Exam Date & Time: 03-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 QUALITY ASSURANCE)
DATE: 03/05/2018
TIME: 2:00 PM - 5:00 PM

Hazards and Safety Management [PQA-MQA201T]

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

a

Answer all the questions.

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

1) Explain in detail the stages of fire and explosion hazard management process. (5)

2) Define and classify explosion with examples. (5)

3) Write and explain the schematic diagram of air handling unit. (5)

4) Explain the stages of preliminary hazard analysis in brief. (5)

5) Explain renewable and non-renewable energy resources with examples. (5)

6) Explain the hazards of methylating agents with examples (5)

7) Explain the control measures for chemical hazards in brief. (5)

8) How to minimize the contaminants due to building and facility in pharmaceutical industry? (5)

b

Answer all the questions.

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

9) What are toxic gases? Write examples. (2)

A)

Vasanthakumar

B) List the entry routes of chemicals in to the human body.

C) List the sources of radioactivity. (2)

D) Name toxic intermediate compounds as sources of chemical hazard. (2)

E) List the sources of waste in pharmaceutical industry. (2)

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

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MANIPAL ACADEMY OF HIGHER EDUCATION

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

Pharmaceutical Validation [PQA-MQA202T]

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

a

Answer all the questions.

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

1) What are qualification and calibration? Differentiate the same. (5)

2) Explain operational qualification of FTIR. (5)

3) Explain the design qualification of dissolution test apparatus. (5)

4) Write a note on validation of pharmaceutical water system. (5)

5) What is analytical method validation? Explain accuracy as per ICH guideline. (5)

6) Write a note on process validation of aseptic filling. (5)

7) Define Electronic records and Electronic signatures. Discuss the requirements of Electronic records as per 21CFR part 11. (5)

8) Explain the primary process parameters in cleaning validation. (5)

b

Answer all the questions.

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

9) what is VMP? Enlist its scope. (2)

A)

B) Name the phases of validation.

C) Name the parameters to be checked for system suitability test for HPLC with its tolerance limit. (2)

D) Why the life cycle approach is essential for process validation? (2)

E) What is CIP? (2)

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e & 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 QUALITY ASSURANCE)
DATE: 07/05/2018
TIME: 2:00 PM - 5:00 PM

Audits and Regulatory Compliance [PQA-MQA203T]

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

a

Answer all the questions.

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

1) Discuss in detail about management of audit in terms of planning process and responsibilities (5)

2) Explain the role of quality systems and audits in pharmaceutical manufacturing facility. (5)

3) Prepare a detailed audit checklist for GMP certified liquid oral dosage formulation manufacturing facility. (5)

4) Prepare detailed audit checklist for packing material supply vendor (5)

5) Explain the importance of pharmaceutical warehousing facility and write a summarised checklist for auditing a warehouse. (5)

6) Write a detailed checklist for auditing microbiology laboratory. (5)

7) Classify and explain in detail about GMP deficiencies with examples (5)

8) Write the audit checklist for Effluent Treatment Plant (5)

b

Answer all the questions.

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

9) Write a note on administration of an audit (2)

A)

B) Write a note on management responsibilities toward audit (2)

C) Write the requirements for water distribution system pipework in Pharmaceutical industry. (2)

D) Give a comparative chart for HVAC parameters in sterile and non-sterile area (2)

E) Write the parameters to be checked in Effluent and its standards before discharge into the environment as per EPA (2)

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Date & 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 QUALITY ASSURANCE)
DATE: 09/05/2018
TIME: 2:00 PM - 5:00 PM

Pharmaceutical Manufacturing Technology [PQA-MQA204T]

Duration: 180 mins.

Marks: 50

a

Answer all the questions.

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

1) Enlist and explain legal requirements and licences to set up API and formulation industry. (5)

2) Write a note on improved material handling. (5)

3) Write a note on film coating methods employed in tablet coating. (5)

4) Explain different types of closures and closure liners used in packaging. (5)

5) Write a note on principles of production planning. (5)

6) Write a note on design space and its significance in QbD. (5)

7) What is 'critical area' according to USFDA guidelines on asceptic processing? Expain in detail. (5)

8) Write a note on Process Automation of sterile semisolid preparations. (5)

b

Answer all the questions.

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

9) Define the terms production scheduling and routing. (2)

A)

B) Differentiate between at-line and in-line production control.

C) Differentiate between thermo plastic and thermos-set plastic

D) Differentiate between Type-I and Type-II glass.

E) Differentiate Clean in Place and Sterilization in Place. (2)

(2)

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