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Date & Time: 03-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 Analysis
 Date: 03-12-2018

Advanced Pharmaceutical Analysis [PCH-MPA102T]

Duration: 180 mins.

Marks: 75

SECTION - A

Answer all the questions.

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

- 1) Discuss the rationale for reporting, identification and qualification of an organic impurity as per ICH guidelines. Add a note on sources of organic impurities. (10)
- 2) What is biomarker? Discuss the evaluation of phytoconstituents by using HPTLC fingerprinting? (10)
- 3) What is photostability of pharmaceuticals? Explain photostability testing guidelines (10)
- 4) Explain the principle and procedure of assay of Heparin IP (10)
- 5) What are immune assays? Explain the basic principle in enzyme immune assay (10)

SECTION - B

Answer all the questions.

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

- 6) What are residual solvents? Classify them as per ICH guidelines with examples. (5)
- 7) Name few class-1 elemental impurities. Give the working principle of any one instrument used to identify the elemental impurities. (5)
- 8) Define the following terms as per ICH guidelines: (5)

i) new drug substance	ii) new drug product
iii) identification threshold	iv) qualification threshold
- 9) What are advantages and disadvantages of immune assay? Explain (5)
- 10) Write a note on ICH stability guidelines for biological products (5)

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MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization – Pharmaceutical Analysis

Date: 05-12-2018

Pharmaceutical Validation [PCH-MPA103T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) a) What are patents? Explain the conditions to be satisfied by an invention to be patentable. (5) (10)
b) Write a note different types of infringement of patents (5)
- 2) a) What is specificity and accuracy of an analytical method? How specificity and accuracy studies are carried out for a chromatographic method. (6) (10)
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) a) Explain the elements of cleaning validation master plan. (6) (10)
b) Write a note on mechanism of contamination and types of cleaning situations(4)
- 4) Explain the procedure for checking following parameters of an UV-Visible spectrophotometer. a) Spectral slit-width b) Wavelength accuracy c) Wavelength precision (10)
- 5) Explain in detail about regulatory requirement for design of HVAC systems and components (10)

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) What is system suitability testing? Explain how system suitability parameters are established for a chromatographic method (5)
- 8) How are the following parameters assessed during qualification of dissolution apparatus?. a) Vessel Verticality b) Basket Depth c) Paddle Depth (5)
- 9) List out the requirements for weights used in the qualification of Balances (5)

10) Explain the terms DQ, IQ, OQ, PQ.

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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 Analysis

Date : 07-12-2018

Food Analysis [PCH-MPA104T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) a) Write the principle and procedure involved in the microbiological assay of folic acid (5)
b) Discuss the principle and procedure involved in any two non-solvent wet extraction method for milk fat determination (5) (10)
- 2) a) Explain the method used for determination of iodine value, saponification value of oils/fats. Add a note on their significance. (6)
b) Discuss the principle and method involved in the determination of Hexanal and TBARS for assessing lipid oxidation of given fat or oil. (4) (10)
- 3) a) Write the principle and procedure involved in the assay of vitamin-C in fruit juice with chemical reactions. (5)
b) What are the reasons for adding colour additives in food products? How food colours are classified and add note on determination of synthetic food colours (5) (10)
- 4) Explain the methods of determination of methanol, higher alcohol and total aldehyde in spirits (10)
- 5) Enlist the various methods of analysis of proteins. Explain the principle and procedure involved in Kjeldahl method and Ninhydrin method. (10)

SECTION - B

Answer all the questions.

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

- 6) Write the methods used for detection and estimation any one preservative used in food products (5)
- 7) Explain the following
i) Caramelisation ii) Millard Reaction iii) Gelatinization iv) Retrogradation (5)
- 8) Explain the method of determination of total solids in the ice cream and total ash on (5)

PTO

dry basis in milk powder

9)

Explain the method of determination of salt content in Butter

10)

What are pests? Discuss the effect of pests on various food. Explain the pesticide cycle

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Exam Date & Time: 31-Dec-2018 (09:30 AM - 12:30 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm Semester I – End Semester Examination, December 2018

PCH-MPA104T:Food Analysis

Date:31/12/2018

Food Analysis [PCH-MPA104T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) a) Write the principle and procedure involved in the microbiological assay of Vitamin B12 (6)
b) Discuss the methods used for the detection of any two natural colours in food. (4) (10)
- 2) a) Write any two solvent extraction methods including general sample preparation used for determination of total lipid content of a food. (6)
b) What are the different types of adulteration in edible oil and fats? Discuss the sodium azide test for synthetically made mustard oil and Halphen's test for detection of cotton seed oil (4) (10)
- 3) a) What is Agmark? Discuss its salient features and importance. (5)
b) Write the principle, reactions and procedure involved in the assay of vitamin-C in food samples by 2,6-Dichloroindophenol Titrimetric Method (5) (10)
- 4) a) Explain the enzymatic methods of carbohydrate analysis (5)
b) Explain the procedure involved in the analysis of spirits (5) (10)
- 5) What are pesticide residues? Explain in detail the methods of determination of pesticide residues in food grains, fruits and vegetables (10)

SECTION - B

Answer all the questions.

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

- 6) Write a note on FDA Food Safety Modernization Act (5)
- 7) How will you determine the total solids and over-run in ice cream? Explain the procedure (5)
- 8) How will you estimate the percentage of protein by Kjeldahl method? Explain in detail (5)

PA104T

- 9) Explain the phenol-sulfuric acid method of analysis of total carbohydrate content (5)
- 10) Explain the analytical methods involved in the analysis of vinegar (5)

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