofen.

2) Describe in detail GABA receptors.

3) Define and classify receptors. What are the forces that help in effective binding of ligands with receptors ?

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

   a) Functional group interconversion

   b) Role of HIV reverse transcriptase.

   c) Antibody directed enzyme prodrug therapy.

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

5) What do you understand by prodrug approach ? How prodrug approach offer benefit in the development of drug to prolong the duration of action, site specific and reduce the side effects.

6) Describe the detail structure and role of G-protein couple receptors. Write a note on drugs acting on GABA and adrenergic receptors.

SLR-U – 11

Seat No.	

M.Pharmacy (Semester – I) Examination, 2014
PHARMACEUTICAL CHEMISTRY (New)
Drug Design (Elective)

Day and Date : Wednesday, 17-12-2014 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Explain rational method of drug discovery with an emphasis on QSAR.
2) What are angiotensin – II receptor and explain their antagonists along with their application in the treatment of hypertension related diseases.
3) Describe the design of proton pump inhibitors. Explain the applications of H_2-receptor antagonist in Gastroesophageal reflux disease.
4) Write short notes on **any two** :
   a) Antipsychotic agents
   b) H_2 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) Explain in detail the life cycle of HIV. **4**
   B) Classify anti-HIV drugs with examples and explain mechanism of action of any one drug at molecular level. **6**
   C) Explain the design and development of HIV protease inhibitors. **10**

SLR-U – 12

Seat No.	

M.Pharm. (Pharmaceutics) (Semester – II) Examination, 2014
ADVANCED PHARMACEUTICS – II

Day and Date : Saturday, 13-12-2014 Max. Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

Instructions *: 1) Question number* ***one*** *and* ***five*** *are* ***compulsory****.*
2) Answer ***any two*** *questions from the remaining* ***three*** *in* ***each*** *Section.*
3) Figures to the ***right*** *indications* ***full*** *marks.*

SECTION – I

1. Explain in detail approaches and technologies for the development of transdermal drug delivery. **10**

2. Describe the principle involved in modified release oral dosage form. Explain osmotic pumps and pH controlled oral drug delivery system. **20**

3. Explain the fabrication, biocompatibility and performance evaluation of implants. **20**

4. Write on floating pulsatile drug delivery system and multiple unit particulate system. **20**

SECTION – II

5. Explain methods of preparation and characterization of niosomes. **10**

6. Describe structural complexity of protein and peptide drugs and routs of peptide delivery. **20**

7. Discuss in detail about development of ocular drug delivery system. **20**

8. Write short note on **any two** : **(2×10)**
   a) Pulmonary, rectal and vaginal mucoadhesive drug delivery.
   b) Ion exchange and gel diffusion controlled oral dosage forms.
   c) Delivery systems based on the metabolic activity of colonic bacteria.

SLR-U – 13

Seat No.	

M.Pharm. (Semester – II) Examination, 2014
PHARMACEUTICS
Advanced Pharmaceutics – III

Day and Date : Tuesday, 16-12-2014 Max. Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

***Note** : 1) Question No. **1** and **5 compulsory**.*
*2) Answer **any two** questions from the remaining questions from Section **I** and **two** questions from the remaining from Section – **II**.*

SECTION – I

1. What is biotransformation ? Give a brief account on Phase – I reactions. **10**

2. Give an account on physiological barriers to drug distribution. Add a note on perfusion and permeability limitation with suitable example with mathematical derivation. **20**

3. Define the term excretion. Discuss the principle process that determines the urinary excretion of drug. **20**

4. Write a brief note on : **20**
   a) Multi compartment modeling for estimation of pharmacokinetic parameters.
   b) Mathematical models for dose response relationships.

SECTION – II

5. Write a brief note on In-Vivo-In-Vitro Correlation. **10**

6. What do you mean by bioequivalence studies ? Explain the terms Pharmaceutical, biological and therapeutic equivalence. Add a brief note on need of bioequivalence studies for ANDA. **20**

7. What is dose regimen ? Explain in brief individualization of dosage regimen. **20**

8. Explain the different factors affecting the drug absorption. Add a note on pharmaceutical dissolution testing. **20**

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SLR-U – 14

Seat No.	

M. Pharm. (Semester – II) Examination, 2014
PHARMACEUTICS
Sterile Product Formulation and Technology

Day and Date : Thursday, 18-12-2014 Max. Marks : 100

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

***Instructions** : 1) Q. **1** and Q. **5** are **compulsory**.*
*2) Solve **any two** questions from the **remaining three** in **each** Section.*
*3) Figures to the **right** indicate **full** marks.*

SECTION – I

1. Giving relevant examples discuss the aqueous solvents used in parenterals. **10**

2. i) Explain the role of chemical and microbiological stabilizers used in ophthalmics. **20**

   ii) Write a note on radiation sterilization.

3. Explain the objectives for motivation of employees. Describe the methods of training given to personnel. **20**

4. Give design and validation of HEPA filters. **20**

SECTION – II

5. Describe the formulation of parenteral suspensions. **10**

6. Giving relevant examples describe the quality assurance of parenterals. **20**

7. Give an account for quality control tests for glass containers for parenterals. **20**

8. Explain in detail the method of preparation of parenterals by BFS. Describe its modifications. **20**

SLR-U – 15

Seat No.	

M.Pharm. (Semester – II) Examination, 2014
QUALITY ASSURANCE
Quality Assurance Techniques – II

Day and Date : Saturday, 13-12-2014 Total Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

Instructions *: 1) Q.**1** and Q.**5** are **compulsory**.*
*2) Solve **any two** questions from the rest from **each Section**.*
*3) Figures to the **right** indicate **full** marks.*

SECTION – I

1. Give the objectives and the special provisions made under Factory Act. **10**

2. Define equipment validation. Discuss preventive maintenance. Give an account on calibration of equipment. **20**

3. Discuss the differences and similarities between process qualifications and process validation. Write a note on protocol, methodology and interpretation of data for process validation of compression. **20**

4. Write a note on Narcotic Drugs and Psychotropic Substances Act with offence and penalties there under. **20**

SECTION – II

5. How the patent could be filed ? What documents are required to file a patent ? What rights are given by the Act ? **10**

6. Solve the following : **20**
   a) Discuss the significance of recent amendments in "Drug and Cosmetics Act, 1945" with special emphasis on revised schedule M.
   b) Discuss the Consumer Protection Act with respect to its relevance to consumer of pharmaceutical products.

7. Explain the conditions for grant of licenses under manufacturing of drugs (other than homoeopathic) for sale. **20**

8. Write a note on vendor audits, validation of software. **20**

SLR-U – 16

Seat No.	

M. Pharmacy (Semester – II) Examination, 2014
QUALITY ASSURANCE
Quality Assurance Technique – III

Day and Date : Tuesday, 16-12-2014 Total Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

Instructions *: 1) Question No.* ***1*** *and* ***5*** *are* ***compulsory****.*
2) Answer ***any two*** *questions from the remaining* ***three*** *questions of* ***each*** *Section.*
3) Figures to the ***right*** *indicate* ***full*** *marks.*

SECTION – I

1. What is the importance of dissolution test ? What is ANOVA ? What is correlation ? **10**

2. Why HPLC performance is verified ? Discuss the performance verification of pump, injector and UV-visible detector modules in HPLC. **20**

3. Give the types of analytical procedures to be validated. Name and define typical validation characteristic which should be considered for validation (ICH). Name category of assays for which validation should be required (USP). **20**

4. What are cGMPs ? Define drug product, strength, and batch. Give guidelines for sampling and testing of in-process material and drug products in establishing appropriate process control. Discuss process validation. **20**

SECTION – II

5. What is validation of analytical method ? Explain the types of correlation. **10**

6. What is the goal of CPCSEA guidelines ? Give the guidelines for functional area, anaesthesia and euthanasia as per CPCSEA. **20**

7. What is biostatics ? Explain the graphical presentation of data with example. What is the regression analysis ? Explain parametric tests. **20**

8. Give guidelines for building and facilities as per cGMP (subpart-C). **20**

SLR-U – 17

Seat No.	

M.Pharm. (Quality Assurance) (Semester – II) Examination, 2014
QUALITY CONTROL

Day and Date : Thursday, 18-12-2014 Total Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

Instructions *: 1) Q.* ***1*** *and Q.* ***5*** *are* ***compulsory****.*
2) Solve ***any two*** *questions from the remaining* ***three*** *in* ***each*** *Section.*
3) ***Figures*** *to the right indicate* ***full*** *marks.*

SECTION – I

1. Discuss the importance of monitoring of clinical trials. **10**

2. a) Discuss the role of a QA unit in a drug testing laboratory. **20**
   b) Write a note on evaluation of label paper and paper boards.

3. Giving suitable examples elaborate on the statistical methods and their applications in drug product development. **20**

4. Explain the concept of pharmaceutical and therapeutic equivalence in product development. Give suitable examples. **20**

SECTION – II

5. Explain the difference between QA and QC activities. **10**

6. Justify Process Analytical Technology (PAT) as a framework for innovative pharmaceutical Manufacturing. **20**

7. What are the ideal characteristics of an ideal packages ? Describe the factors to be considered while developing the packaging for a particular formulation. **20**

8. Explain in detail the protocol for accelerated stability studies for different types of dosage forms as per ICH guidelines to determine shelf life of formulations. **20**

SLR-U – 18

Seat No.	

M.Pharm. (Semester – II) Examination, 2014
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – II

Day and Date : Saturday, 13-12-2014 Total Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

Instructions *: 1) Question number* ***1*** *and* ***5*** *are* ***compulsory****.*
2) Answer ***any two*** *questions from the remaining* ***three*** *in* ***each*** *Section.*
3) Figures to the ***right*** *indicate* ***full*** *marks.*

SECTION – I

1. What do you mean by chirality ? Give the chiral synthesis of propranolol. **10**

2. What are the different approaches in combinatorial synthesis ? Explain. **20**

3. Write short notes on : **20**
   a) Bio conversions of prostaglandin
   b) Asymmetric synthesis of Timolol and Vitamin C.

4. What are the causes of Alzheimer's disease ? Explain the types of drugs used for treatment of Alzheimer's disease with one example each. **20**

SECTION – II

5. What is high throughput screening ? How does it play a role in drug design ? **10**

6. Explain regiospecificity, reaction specificity and stereospecificity in microbial conversion with suitable example. **20**

7. Describe the life cycle of HIV in detail. **20**

8. Write short notes on : **20**
   a) Applications of combinatorial chemistry.
   b) Current approaches of HIV treatment.

SLR-U – 19

Seat No.	

M. Pharmacy (Semester – II) Examination, 2014
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Chemistry – III

Day and Date : Tuesday, 16-12-2014 Max. Marks : 100

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

***Instructions**: 1) Answer to the **two** sections must be written in **separate** answer books.*

*2) Question numbers **one** and **five** are **compulsory**.*

*3) Answer **any two** questions from the **remaining three** questions in **each** Section.*

*4) Figures to the **right** indicate **full** marks.*

SECTION – I

1. Compare structure based drug design and ligand based drug design. **10**

2. Explain with examples how LogP of drugs calculated using π values. List of different models to establish QSAR and explain any one in detail. **20**

3. Why energy minimization is required in computational studies ? Explain any two energy minimization methods in detail. **20**

4. Write short notes on **any two** : **20**

   a) Applications of bioinformatics in drug discovery

   b) Proteomics

   c) Genomics.

P.T.O.

SECTION – II

5. Describe the role of amine and amide groups in establishing structure activity relations with suitable examples. **10**

6. What are peptides and proteins and with examples describe different way to synthesize peptides ? **20**

7. What are the different stages of drug discovery processes and explain in detail lead identification process ? **20**

8. Write short notes on **any two** : **20**

   a) Different ways to study conformation analysis

   b) Topliss decisions tree

   c) Ligand based drug design.

SLR- U – 2

Seat No.	

M.Pharmacy (First Semester) (New) Examination, 2014
PHARMACEUTICS
Advanced Pharmaceutics – I

Day and Date : Monday, 15-12-2014 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Discuss the applications of polymers in pharmaceutical formulations.

2) Define the term solid dispersion. How are they prepared ?

3) Explain the factors responsible for destabilization of pharmaceutical products.

4) Describe the characterization of powders by size and shape. Add a note on handling of solids.

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

5) Define the terms Surfactant and CMC. Enumerate the factors affecting CMC. Explain the mechanism of reduction in surface tension by surfactant.

6) Explain the mechanisms of drug release. With neat labelled diagrams explain various dissolution testing apparatus.

SLR-U – 20

Seat No.	

M.Pharm. (Pharmaceutical Chemistry) (Semester – II) Examination, 2014
QUALITY CONTROL

Day and Date : Thursday, 18-12-2014 Total Marks : 100
Time : 10.30 a.m. to 1.30 p.m.

***Instructions** : 1) Q. **1** and Q. **5** are **compulsory**.*
*2) Solve **any two** questions from the remaining **three** in **each** Section.*
*3) **Figures** to the right indicate **full** marks.*

SECTION – I

1. Discuss the importance of monitoring of clinical trials. **10**

2. a) Discuss the role of a QA unit in a drug testing laboratory. **20**
   b) Write a note on evaluation of label paper and paper boards.

3. Giving suitable examples elaborate on the statistical methods and their applications in drug product development. **20**

4. Explain the concept of pharmaceutical and therapeutic equivalence in product development. Give suitable examples. **20**

SECTION – II

5. Explain the difference between QA and QC activities. **10**

6. Justify Process Analytical Technology (PAT) as a framework for innovative pharmaceutical Manufacturing. **20**

7. What are the ideal characteristics of an ideal packages ? Describe the factors to be considered while developing the packaging for a particular formulation. **20**

8. Explain in detail the protocol for accelerated stability studies for different types of dosage forms as per ICH guidelines to determine shelf life of formulations. **20**

SLR-U – 3

Seat No.	

M.Pharm. (Semester – I) (New) Examination, 2014
PHARMACEUTICS
Biopharmaceutics and Pharmacokinetics (Elective)

Day and Date : Wednesday, 17-12-2014 Total Marks : 70

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

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

1) Explain the Michaelis Menten equation and method to determine K_m and V_{max}. **10**

2) What do you mean by Renal clearance ? Write in brief factor affecting renal clearance along with derivation for calculation of renal clearance. **10**

3) Describe in detail *In-Vitro* drug dissolution testing models. **10**

4) Define distribution. Write a note on volume of distribution. **10**

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

5) What are the assumptions of One-Compartment open model ? Explain in detailed one compartment open model for intravenous bolus administration and intravenous infusion. **20**

6) What are the objectives of bioavailability studies ? Describe the method for measurement of bioavailability. **20**

SLR-U – 4

Seat No.	

M. Pharmacy (Semester – I) Examination, 2014
PHARMACEUTICS (Elective)
Advances in Drug Delivery (New)

Day and Date : Wednesday, 17-12-2014 Max. Marks : 70

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

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

1) Classify the polymers. Write on applications of biodegradable polymers used in controlled Drug deliver system.
2) Explain the technologies used to design buccal tablet and give its advantages.
3) Write note on Intrauterine Drug Delivery System (IUD).
4) Discuss the various methods for enhancement of dissolution characteristics evaluation thereof.

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

5) Discuss technologies for developing transdermal drug delivery system and evaluation thereof.
6) Describe in details regulatory considerations in controlled drug release formulation.

SLR-U – 5

Seat No.	

M.Pharm. (Semester – I) (New) Examination, 2014
PHARMACEUTICS
Product Development (Elective)

Day and Date : Wednesday, 17-12-2014 Max. Marks : 70

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

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

1) Define – Experiment, Independent variables, dependent variables, extraneous variables and control. Describe a 3^2 factorial design with suitable example.

2) Classify the packaging materials for pharmaceutical dosage forms. Write a note on glass as packaging material.

3) What is validation ? Describe various types of validation.

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

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

5) Define Preformulation. Describe the process of preformulation in detail.

6) Discuss various techniques of granulation and evaluation tests for granules.

SLR-U – 6

Seat No.	

M. Pharmacy (Sem. – I) Examination, 2014
QUALITY ASSURANCE
Advanced Pharmaceutical Analysis (New)

Day and Date : Friday, 12-12-2014 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 analytical technique ? Give its types. Explain the theory involved in thermogravimetry analysis.
3) Name different immunochemical techniques. Explain one technique and give its applications.
4) Write notes on X-ray diffraction and process validation.

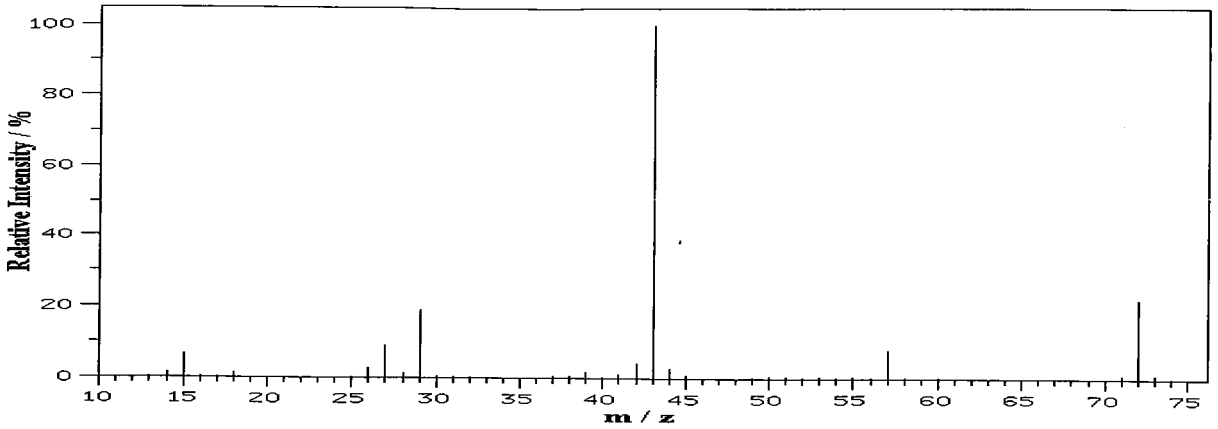
B. Answer **all** : **(2×20=40)**

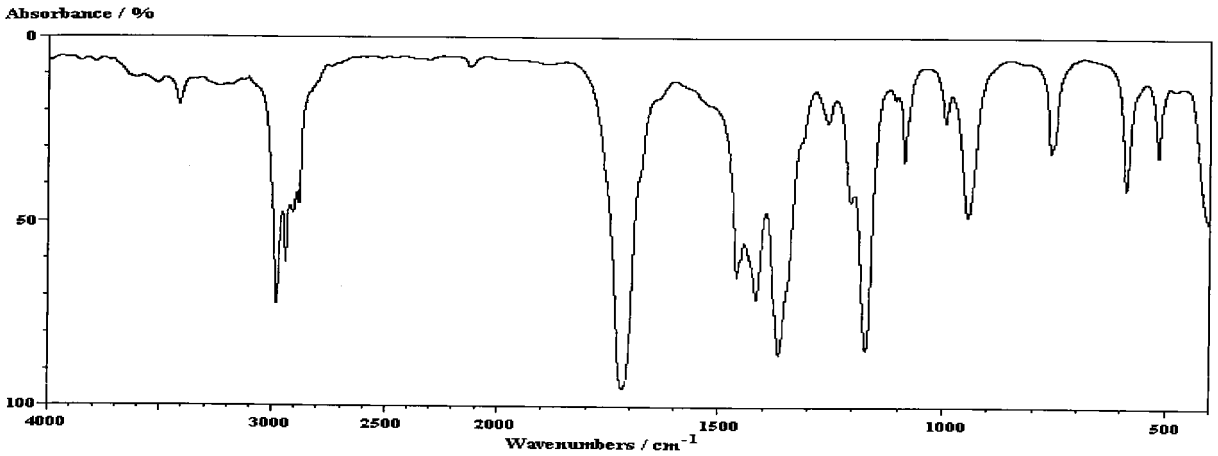
5) Derive simultaneous equation for sample containing two UV absorbing drugs, each of which absorb at the λ_{max} of the other. Discuss the chemical derivatisation in indirect UV-V is spectrophotometric assays.
6) Classify liquid chromatography by separation mechanism. What is the scope of HPLC ? Name the different components of GC instrument and explain their role.

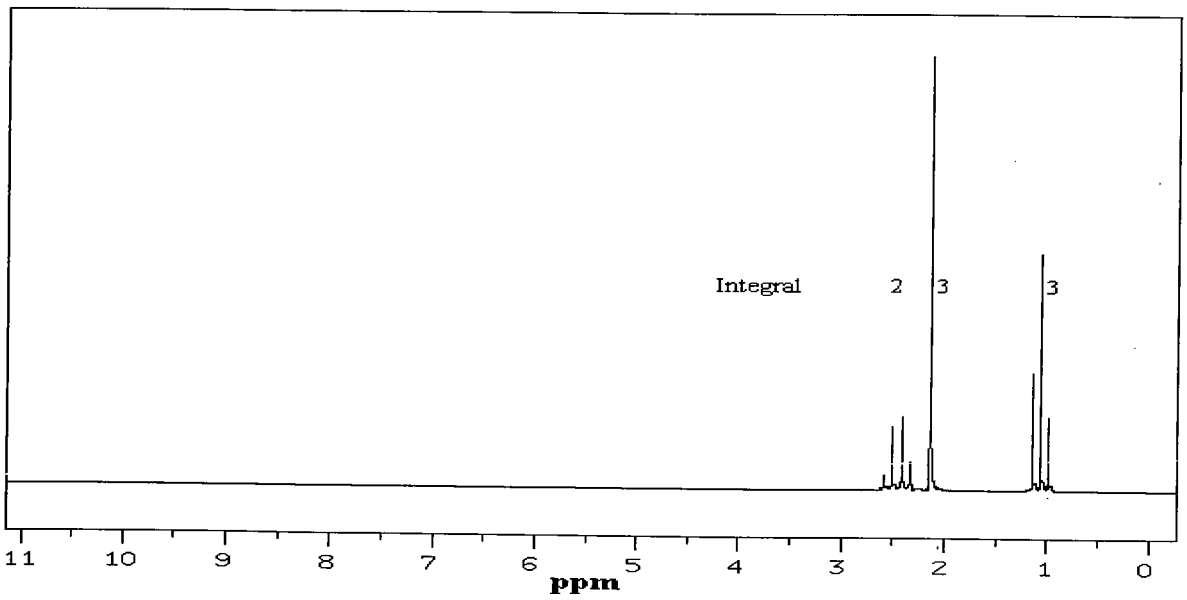
P.T.O.

SLR-U – 6

Spectra







SLR-U – 7

Seat No.	

M.Pharm. (Quality Assurance) (Semester – I) (New) Examination, 2014
QUALITY ASSURANCE TECHNIQUES – I

Day and Date : Monday, 15-12-2014 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) Write notes on the following :
   i) Documentation related to maintenance and environmental control of pharmaceutical facility.
   ii) Importance of standard operating procedures.
2) Give the requirements for premises, location and building requirements for pharma manufacturing unit as per GMP.
3) Describe the importance of monitoring during clinical trials.
4) Describe the documentation used in the selection of vendors, receipt, storage and release of raw materials for production.

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

5) i) Write a note on Good Laboratory Practices.
   ii) Explain the methodology of generation of stability data according to ICH guidelines.
6) What is meant by ISO certification ? Explain the different parameters of ISO 9002 and describe these parameters giving suitable examples.

SLR-U – 8

Seat No.	

M.Pharm. (Quality Assurance) (Semester – I) (New) Examination, 2014
QUALITY ASSURANCE (Elective)

Day and Date : Wednesday, 17-12-2014 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) Write notes on the following :
   i) Complaint handling.
   ii) Batch release procedure
2) Discuss the handling of returned goods and recovered materials.
3) Explain the GMP requirements of packaging and labeling materials.
4) Describe the cGMP guidelines for product recall.

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

5) i) Explain the cGMP guidelines to avoid product mix-up and cross contamination.
   ii) Describe the pharmaceutical evaluation of antibiotics.
6) Giving suitable examples describe process validation.

SLR-U – 9

Seat No.	

M. Pharmacy (Sem. – I) Examination, 2014
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Analysis (New)

Day and Date : Friday, 12-12-2014 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 analytical technique ? Give its types. Explain the theory involved in thermogravimetry analysis.

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

4) Write notes on X-ray diffraction and process validation.

B. Answer **all** : **(2×20=40)**

5) Derive simultaneous equation for sample containing two UV absorbing drugs, each of which absorb at the λ_{max} of the other. Discuss the chemical derivatisation in indirect UV-V is spectrophotometric assays.

6) Classify liquid chromatography by separation mechanism. What is the scope of HPLC ? Name the different components of GC instrument and explain their role.

P.T.O.

SLR-U – 9

Spectra