SLR-H – 1

Seat No.	

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

Day and Date : Saturday, 17-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 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. Name different immunochemical techniques.. Explain ELISA technique and give its applications. **10**
2. Name the main components of mass spectrometer with their functions Explain the mass spectrum. Discuss the application of mass spectrometry. **20**
3. How will you approach the analysis of infrared spectrum ? Explain the factors influencing vibrational frequencies. **20**
4. Discuss the magnetic anisotropy. What information can be obtained from J-coupling for structure determination in NMR ? **20**

SECTION – II

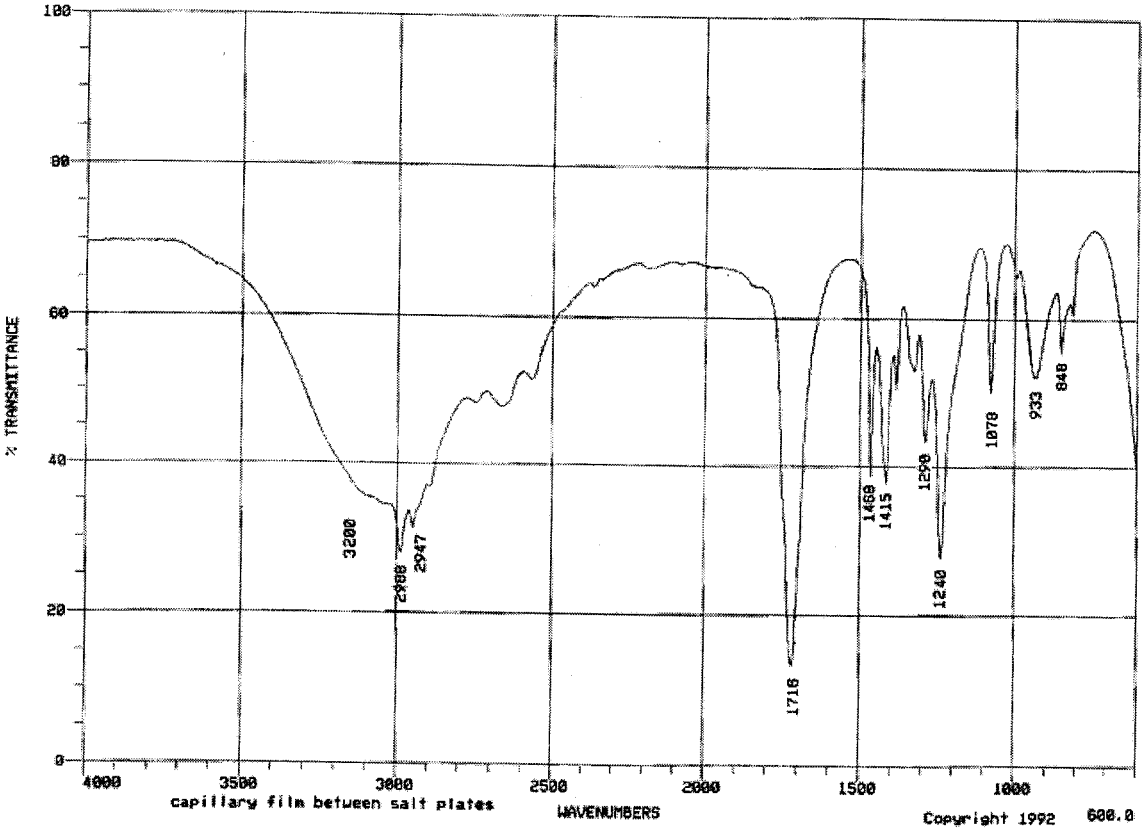
5. Determine the structure of the compound from given IR, NMR spectrum and molecular formula. **10**
6. Discuss the method development in partition chromatography. Give the applications of HPLC. **20**
7. What is thermal analysis ? Explain the theory involved in different types of thermal analytical techniques. Give the applications of differential thermal analysis. **20**
8. Write short notes on :
   a) Laser **6**
   b) X-ray diffraction **8**
   c) Reference Standard **6**

P.T.O.

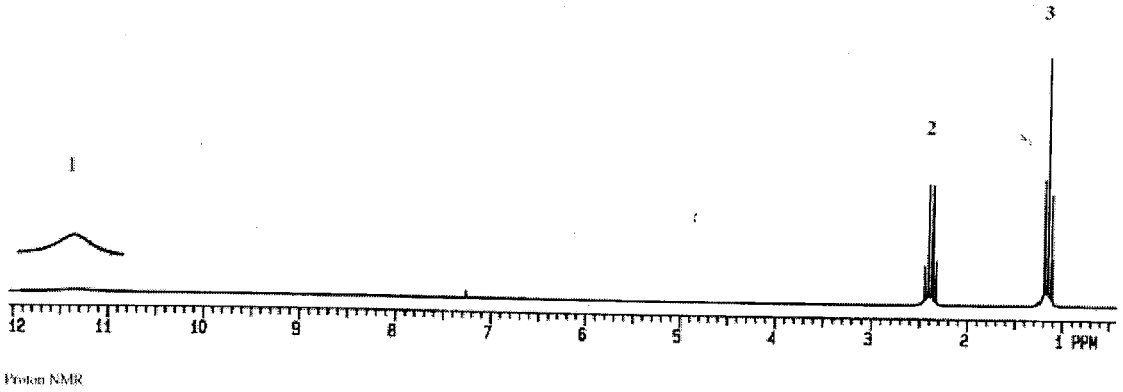
SLR-H – 1

I

$C_3H_6O_2$
MW 74
IR



NMR



Proton NMR

SLR-H – 13

Seat No.	

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

Day and Date : Monday, 19-5-2014 Max. Marks : 100
Time : 10.00 a.m. to 1.00 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** indicate **full** marks.*

SECTION – I

1. What is resealed erythrocytes ? Explain in detail methods of entrapment and characterization. **10**

2. Describe in detail fundamental concepts of controlled release dosage forms. **20**

3. Explain about mechanism of drug penetration through skin and evaluation of transdermal drug delivery system. **20**

4. Discuss about magnetism and hydrolysis activated drug delivery system. **20**

SECTION – II

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

6. Describe mechanism of mucoadhesion and development of mucoadhesive Buccal and nasal drug delivery system. **20**

7. Discuss the different approaches to colon specific drug delivery. **20**

8. Write short note on **any two** : **(2×10)**
   a) Regulatory perspectives for proteins and peptide drug delivery.
   b) Chronotherapy in cancer treatment.
   c) Evaluation of microspheres.

SLR-H – 14

Seat No.	

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

Day and Date : Wednesday, 21-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

***Instructions**: 1) Answers to **both** Sections should be written in **separate** sheet.*
*2) Question No. **1** and **5** are **compulsory**.*
*3) Answer **any two** questions from **remaining** questions from Section **I** and **any two** questions from the remaining from Section **II**.*

SECTION – I

1. Define Bio-Availability and its related terms. **10**
2. Discuss various dissolution testing models available for solid dosage forms. **20**
3. Classify compartment models and discuss one compartment model kinetics. **20**
4. Discuss different methods of drug detoxification process in the body. **20**

SECTION – II

5. Define dosage regimen and discuss dose adjustment in obese patients. **10**
6. Explain Various Pharmacokinetic and Pharmaco dynamic studies. **20**
7. Define Bio equivalency studies and its related terms. **20**
8. Explain renal excretion processes in detail. **20**

SLR-H – 15

Seat No.	

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

Day and Date : Friday, 23-5-2014 Max. Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

Note : *1) Answer to **both** Sections must be written in **separate** answer sheet.*
*2) Question No. **1** and **5** are **compulsory**.*
*3) Answer **any two** questions from the remaining for Section – **I** and Section – **II**.*

SECTION – I

1. Compare SVP and LVP with reference to manufacturing facilities, methods of preparation and packaging. **10**
2. Explain GMP guidelines for aseptic processing of parenteral formulations. **20**
3. Explain in detail physicochemical properties of materials used in development of parenteral products. **20**
4. Write short notes. (**Any two**) : **20**
   a) Parenteral emulsions.
   b) Environmental control in parenteral production area
   c) Powdered parenteral products.

SECTION – II

5. What is industrial sterilization ? Explain specifications and process selection in large scale sterilization. **10**
6. Discuss the novel drug formulations for ocular drug therapy. **20**
7. What is importance of preformulation in drug delivery system ? Describe in detail preformulation aspects of developing parenteral products. **20**
8. Write short note (**any two)** : **20**
   a) Control and monitoring of microbial count in sterile manufacturing area
   b) Radiopharmaceuticals
   c) Selection of packaging components in parenterals.

SLR- H – 16

Seat No.	

M. Pharmacy (Semester – II) Examination, 2014
COSMETICOLOGY
Pharmaceutics

Day and Date : Friday, 23-5-2014 Max. Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

Instructions *: 1) Answer to* ***both*** *Sections must be written in* ***separate*** *sheet.*
2) Question No. ***1*** *and* ***5*** *are* ***compulsory****.*
3) Answer ***any two*** *questions from the* ***remaining three*** *questions in Section –* ***I*** *and Section –* ***II****.*

SECTION – I

1. Explain in detail physiological consideration of skin, hair and nail. **10**
2. Discuss in detail manufacturing of creams, sticks and aerosol cosmetics. **20**
3. Describe microbiological and psychometric evaluation of cosmetics. **20**
4. Explain in detail about herbal cosmetics. **20**

SECTION – II

5. Describe liposomes, hair waving and cosmetic surgery as advance in cosmetics. **10**
6. Discuss about regulatory requirements for manufacture and sale of cosmetics. **20**
7. What are different rheological additives in cosmetics ? Explain hair products. **20**
8. Explain in detail about safety testing of cosmetics. **20**

SLR-H – 17

Seat No.	

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

Day and Date : Monday, 19-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 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. Explain prohibition, control and regulation as per section 8 of narcotic drugs and psychotropic substances act. **10**

2. Write a detail account on conduct of process validation. **20**

3. What is validation ? Give the types of validation. Discuss all the five steps of equipment validation. **20**

4. Give the objectives of consumer protection act. Which are the consumer dispute redressal agencies ? Explain state and national commission. **20**

SECTION – II

5. State the rules for labeling of drugs other than homeopathic medicine. **10**

6. What is intellectual proper right ? Give its types and process of filing patent. Write a note on Indian Patent Act. **20**

7. Give a detail account on drug and magic remedies Act 1954 and rules 1955 with a special emphasis on classes of prohibited advertisement, exempted advertisement and penalties there under. **20**

8. Write a note on : **20**
   a) Validation of effective cleaning
   b) Validation of computer system.

SLR-H – 18

Seat No.	

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

Day and Date : Wednesday, 21-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 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 ? **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. Why are cGMPs so important ? Give guideline for drug product containers and closures (subpart-E) and warehousing procedures (subpart-H). **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 ANOVA ? Explain the experimental study design in clinical trials. **20**

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

SLR-H – 19

Seat No.	

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

Day and Date : Friday, 23-5-2014 Total Marks : 100

Time : 10.00 a.m. to 1.00 p.m.

Instructions** : 1) Question No. **1** and **5** are **compulsory.

*2) Solve **any two** from the remaining from **each** Section.*

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

SECTION – I

1. Compare and contrast Pharmaceutical equivalence and therapeutic equivalence. Add a brief note on need of bioequivalence studies. **10**

2. What is stability testing ? Explain its need along with the different parameters to be considered in stability testing with example. **20**

3. What are pharmaceutical packaging materials ? Enlist different packaging materials used in pharmaceutical industry along with the quality control measures of each. Explain at least two tests for each material in detail ? **20**

4. Explain in brief : **20**

   a) IPQC tests for liquid orals.

   b) Applications of Quality Risk Management.

SECTION – II

5. What are the different techniques of sampling ? Add a brief account on merits and demerits of each. **10**

6. Explain the concept of QbD in pharmaceutical manufacturing. **20**

7. Explain in brief the different components of Indian Pharmacopoeia. Explain in detail the appendices covered in IP 1996. **20**

8. What is the importance of statistics in research ? Explain its uses in pharmacy. Add a note on different statistical tools used in pharmaceutical research with its importance. **20**

SLR-H – 2

Seat No.	

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

Day and Date : Tuesday, 20-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

***Instructions** : 1) Answers to **both** Sections should be written in **separate** sheet.*

*2) Question **No.1** and **5** are **compulsory.***

*3) Answer **any two** questions from remaining questions from Section **I** and **any two** questions from the remaining from Section **II.***

SECTION – I

1. Write about biological implications of surfactants. **10**

2. Discuss various methods used to study compressibility, compactibility and consolidation of granules. **20**

3. What do you mean by drug dissolution ? Explain various factors affecting dissolution rate. **20**

4. Write note on the following : **20**

   a) Types of solid dispersions.

   b) ICH guidelines for accelerated stability testing of various dosage forms.

P.T.O.

SECTION – II

5. What do you mean by Tg of polymers ? Write its importance in tablet formulation design. **10**

6. Discuss various factors influencing destabilization and stabilization of pharmaceutical products. How shelf of pharmaceutical products can be enhanced ? **20**

7. What do you mean by micellisation ? What are its types ? Discuss in detail thermodynamics and kinetics of micelle formation. **20**

8. Write note on the following : **20**

   a) Dissolution test apparatus (USP)

   b) Characterization of solid dispersions.

———————

SLR-H – 21

Seat No.	

M.Pharm. (Sem. – II) Examination, 2014
ADVANCED PHARMACEUTICAL CHEMISTRY – II
Pharmaceutical Chemistry

Day and Date : Monday, 19-5-2014 Max. Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

***Instructions** : 1) Answer to **both** Sections must be written in **separate** answer sheets.*
*2) Question No. **1** and **5** are **compulsory**.*
*3) Answer **any two** questions from the remaining **three** in each Section.*
*4) Figures to the **right** indicate **full** marks.*

SECTION – I

1. Write a note on screening of combinatorial libraries and its contribution in drug discovery. **10**

2. What are the different methods employed for the asymmetric synthesis? Add a note on asymmetric synthesis of Propranolol. **20**

3. Describe the life cycle of HIV and various targets of drugs used in the treatment of AIDS. Give classification and structure of drugs used in the treatment of AIDS. **20**

4. Write elaborate notes on asymmetric synthesis of Diltiazem and Thienamycin. **20**

SECTION – II

5. Write note on enzyme immobilization techniques and bioconversion of steroids. **10**

6. Write a note on high throughputs screening and small molecule libraries. **20**

7. Give a detailed note of the medicinal chemistry of drugs used in the treatment of Alzheimer's and Parkinson's disease. **20**

8. Write note on enzyme immobilization techniques and microbial bioconversion of antibiotics. **20**

SLR-H – 22

Seat No.	

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

Day and Date : Wednesday, 21-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 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** in **each** Section.*
*4) Figures to the **right** indicate **full** marks.*

SECTION – I

1. Explain different phases of drug discovery. **10**
2. Describe in detail methods adopted in peptide synthesis. **20**
3. Elaborate Hansch and Free Wilson QSAR modes in detail. **20**
4. Write short notes on **any two** : **20**
   a) Craig plot
   b) Chemo informatics
   c) Proteomics.

SECTION – II

5. Explain the chemistry and vital role played by interferon. **10**
6. What is energy minimization and why it is important in computational drug discovery ? Explain at list two different energy minimization methods. **20**
7. With examples enumerate in detail different sources for drugs. **20**
8. Write short notes on **any two** : **20**
   a) Molecular dynamic simulations.
   b) Force fields.
   c) Montecarlo simulations.

SLR-H – 23

Seat No.	

M. Pharm. (Semester – II) Examination, 2014
PHARMACEUTICAL CHEMISTRY
Quality Control

Day and Date : Friday, 23-5-2014 Total Marks : 100

Time : 10.00 a.m. to 1.00 p.m.

Instructions** : 1) Question No. **1** and **5** are **compulsory.

*2) Solve **any two** from the remaining from **each** Section.*

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

SECTION – I

1. Compare and contrast Pharmaceutical equivalence and therapeutic equivalence. Add a brief note on need of bioequivalence studies. **10**

2. What is stability testing ? Explain its need along with the different parameters to be considered in stability testing with example. **20**

3. What are pharmaceutical packaging materials ? Enlist different packaging materials used in pharmaceutical industry along with the quality control measures of each. Explain at least two tests for each material in detail ? **20**

4. Explain in brief : **20**
   a) IPQC tests for liquid orals.
   b) Applications of Quality Risk Management.

SECTION – II

5. What are the different techniques of sampling ? Add a brief account on merits and demerits of each. **10**

6. Explain the concept of QbD in pharmaceutical manufacturing. **20**

7. Explain in brief the different components of Indian Pharmacopoeia. Explain in detail the appendices covered in IP 1996. **20**

8. What is the importance of statistics in research ? Explain its uses in pharmacy. Add a note on different statistical tools used in pharmaceutical research with its importance. **20**

SLR-H – 24

Seat No.	

M.Pharm. (Semester – II) Examination, 2014
PHARMACEUTICAL CHEMISTRY
Therapeutic Drug Monitoring

Day and Date : Friday, 23-5-2014 Max. Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

Instructions : *1) Answer to **both** Sections must be written in **separate** answer sheets.*
*2) Question No.**1** and **5** are **compulsory**.*
*3) Answer **any two** questions from remaining questions of section – **I** and **any two** questions from the remaining questions of section – **II**.*

SECTION – I

1. Describe the principle and procedure of EMIT. **10**
2. Why is TDM necessary? Discuss criteria for valid TDM. **20**
3. Discuss therapeutic management of Asthma. Add a note on the monitoring of patient and precautions to be taken during asthma. **20**
4. Write short notes on (**any two**) : **20**
   a) Importance of TDM in ADR
   b) Guidelines for sampling time of TDM
   c) Application of HPTLC in TDM.

SECTION – II

5. Discuss the various laboratory tests used in renal dysfunction. **10**
6. Give detailed account on TDM of Phenytoin. **20**
7. Explain in detail TDM of Lithium. **20**
8. Write short notes on (**any two**) : **20**
   a) TDM of Antitubercular drugs
   b) Prevention of communicable diseases
   c) Estimation of Amylase and its significance.

SLR-H – 3

Seat No.	

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

Day and Date : Thursday, 22-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 p.m.

***Note** : 1) Question No. **1** and **5** are **compulsory**.*
*2) Solve **any 2** questions from the remaining from **each** section.*
*3) Figures to the **right** indicate **full** marks.*
*4) Answers to the **two** sections should be written in **separate** answer books.*

SECTION – I

1. Define dissolution rate. Describe in detail official (USP) methods of dissolution. **10**

2. What is open and closed model in pharmacokinetics ? Explain in detailed one compartment open model for Extra vascular administration. **20**

3. Explain physiological barriers to distribution of drugs with neat labeled diagram. **20**

4. Answer the following : **20**
   1) Discuss the concept of pH partition hypothesis and give it's limitations.
   2) How you will estimate the Renal clearance ? Give various factors affecting renal clearance.

SECTION – II

5. What is the method of residuals ? How is it used for calculating Ka ? **10**

6. Describe in detail various Dosage form factors affecting on absorption of drug. **20**

7. Explain in detail various transport mechanism of drug. **20**

8. Answer the following : **20**
   1) Discuss the relationship between plasma concentration and therapeutic response.
   2) Explain the significance of Binding of drugs and Kinetics of plasma protein bindings of drugs ?

SLR-H – 5

Seat No.	

M.Pharmacy (Semester – I) Examination, 2014
PHARMACEUTICS
Product Development

Day and Date : Thursday, 22-5-2014 Total Marks :100
Time : 10.00 a.m. to 1.00 p.m.

Note : *1) Question No. **1** and **5** are **compulsory**.*
*2) Solve **any 2** questions from the remaining from **each** Section.*
*3) Figures to the **right** indicate **full** marks.*
*4) Answers to the **two** Sections should be written in **separate** answer books.*

SECTION – I

1. Define and classify validation. Give its advantages and explain it's type. **10**
2. Describe in detail evaluation of plastic and glass as per IP. **20**
3. With suitable example discuss the suspension formulation with reference to it's components, manufacturing and evaluation. **20**
4. Write a note on : **20**
   1) Analysis of variance (ANOVA) in product development.
   2) Objectives and importance of product development.

SECTION – II

1. What are objectives of preformulation study ? Mention various parameters to be investigated during this study. **10**
2. Discuss linear and non-linear regression analysis. Add a note on ANOVA. **20**
3. Discus regulatory requirement of US and UK market. Add a note on patent fillings. **20**
4. Write a note on : **20**
   1) Microcapsules
   2) Response surface analysis.

SLR-H – 7

Seat No.	

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

Day and Date : Tuesday, 20-5-2014 Total Marks : 100
Time : 10.00 a.m. to 1.00 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. Write a note on concept of GMP. Discuss in short GMP guidelines on protocol methodologies. **10**

2. Give a detail account on product recall documents and preventive maintenance record. **20**

3. Define validation. Write a note on type of validation. **20**

4. Explain quality assurance related documents for audits and SOPs. **20**

SECTION – II

5. Define GLP and give an account on microbial limit test. **10**

6. Write a note on ISO 9000 - 2001, its implementation and functions. **20**

7. How GLP regulates for post marketing surveillance in context of clinical trials, bioassays and pyrogen testing. **20**

8. Define GMP. Explain component of GMP and Q.C. **20**
