SLR-TL – 1

Seat No.	

Set P

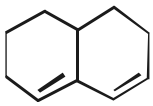
Master of Pharmacy (Semester – I) (New CBCS) Examination, 2017
PHARMACEUTICS
Modern Pharmaceutical Analytical Techniques

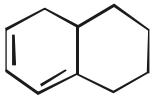
Day and Date : Tuesday, 28-11-2017 Total Marks : 75

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

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

1) Calculate the λ_{max} of following structures.

a) 

b) 

2) Write a note on gel electrophoresis.

3) What is coupling constant and how coupling of signals help to identify compounds ?

4) Explain the factors which influences absorption of infra radiations by compounds.

5) Draw the neat diagram of modern NMR and briefly explain its components.

6) Describe MALDI.

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

1) What do you mean by ELISA and in detail the types of ELISA ?

2) Explain in detail Bragg's law and instrumentation of typical X ray crystallography.

3) What are the different ionization techniques in Mass spectrometer. Explain with example ionization process in 70eV mass spectrometer.

P.T.O.

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 spectroscopy ?

III. Answer **any two** of the following : **(10×2=20)**

a) What do you mean by chromatography ? Classify chromatography with examples.

b) Write the principle involved in high performance liquid chromatography. With neat diagram explain different parts of HPLC.

c) Write about applications of HPLC.

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SLR-TL – 2

Seat No.	

Set P

M.Pharmacy (Pharmaceutics) (Semester – I) Examination, 2017
DRUG DELIVERY SYSTEM (New CBCS)

Day and Date : Thursday, 30-11-2017 Max. Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

1. Answer **any five** of the following : **(5×5=25)**
   A) Write a note on need of development of rate controlled and modified release drug delivery systems. Compare them with conventional dosage forms.
   B) Describe various mechanisms of mucoadhesion.
   C) Write a short note on mucosal vaccine delivery systems.
   D) Describe the mechanisms of drug release from sustained release formulations.
   E) Write a note on barriers to delivery of proteins and peptides.
   F) What are the challenges in ocular drug delivery ? What are the approaches to overcome them ?

2. Answer **any three** of the following : **(10×3=30)**
   A) Classify and describe the mechanisms of modulated drug delivery systems.
   B) Write a note on evaluation of mucoadhesive drug delivery systems.
   C) Write a note on polymers used in various drug delivery systems.
   D) Define :
      i) Controlled release
      ii) Sustained release
      iii) Modified release
      iv) Extended release. What are the ideal characteristics of the drug for CR formulations ? Highlight the advantages and disadvantages of SR/CR formulations.

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

   Describe the structure of skin and mechanisms of drug diffusion across the skin. Write a note on formulation and evaluation of transdermal drug delivery system.

SLR-TL – 3

Seat No.	

Set P

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2017
Pharmaceutics
MODERN PHARMACEUTICS

Day and Date : Monday, 4-12-2017 Max. Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

1. Solve **any five**. **(5×5=25)**

   1) Add a note on parenteral formulations.

   2) Discuss contour designs of optimization.

   3) Discuss student T-test.

   4) Discuss ideal layout of the pharmaceutical industry.

   5) Add a note on the physics of tablet compression.

   6) Discuss inventory management.

2. Solve **any three**. **(3×10=30)**

   1) Discuss compaction profiles of a tablet.

   2) Discuss different statistical designs of dissolution parameters.

   3) Add a note on sales forecasting, budget and cost control in pharmaceuticals.

   4) Elaborate stability testing of pharmaceuticals.

3. Solve **any one**. **(1×20=20)**

   1) Give the types of validation and what do you mean by IQ, OQ and PQ ?

   2) Add a note on pharmaceutical disperse systems and give its theories.

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SLR-TL – 4

Seat No.	

Set P

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2017
(Pharmaceutics)
REGULATORY AFFAIRS

Day and Date : Wednesday, 6-12-2017 Max. Marks : 75

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

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

1) Describe the essential features of clinical trials.
2) Write a note on ICH guidelines on stability.
3) Give the procedure for preparation of common technical document.
4) What are the benefits after Hatch-Waxman amendment of Federal Drugs and Cosmetics Act ?
5) What is orange book ? Explain the important facts of orange book.
6) Describe the global scenario of regulatory network in pharmaceutical industry.

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

1) Describe the procedure for monitoring and reporting the adverse drug reactions.
2) Explain in detail Phase-II and Phase-III study Indian regulatory authority.
3) Explain the regulatory requirements of Good Documentation Practices.
4) Explain format and contents of NDA.

III. Give the content, format and regulatory requirements for submission of Investigational New Drug (IND). **20**

SLR-TL – 5

Seat No.	

Set **P**

M. Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2017
PHARMACEUTICS (Old)
Advanced Pharmaceutical Analysis

Day and Date : Tuesday, 28-11-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Explain chemical environment and chemical shift.

2) Explain theory, instrumentation and applications of differential scanning calorimeter.

3) Write note on laser and reference standard.

4) Write note on X-ray diffraction.

B. Answer **all** : **(2×20=40)**

5) Explain the partition chromatography with normal and reverse phase. Discuss the theory and applications of GLC.

6) Discuss the various techniques employed for placing the sample in the path of infrared radiations and applications of IR.

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SLR-TL – 6

Seat No.	

Set P

M.Pharmacy (Semester – I) (CBCS/CGPA Pattern) Examination, 2017
PHARMACEUTICS (Old)
Advanced Pharmaceutics – I

Day and Date : Thursday, 30-11-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Explain the various methods of granulation. Enlist the advantages and disadvantages of each method.
2) Discuss in brief the methods by which the dissolution rate can be enhanced. Explain the dissolution testing of uncoated tablets.
3) Highlight the applications of polymers in pharmaceutical industry. Add a note on characterization of polymers.
4) Define the term solid dispersion. Enlist the ideal properties of carriers used in solid dispersion. Add a note on “overages”.

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

1) Discuss the factors responsible for destabilization of pharmaceutical products. How can they be overcome ?
2) Write a note on :
   a) Cyclodextrin complexation.
   b) Hydrotrophy in pharmaceuticals.

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SLR-TL – 7

Seat No.	

Set P

M. Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2017
PHARMACEUTICS (Biopharmaceutics and Pharmacokinetics) (Elective) (Old)

Day and Date : Monday, 4-12-2017 Max. Marks : 70

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

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

1) How you will estimate the Renal clearance ? Give various factors affecting renal clearance.

2) What is drug distribution ? Explain the various factors affecting on drug distribution.

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

4) Describe the Dosage form factors affecting on absorption.

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

5) What is bioavailability ? Give the method for enhancement of bioavailabilty.

6) Give the assumption of Multicompartment model. Explain the Two-Compartment Open modeling for intravenous bolus administration and intravenous infusion.

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SLR-TL – 8

Seat No.	

Set P

M. Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2017
Pharmaceutics (Old)
ADVANCED DRUG DELIVERY (Elective)

Day and Date : Monday, 4-12-2017 Max. Marks : 70

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

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

1) Explain the technologies used to design buccal tablet and give its advantages.
2) Describe the general methods of analysis of protein and peptide drugs.
3) Discuss the permeation enhancers used in transdermal drug delivery system.
4) Explain the various barriers to transport proteins and peptides drugs.

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

5) Discuss technologies for developing transdermal drug delivery system and evaluation there of.
6) Explain the various methods used for developing nanoparticles drug delivery system.

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SLR-TL – 9

Seat No.	

Set P

M.Pharm. (Semester – I) (CGPA/CBCS) Examination, 2017
PHARMACEUTICS
Product Development (Old) (Elective)

Day and Date : Monday, 4-12-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Describe the factorial design with suitable example. What are the advantages of factorial design over trial and error approach ?
2) Write a note on primary and secondary packaging materials for pharmaceutical. Add a note on selection of packaging materials.
3) Describe the concept and types of validation.
4) Add a note on concept of NDA and ANDA with process of patent filing.

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

5) Write a detailed note on preformulation studies in pharmaceutical product development.
6) Give a full account of tablet manufacturing process.

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SLR- TL – 10

Seat No.	

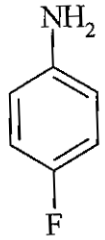
Set P

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2017
(Quality Assurance)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

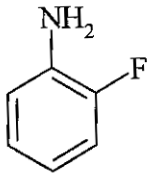
Day and Date : Tuesday, 28-11-2017 Total Marks : 75
Time : 10.30 a.m. 1.30 p.m.

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

1) How do you differentiate following compounds by 1H NMR in DMSO D_6.



a)



b)

2) Write a note on gel electrophoresis.

3) What is coupling constant and how coupling of signals help to identify compounds ?

4) Explain the factors which influences absorption of infra radiations by compounds.

5) Write the principle and applications of potentiometer.

6) With examples elaborate Woodward Fischer rules to calculate λ_{max} in butadienes.

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

1) What do you mean by chemical shift in NMR and explain factors which contribute for chemical shifts of protons ?

2) Explain in detail Bragg's law and instrumentation of typical X ray crystallography.

P.T.O.

3) With neat diagram of HPLC describe pumps and detectors used in HPLC.

4) List out the different types of ionization techniques in Mass spectrometer and explain in detail electron impact ionization and electro spray ionization.

III. a) What is the principle in DSC. With diagram elaborate instrumentation of DSC. **20**

b) Write the applications of DSC, DTA and TGA.

SLR-TL – 11

Seat No.	

Set P

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2017
QUALITY ASSURANCE
Quality Management System

Day and Date : Thursday, 30-11-2017 Total Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

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

1) Explain in brief quality by design.
2) Write down the models of cost of quality.
3) Give detail focus on principles of six sigma.
4) Explain in detail benchmarking.
5) Write an account on OSHAS guidelines.
6) Write a note on NABL certification and accreditation.

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

1) Explain in detail six system inspection model.
2) Explain in detail measurement of statistical process control and quality improvement.
3) Write in detail about the impacts of customer focus on quality.
4) Explain in detail regulatory compliance through quality management and development of quality culture.

III. Explain in detail quality by design and process development report. **20**

SLR-TL – 12

Seat No.	

Master of Pharmacy (Semester – I) (New CBCS) Examination, 2017
QUALITY ASSURANCE
Quality Control and Quality Assurance

Day and Date : Monday, 4-12-2017 Max. Marks : 75

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

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

1) What are non clinical laboratory study, testing facility and quality assurance unit ?

2) What is pharmaceutical inspection convention ? Give its objectives.

3) Give QC tests for containers and closures.

4) What are change control, change-in of components and calculation of yield ?

5) What are CDER and CBER ?

6) Give overview of ICH guidelines.

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

1) Give role/functions of the QA and QC.

2) Explain the GMP guidelines for organization and personnel responsibilities.

3) Give the IPQC and FPQC tests for parenteral and ophthalmic products.

4) Describe the sampling and testing of in-process materials and drug product.

III. Give details of the master formula record. **20**

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SLR-TL – 13

Seat No.	

M.Pharmacy (Semester – I) (New CBCS) Examination, 2017
QUALITY ASSURANCE
Product Development & Technology Transfer

Day and Date : Wednesday, 6-12-2017 Max. Marks : 75
Time : 10.30 a.m. to 1.30 p.m.

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

   1) Discuss the role of particle size design of dosage forms.

   2) Write note on Medical device packaging.

   3) Discuss the importance of solubilisation in preformulation.

   4) Discuss the Scale Up Post Approval Changes (SUPAC) studies.

   5) Explain the significance of Pilot plant and scale up studies and write about the parameters involved in the scale up process of tablets.

   6) Discuss the process of product registration as per the guidelines by CDSCO.

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

   1) Discuss the steps involved in technology transfer process.

   2) Discuss in detail about different types of Pharmaceutical containers and closures including their merits and demerits.

   3) Explain factors affecting polymorphism and discuss the various characterization techniques for polymorphism.

   4) Discuss the methods to enhancement of solubility of drug.

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

SLR-TL – 24

Seat No.	

Set P

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2017
Pharmaceutics
ADVANCED PHARMACEUTICS – II

Day & Date : Wednesday, 29-11-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Explain in detail development of ocular drug delivery system.

2) What are different factors affecting colonic absorption of drug ? Explain evaluation of colon specific delivery system.

3) Write an account on :
   A) Chronotherapy in cancer treatment.
   B) Routes for peptide delivery.

4) Explain briefly evaluation microspheres and structural complexity of proteins and peptides drugs.

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

1) Explain mechanism of mucoadhesion. Describe briefly in vitro, ex vivo and in vivo evaluations of nasal drug delivery system.

2) What are different technologies for developing TDDS ? Explain them in detail.

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SLR-TL – 25

Seat No.	

Set P

M. Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2017
Pharmaceutics
ADVANCED PHARMACEUTICS – III

Day and Date : Saturday, 2-12-2017 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Discuss the factors affecting drug metabolism.
2) Define compartment and pharmacokinetics ? Explain the differences between the kinetics of one compartment and two compartment models with bolus IV dose.
3) Describe the interrelationships between pharmacokinetic parameters and physiological variables.
4) What is renal clearance ? How do you adjust the dosage for patients with renal failure ?

B. Answer **all** : **(2×20=40)**

5) What is absorption ? Discuss the mechanisms of drug absorption.
6) What is protein binding ? Discuss the significance and kinetics of protein binding.

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SLR-TL – 26

Seat No.	

Set P

M.Pharmacy (Semester – II) Examination, 2017
PHARMACEUTICS (CGPA/CBCS)
Sterile Product Formulation and Technology (Elective)

Day and Date : Tuesday, 5-12-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Explain in detail formulation and characterization of loaded erythrocytes.
2) What is importance of sterilization in parenterals ? Explain various methods of sterilization used in formulation and development of parenterals.
3) Explain in detail formulation and characterization of dry product injection.
4) Explain in detail applications of protein peptide drug delivery system in sustained release parenterals.

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

5) Explain in detail pharmacopoeial requirement for LVP and SVP.
6) Explain in detail sterile diagnostics and radiopharmaceuticals.

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SLR-TL – 27

Seat No.	

Set P

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2017
PHARMACEUTICS
Cosmeticology (Elective)

Day and Date : Tuesday, 5-12-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Discuss rheology of nail products and antiperspirants.
2) Explain microbiological and psychometric evaluation of cosmetics.
3) Describe about formulation of herbal cosmetics with examples.
4) Elaborate photoallergy and ocular irritation protocols.

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

1) Explain permanent hair coloration and cosmetic surgery as advances in cosmetics.
2) Describe in detail manufacturing techniques of aerosol cosmetics and sticks cosmetics.

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SLR-TL – 28

Seat No.	

Set **P**

M. Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2017
Quality Assurance
QUALITY ASSURANCE TECHNIQUE – II

Day and Date : Wednesday, 29-11-2017 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Name the different steps involved in vendor validation and explain it in detail.

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

3) What do you mean by validation of services ? Write a note on it.

4) What are the different methods used for sampling in the validation of cleaning methods ? Explain with example.

B. Answer **all** : **(2×20=40)**

5) What is process validation ? Write a detail account on validation of compression.

6) Why equipment validation is important ? Give the format for the document of installation qualification and operational qualification of autoclave.

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SLR-TL – 29

Seat No.	

Set P

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2017
Quality Assurance
QUALITY ASSURANCE TECHNIQUE – III

Day and Date : Saturday, 2-12-2017 Max. Marks : 70

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

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

1) Discuss the performance verification of pump, injector and UV-visible detector modules in HPLC.
2) What is the importance of dissolution test ? Why are cGMPs so important ?
3) Explain correlation and ANOVA.
4) Give the guidelines for functional area, anaesthesia and euthanasia as per CPCSEA.

B. Answer **all** : **(2×20=40)**

5) Give the types of analytical procedures to be validated. Name and define typical validation characteristic which should be considered for validation (ICH).
6) Give guidelines for building and facilities as per cGMP (subpart – C).

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SLR-TL – 30

Seat No.	

Set P

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2017
QUALITY ASSURANCE
Quality Control

Day and Date : Tuesday, 5-12-2017 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What is the need for sampling ? Explain the different techniques of sampling.
2) Write in brief about quality assurance. Add a note on cGMP with special reference to QA aspects.
3) Explain in brief the methodology and applications of quality risk management.
4) What is statistics ? Explain the different statistical tools available for pharmaceutical research.

B. Answer **all** : **(2×20=40)**

5) Explain in brief stability testing of pharmaceuticals. Add a note on determination of shelf life.
6) Write a brief note on :
   a) Process analytical technology.
   b) General steps in conduct of BABE studies.
