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.

Advanced Pharmaceutical Analysis [PCH-MPA102T - S2]

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

SECTION - A

Answer all the questions.

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

1) How do you carry out impurity profiling of pharmaceuticals? Explain (10)

2) Explain the principle and specific advantages of Fluorescent immune assay and Enzyme immune assay (10)

3) What is elemental impurity? Classify those as per ICH guidelines with few examples.
What are the possible sources of elemental impurities?
Give the working principle involved in graphite furnace-AAS. (10)

4) Discuss with an example the possible sources of organic impurities in new drug substances? (10)

5) What is Photo stability of a drug? Explain the photo stability testing guidelines for pharmaceuticals (10)

SECTION - B

Answer all the questions.

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

6) Classify organic solvents with examples. Discuss the reporting levels of residual solvents as per ICH guidelines. (5)

7) Define the following terminology as per the ICH guidelines:
i) medDRA ii) unidentified impurity
iii) enantiomeric impurity iv) qualification threshold (5)

8) Discuss the evaluation of in-house and marketed extracts of phytoconstituents. (5)

9) What is analytical method validation? Define any 4 important method validation parameters (5)

10) What is Accelerated stability study? Write a note (5)

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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.

Pharmaceutical Validation [PCH-MPA103T - S3]

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

SECTION - A

Answer all the questions.

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

1) What are patents? Explain the conditions to be satisfied by an invention to be patentable. (5)

A)

B) Discuss on the different stage of filing a patent application (5)

2) What is specificity and accuracy of an analytical method? How specificity and accuracy studies are carried out for a chromatographic method (6)

A)

B) What are the analytical method validation parameters as per ICH and USP? Write a note on types of analytical methods to be validated (4)

3) Explain the potential items for a cleaning validation master plan (5)

A)

B) Write a note on different phases of computer system validation (5)

4) How retrospective validation is performed? Explain in detail (5)

A)

B) Explain the WHO requirements with respect to Factory acceptance test and site acceptance test (5)

5) Explain in detail about Requirements for balance use with respect to the following aspects. a) Location of the Balance b) Room Temperature c) Atmospheric humidity d) Light e) Weighing vessel (5)

A)

B) Explain the process involved in the Qualification of liquid chromatography-mass spectrometers (5)

SECTION - B

Answer all the questions.

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

6) What is PCT? What are the objectives of PCT and advantages of PCT (5)

7) Write a note on mechanism of contamination and types of cleaning situations (5)

8) How following parameters are evaluated during Qualification of UV-Visible spectrophotometers? A) Limit of stray light B) Photometric drift (5)

9) Explain the terms validation and qualification. Mention the differences between the two (5)

10) What are the specifications that are laid down for Air filtration and airflow direction as per WHO guidelines on HVAC systems? (5)

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Time: 02-Dec-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Food Analysis [PCH-MPA104T - S2]

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

SECTION - A

Answer all the questions.

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

1) Write the principle and procedure involved in the microbiological assay of Vitamin B2 (6)

A)

B) Discuss the principle and procedure involved in the estimation of benzoates in beverages (4)

2) Discuss the principle and procedure involved in Babcock and Gerber method for milk fat determination (6)

A)

B) Discuss the principle and method involved in the determination of Hexanal and TBARS for assessing lipid oxidation of given fat or oil (4)

3) What is Agmark? Discuss the salient features and importance of Agmark (3)

A)

B) Discuss the methods used for the detection of any two natural colours in food (2)

C) Write the principle, reactions and procedure involved in the assay of vitamin-C in food samples by 2,6-Dichloroindophenol Titrimetric Method (5)

4) How will you determine the total solids and over-run in ice cream? Explain. (5)

A)

B) Explain the procedure involved in the analysis of spirits (5)

5) Write the principle and procedure involved in Somogyi-Nelson method of analysis of reducing sugar content (5)

A)

B) Explain the enzymatic methods of carbohydrate analysis

SECTION - B

Answer all the questions.

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

6) What is FDA FSMA? Write a note on rules and related programmes, background and activities related to FDA FSMA. (5)

7) Discuss Molybdate test for castor oil, Halphen's test for cotton seed oil and Holde's test for mineral oils in edible oils (5)

8) Explain caramelization with example. Give an account on dietery fibre and crude fibre (5)

9) Explain the analysis of organophosphorus pesticides (5)

10) Explain the method of analysis of wine (5)

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