Exam Date & Time: 02-Dec-2019 (02:00 PM - 05:00 PM)

PQA

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

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 the clinical investigations as per USFDA. (10)

2) Describe the modular structure of the eCTD (10)

3) Describe the bulk characterization of solid dosage form in pre-formulation studies. (10)

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

5) Explain the evaluation of plastic containers for parenteral preparations (10)

SECTION - B

Answer all the questions.

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

6) Explain how the Hatch Waxman Act benefits the Innovator, Generic industry and the patients. (5)

7) What are the basic elements of cGMP? Discuss the GMP inspection of GMP and FDA's decisions on the same. (5)

8) What is polymorphism? Enlist its characterisation techniques and explain any one method (5)

9) Explain the importance of solubility determination in pre-formulation (5)

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

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Exam Date & Time: 27-Nov-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Quality Management Systems [PQA-MQA102T - S3]

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

SECTION - A

Answer all the questions.

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

1) Discuss strategic quality management in detail with relevant examples (10)

2) Explain in detail about NABL certification and accreditation (10)

3) Discuss in detail about ICH Q1B guidelines in detail (10)

4) Discuss in detail about Statistical control charts and explain with the help of relevant case studies (10)

5) a. Explain the application of process performance, product quality monitoring system and change management system in product life cycle.
b. Draw the flow chart for Phase 2 Out of specification investigation (10)

SECTION - B

Answer all the questions.

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

6) Discuss the importance of CFR-21 part 11 in detail (5)

7) Explain the advantages of statistical control in the pharmaceutical industries (5)

8) Explain the importance of ICH Q8(R2) (5)

9) Explain bench marking process (5)

10) Complaint was received from Derek Clarke Pharmacy to Global Pharma. Ltd regarding less count of tablets in 500s bottle of Amlodipine 5 mg Tablets. Write the process involved in handling and evaluation of this complaint (5)

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Exam Date & Time: 29-Nov-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Quality Control and Quality Assurance [PQA-MQA103T - S2]

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) A drug substance with 0.5g maximum daily dose has three impurities i.e. Impurity A (0.10%), Impurity B (0.12%), and Impurity C (0.16%). Suggest a strategy to decide about identification and qualification of the listed impurities. Justify the strategy. (10)

3) Organize and explain the best practices for document creation and storage in pharmaceutical industry. (10)

4) What steps to be taken to effectively handle the disposition of unwanted pharmaceuticals? Comment on consequences of improper disposal. (10)

5) How to set-up a clean room? Provide the clean room classification based on airborne particulate matter. (10)

SECTION - B

Answer all the questions.

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

6) Explain the basis for classification of residual solvents in pharmaceutical products with appropriate examples. (5)

7) Prepare a format of Batch Manufacturing Record (BMR) for tablet production. (5)

8) Enlist the contents of quality profiling of a drug to be submitted for the grant of marketing authorization (5)

9) What is ICH? Explain the process to harmonize a new concept under ICH. (5)

10) Write a short note on control on animal house. (5)

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