Exam Date & Time: 03-May-2018 (02:00 PM - 05:00 PM)

Common with PCH-MPL 201T

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL ANALYSIS)
DATE: 03/05/2018
TIME: 2:00 PM - 5:00 PM

Advanced Instrumental Analysis [PCH-MPA201T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) Explain the various steps involved in 2D NMR Spectroscopy with diagram. List out the various 2D NMR techniques. (5)

2) Explain the Mass fragmentation rules. (5)

3) List out the similarities and differences between Proton NMR and ^{13}C NMR. (5)

4) What are metastable ions? When do they appear in a spectra and what is their importance? (5)

5) Explain GC-MS in terms of its principle and application in pharmaceutical sciences (5)

6) What are the common problems in chromatographic columns and how are they solved? (5)

7) What is flash chromatography? Explain the advantages and applications (5)

8) With an example, explain Woodward-Fieser rule for α, β carbonyl compounds (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) Write the respective chemical shift value for the following protons:
i) Aromatic protons
ii) Methyl protons
A) iii) NH_2 protons (2)

iv) OH protons

B) What are deuterium exchange reactions?

C) Define Mass Fragmentation.

D) Mention the IR values for any four important functional groups

E) What you mean by MALDI and TOF?

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Date & Time: 05-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL ANALYSIS)
DATE: 05/05/2018
TIME: 2:00 PM - 5:00 PM

Modern Bioanalytical Techniques [PCH-MPA202T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) Explain solid phase extraction as sample preparation method in biopharmaceutical analysis (5)

2) Discuss any three alternative methods of dissolution testing and their applications (5)

3) Explain in detail the saturation shake flask method for solubility determination (5)

4) Explain how stability is established during bioanalytical method validation as per FDA (5)

5) Write note on storage facilities of a cell culture lab (5)

6) With suitable examples, explain the implications of Pharmacodynamic interactions (5)

7) Explain the ICH recommendation with regard to single and repeated dose toxicity studies as per its guideline on Toxicokinetics. (5)

8) Explain the implications of protein binding. (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) Enlist the various biopharmaceutical considerations in drug product design (2)

A)

B) Explain cross over study design in bioequivalence studies

C) Explain Biosafety level I and III

D) Under what circumstances metabolite concentration must be determined as guideline on Toxicokinetics?

E) Mention the models used during metabolite identification studies.

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Date & Time: 07-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL ANALYSIS)
DATE: 07/05/2018
TIME: 2:00 PM - 5:00 PM

Quality Control and Quality Assurance [PCH-MPA203T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) What is Master Formula Record? Write the procedure to make a MFR (5)

2) How packaging operations are carried out? Explain in detail. (5)

3) Explain the WHO guidelines for distribution records. (5)

4) Explain the hydrolytic resistance test for glass containers. (5)

5) Discuss the cGMP guidelines as per FDA (5)

6) Discuss any two methods for the analysis of raw materials. (5)

7) Explain the test procedures and acceptance criteria for new drug substance (5)

8) Give the detailed set of guidelines for handling of animals as per CPCSEA (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) Enlist the Quality control tests for suppositories. (2)

A)

B) How will you calculate percentage yield? Explain (2)

C) List down the contents of standard operating procedure.

D) How do you carry out the test procedures for the finished products?

E) What are the objectives of GLP?

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ate & Time: 09-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL ANALYSIS)
DATE: 09/05/2018
TIME: 2:00 PM - 5:00 PM

Herbal and Cosmetic Analysis [PCH-MPA204T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) Mention WHO guidelines in quality assessment of herbal drugs. (5)

2) How do you evaluate cosmetic products? (5)

3) Explain the WHO guidelines for herbal drug standardization. (5)

4) What are the main sources of adulteration of herbal drugs? (5)

5) What are the specifications for testing skin care products as per BIS? (5)

6) Explain the protocol for stability testing of natural products. (5)

7) Explain the significance of ash value determination. (5)

8) What are the challenges in monitoring the safety of herbal medicines? (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) What is the difference between Siddha and Unani medicine? (2)

A)

B) What are personal hygiene preparations? (2)

C) Define peroxide value. Give its importance.

D) Give the importance of monograph analysis.

E) Write two methods for the determination of foreign matter.

(2)

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