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Question Paper

Exam Date & Time: 27-Nov-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 27-11-2017
TIME : 2:00PM - 5:00PM

(Common Paper for the following specializations: Pharmaceutics, Industrial Pharmacy, Pharmaceutical Chemistry, Pharmaceutical Analysis, Pharmaceutical Quality Assurance, Pharmaceutical Biotechnology, Pharmacology and Pharmacognosy)

Modern Pharmaceutical Analytical Techniques [PQA-MQA101T]

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

a

Answer all the questions.

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

1) Write a note on Ultra-Performance Liquid Chromatography. (5)

2) With the help of neat and labelled diagram, discuss the working of thermobalance employed in TGA. (5)

3) List the advantages ELISA and potentiometric titrations (5)

4) Explain the qualitative applications of UV/Visible spectroscopy in brief. (5)

5) Explain the working of Golay cell detector (5)

6) Explain the principle and applications of micellar electrokinetic chromatography (5)

7) Explain the information obtained from the proton NMR spectrum (5)

8) What are mass analyzers? Classify them with examples and explain any one (5)

b

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

9) What is void volume and void time in HPLC? (2)

A)

B) List the applications of X ray diffraction. (2)

C) List the structural requirements for a molecule to exhibit fluorescence. (2)

D) List the types of nebulizers used in AAS. (2)

E) How simplification of complex proton NMR spectra can be achieved? (2)

Paper

Time: 29-Nov-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM: MPHARM SEMESTER 1
DATE: 29/11/2017
TIME: 2:00PM - 5:00PM
Quality Management Systems [PQA-MQA102T]

Duration: 180 mins.

Marks: 50

Answer all the questions.

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

1) Write a note on stability testing of drug substance with special emphasis given to scope, selection of batches, testing frequency and storage conditions as per ICH Q1(A)R2. (5)

2) Write a note on statistical control charts based on variables. (5)

3) Write a note on risk assessment as per ICH Q9. (5)

4) Define the concept of regulatory compliance. Enlist the types and reasons for benchmarking in pharmaceutical industry. (5)

5) Discuss Total quality management system in detail. (5)

6) Write in detail about annual product review. (5)

7) Prepare a checklist for OOS investigation. (5)

8) Discuss CAPA in detail.

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

9) Differentiate between stress and accelerated stability testing. (2)

A)

B) Define the terms "Risk" and "Quality Risk Management" as per ICH Q9. (2)

C) Give the significance of statistical process control. (2)

D) Define Six sigma concept. (2)

E) Give any four importance of CFR-21 part 11.

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Paper

e: 01-Dec-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 01-12-2017
TIME : 2:00PM - 5:00PM
Quality Control and Quality Assurance [PQA-MQA103T]

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

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

1) Discuss the responsibilities of study director and quality assurance unit in non-clinical testing facility as per Good Laboratory Practices (GLP). (5)

2) Discuss the building design and construction features of pharmaceutical plant as per cGMP guidelines. (5)

3) Classify impurities in new drug substance. Discuss the approach to develop the specification for the same as per the thresholds. (5)

4) Enlist and explain the IPQC test for tablets and capsules. (5)

5) Explain types of disposal methods for waste and scrap in pharmaceuticals. (5)

6) What is copyright? explain its types. (5)

7) Explain the content and structure of Standard operating procedure (5)

8) Explain in detail about Batch manufacturing record (5)

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

9) Differentiate between Quality Assurance (QA) and Quality Control (QC). (2)

A)

B) Enlist the types of trainings in pharmaceutical industry. (2)

C) Enlist the IPQC tests for parenterals. (2)

D) What are the objectives of IPQC test? (2)

E) Give two examples for level 2 and level 4 documents (2)

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& Time: 04-Dec-2017 (02:00 PM - 05:00 PM)

MANIPAL UNIVERSITY

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 04-12-2017
TIME : 2:00PM - 5:00PM

Product Development and Technology Transfer [PQA-MQA104T]

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

Answer all the questions.

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

1) What is pre-formulation? Why it is essential for drug development. (5)

2) What is solubility? Explain co-solvency and hydrotropy with an example. (5)

3) Briefly discuss on Phase III clinical trials. (5)

4) What are the types of certifications under ANDA application? Write the procedure for ANDA application under paragraph IV certification. (5)

5) Briefly explain the BACPAC guidelines of USFDA. (5)

6) Discuss intra-cutaneous test for plastic containers for injectable preparation. (5)

7) Explain the responsibilities of receiving unit in technology transfer. (5)

8) Explain the documentation required in technology transfer in brief. (5)

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

9) Why stability testing is essential? (2)

A)

B) What are the quality control tests for plastic containers for non-parenteral preparations. (2)

C) What is "sterilization test" and "fragmentation test" for the evaluation of rubber closures. (2)

D) What is a "phase IV clinical trial" as per USFDA? (2)

E) List the stages of formulation development in technology transfer. (2)

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