SLR-B – 1

Seat No.	

M.Pharmacy (Semester – I) Examination, 2016
PHARMACEUTICS
Advanced Pharmaceutical Analysis (CGPA/CBCS)

Day and Date : Monday, 25-4-2016 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What is ELISA ? Explain with its types. Give its application.

2) Write note on X-ray diffraction.

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

4) Write note on laser and reference standard.

B. Answer **all** : **(2×20=40)**

5) What is HPLC ? Name the different parts of HPLC instrument. Discuss detectors used in HPLC.

6) Explain the mechanism of absorption (resonance) in NMR. Discuss chemical environment and chemical shift.

SLR-B – 2

Seat No.	

M.Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2016
PHARMACEUTICS
Advanced Pharmaceutics – I

Day and Date : Wednesday, 27-4-2016 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. **10**

b) Hydrotrophy in pharmaceuticals. **10**

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SLR-B – 3

Seat No.	

M.Pharmacy (Semester – I) (CGPA/CBCS) Examination, 2016
PHARMACEUTICS (Biopharmaceutics and Pharmacokinetics) (Elective)

Day and Date : Friday, 29-4-2016 Max.Marks : 70

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

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

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

2) Discuss the concept of pH partition hypothesis and give its limitations.

3) How would you estimate elimination rate constant, elimination half-life and clearance drug considering One-Compartment Open Model for an IV bolus administration.

4) How non-linear kinetics of a drug is detected ? Explain the causes of non linearity.

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

5) What is distribution ? Describe in detail factor affecting distribution of drug. Give an account of volume of distribution.

6) Define dissolution rate. Describe in detail theories of drug dissolution.

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SLR-B – 4

Seat No.	

M.Pharmacy (Pharmaceutics) Examination, 2016
(CGPA/CBCS) (Elective)
ADVANCES IN DRUG DELIVERY

Day and Date : Friday, 29-4-2016 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Describe in detail regulatory considerations in designing of Protein and peptide drug delivery system.

2) Explain the technologies used to design and evaluation of Buccal tablet and give mechanisms of transports of drugs through mucosal routes.

3) Discuss the various methods for enhancement of dissolution characteristics evaluation thereof.

4) What are the polymers ? Classification of polymers and applications of polymers in drug delivery system.

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

5) Discuss the design, development and evaluation of Occusert controlled drug delivery system.

6) Describe in detailed methods of preparation, evaluation of liposomal drug delivery system.

SLR-B – 6

Seat No.	

M.Pharmacy (Semester – I) Examination, 2016
QUALITY ASSURANCE
Advanced Pharmaceutical Analysis (CGPA/CBCS)

Day and Date : Monday, 25-4-2016 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What is ELISA ? Explain with its types. Give its application.

2) Write note on X-ray diffraction.

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

4) Write note on laser and reference standard.

B. Answer **all** : **(2×20=40)**

5) What is HPLC ? Name the different parts of HPLC instrument. Discuss detectors used in HPLC.

6) Explain the mechanism of absorption (resonance) in NMR. Discuss chemical environment and chemical shift.

SLR-B – 9

Seat No.	

M.Pharmacy (Semester – I) Examination, 2016
PHARMACEUTICAL CHEMISTRY
Advanced Pharmaceutical Analysis (CGPA/CBCS)

Day and Date : Monday, 25-4-2016 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What is ELISA ? Explain with its types. Give its application.

2) Write note on X-ray diffraction.

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

4) Write note on laser and reference standard.

B. Answer **all** : **(2×20=40)**

5) What is HPLC ? Name the different parts of HPLC instrument. Discuss detectors used in HPLC.

6) Explain the mechanism of absorption (resonance) in NMR. Discuss chemical environment and chemical shift.

SLR-B – 12

Seat No.	

M. Pharm. (Pharmaceutics) (Semester – II) Examination, 2016
(CGPA/CBCS)
ADVANCED PHARMACEUTICS – II

Day and Date :Tuesday, 26-4-2016 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What are various pathways of permeation through skin ? Explain penetration enhancers in TDDS.
2) Describe about gel diffusion controlled and modulation of gastrointestinal transit time oral drug delivery system.
3) Explain various routes for peptide delivery and add note on immunogenicity and stability of insulin.
4) Discuss about development of pulmonary and vaginal drug delivery.

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

1) Explain factors affecting ocular absorption and development of ocular drug delivery system.
2) Write a note on :
   A) Drug entrapment techniques and targeting in microspheres.
   B) Application and immunological consideration of liposomes.

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SLR-B – 13

Seat No.	

M. Pharm. (Pharmaceutics) (Semester – II) Examination, 2016
(CGPA/CBCS)
ADVANCED PHARMACEUTICS – III

Day and Date :Thursday, 28-4-2016 Max. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) a) Define Biopharmaceutics, Pharmacokinetics, Pharmacodynamics, Chrono Pharmacokinetics and Clinical Pharmacokinetics.
   b) Enlist the barriers to drug distribution. Describe blood-brain barrier in detail.
2) Describe the factors affecting clearance.
3) Discuss the study design protocol for bioavailability studies.
4) Write a note on non-linear pharmacokinetics with Michaelis Menten equation.

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

5) Describe the factors affecting drug-protein binding. What are the effects of protein drug binding on pharmacokinetic parameters ?
6) Write a note on physicochemical factors affecting drug absorption with special emphasis on pH-partition hypothesis.

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SLR-B – 14

Seat No.	

M.Pharmacy (Semester – II) (CGPA/CBCS) Examination, 2016
PHARMACEUTICS
Sterile Product Formulation and Technology

Day and Date : Saturday, 30-4-2016 Total Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) What is importance of sterilization in parenterals ? Explain various methods of sterilization used in formulation and development of parenterals.

2) Explain in detail formulation and characterization of dry product injection.

3) Explain in detail formulation and characterization of loaded erythrocytes.

4) Explain in detail selection of polymeric components for parenterals.

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

1) Explain in detail pharmacopoeial requirement for LVP and SVP.

2) Discuss in detail preparation of various powdered parenteral products.

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SLR-B – 15

Seat No.	

M.Pharmacy (Semester – II) (CGPA /CBCS) Examination, 2016
(New CGPA Pattern)
PHARMACEUTICS
Cosmeticology

Day and Date : Saturday, 30-4-2016 Max. Marks : 70

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

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

1) Explain in detail herbal cosmetics.

2) Describe skin irritation and sensitization clinical safety protocols for cosmetics.

3) Elaborate in brief about :

   A) Aerosol cosmetics

   B) Regulatory perspectives for sale of cosmetics.

4) Explain briefly manufacturing of creams and powder cosmetics.

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

1) Explain physiological considerations for cosmetics.

2) Write a short note on :

   A) Rheology of antiperspirant and nail products

   B) Hair waving and hair planting advance cosmetics.

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SLR-B – 16

Master of Pharmacy (Semester – II) (Quality Assurance) (CGPA/CBCS) Examination, 2016
QUALITY ASSURANCE TECHNIQUES – II

Day and Date : Tuesday, 26-4-2016 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) Explain the types of process validation giving suitable examples.
2) Describe the provisions of Factories Act, 1948 regarding health and safety of employees.
3) Give an exhaustive account on validation documentation.
4) Describe salient features of Revised Schedule-M under Drugs and Cosmetics Act.

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

5) i) Explain the important consideration in validation of cleaning.
   ii) Describe the recent development in IPR laws impacting pharmaceutical industry in India.
6) Giving suitable example explain the steps involved in analytical method validation.

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SLR-B – 17

Seat No.	

M. Pharmacy (Semester – II) (Quality Assurance) Examination, 2016 (CGPA/CBCS)
QUALITY ASSURANCE TECHNIQUES – III

Day and Date : Thursday, 28-4-2016 Total. Marks : 70
Time : 10.30 a.m. to 1.30 p.m.

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

1) Define : Active Ingredient, In-process Material, Theoretical Yield, Biostatics and goal of CPCSEA.

2) What is ANOVA ? What is correlation ? Explain the types of correlation.

3) What is OECD ? What are its 3R-principles ? Discuss the conduct of non-clinical laboratory study (FDA/GLP).

4) Why HPLC performance is verified ? Name characteristics for performance verification of HPLC. What is CFR ?

B. Answer **all** : **(2×20 = 40)**

5) What is validation of Analytical method ? Name typical analytical characteristics used in method validation. Discuss these characteristics including definition, determination etc. of each character (USP).

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

SLR-B – 18

Seat No.	

Master of Pharmacy (Quality Assurance) (Semester – II) (CGPA CBCS) Examination, 2016
QUALITY CONTROL

Day and Date : Saturday, 30-4-2016 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 important steps of monitoring of clinical trials.
2) Explain the role of important components of Quality Assurance in pharmaceutical manufacturing.
3) Describe the usefulness of Quality Risk Management in process development.
4) Describe the factors to be considered while developing the packaging for a new formulation.

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

5) i) What is the need of Quality by Design ? Explain important elements of the same.
   ii) Describe the role of statistics in drug product development.
6) Explain in detail the methodology of long-term and accelerated stability testing of new drug product as per ICH.

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SLR-B – 21

Seat No.	

Master of Pharmacy (Pharmaceutical Chemistry) (Semester – II) (CGPA CBCS) Examination, 2016
QUALITY CONTROL

Day and Date : Saturday, 30-4-2016 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 important steps of monitoring of clinical trials.
2) Explain the role of important components of Quality Assurance in pharmaceutical manufacturing.
3) Describe the usefulness of Quality Risk Management in process development.
4) Describe the factors to be considered while developing the packaging for a new formulation.

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

5) i) What is the need of Quality by Design ? Explain important elements of the same.
   ii) Describe the role of statistics in drug product development.
6) Explain in detail the methodology of long-term and accelerated stability testing of new drug product as per ICH.

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