Exam Date & Time: 01-Dec-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Date:01-12-2018
(PQA-MPH101T/PQA-MIP101T/PQA-MPC101T/PQA-MPA101T/PQA-MPB101T/PQA-MPG101T /PQA-MPL101T)

Modern Pharmaceutical Analytical Techniques [PQA-MQA101T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Write a note on pumps used in HPLC (10)

2) Explain the theory of UV-Visible spectroscopy. List the qualitative applications of UV-Visible spectroscopy (10)

3) Explain the radiation sources of IR spectrometer. Comment on IR of peaks of paracetamol and aspirin. (10)

4) Why does a signal for a particular set of protons is split into a multiplet? Discuss with suitable example (10)

5) Classify with example ionization techniques in mass spectrometry. Explain the principle of soft ionisation techniques. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Write a note on differential scanning calorimetry. (5)

7) Explain the principle and application of ion exchange chromatography. (5)

8) What is the role of excitation and emission filters in fluorimeter? Explain the interferences in flame photometry in brief. (5)

9) List the factors affecting electrophoresis. Write the applications of Radio immune assay (5)

10) Name indicator and reference electrodes in the acids-base, redox and complexometric potentiometric titrations. List requirements for the crystalline solid (5)

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2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specalization: Pharmaceutical Quality Assurance
Date: 03-12-2018
Quality Management Systems [PQA-MQA102T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Explain in detail about Total Quality Management. (10)

2) Discuss in detail about Quality risk management (10)

3) Discuss in detail about Bench marking (10)

4) Explain the process of long-term stability studies for zone III countries with the help of a stability study protocol for semisolids (10)

5) Write in short about the packaging and labelling system (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Explain the evolution of quality and its impact on the pharma industry (5)

7) Explain in detail about ISO 9001:2008 (5)

8) Explain P chart with suitable examples (5)

9) Explain in detail about evaluation of the complaints. (5)

10) Write the evaluation activities involved in quality system control (5)

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

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization:Pharmaceutical Quality Assurance
Date:05-12-2018
Quality Control and Quality Assurance [PQA-MQA103T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Write a note on good warehousing practices. (10)

2) Discuss ICH Q3A guideline in detail. (10)

3) Write a note on Master Formula Record (MFR). (10)

4) How the expiry date of pharmaceutical product is calculated? (10)

5) Write a note on stability testing for new substance and product as per ICH guidelines. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Enlist and explain IPQC tests for parenterals and ophthalmics. (5)

7) Write a note on Good Documentation Practices (GDP). (5)

8) Write a note on process deviations. (5)

9) Differentiate between inventions and discoveries. Enlist non-patentable inventions as per Indian Patent Act-1970. (5)

10) Differentiate between regulated and non-regulated markets. (5)

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

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization:Pharmaceutical Quality assurance
Date:07-12-2018
Product Development and Technology Transfer [PQA-MQA104T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Discuss SUPAC guidelines of USFDA (10)

2) What is stability analysis? Explain stability testing methods (10)

3) What is a "phase III clinical trial" as per USFDA? Explain. (10)

4) Explain the steps involved in technology transfer in analytical R & D (10)

5) Discuss the quality control tests for metal containers for eye ointments (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Enlist the techniques for the study of crystal properties in pre-formulation and explain any one. (5)

7) What is technology transfer? Why it is done? Explain (5)

8) Explain CTD structure as per FDA (5)

9) Explain bulk characterization of solid dosage form in pre-formulation studies. (5)

10) Discuss the adverse event reporting requirements of PMS of USFDA (5)

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