

# Question Paper

Exam Date & 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**

**Advanced Pharmaceutical Analysis [PCH-MPA102T]**

**Marks: 50**

**Duration: 180 mins.**

**Answer all the questions.**

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

- 1) What are residual solvents? Classify them as per ICH guidelines with examples. (5)
- 2) List out the analytical instruments used for determining elemental impurities. Give the working principle involved in ICP-MS. (5)
- 3) What is biomarker? Discuss the evaluation of phytoconstituents by using HPTLC fingerprinting? (5)
- 4) Discuss the rationale for reporting, identification and qualification of an organic impurity as per ICH guidelines. (5)
- 5) Explain competitive and non-competitive immunoassay (5)
- 6) How do you assay Heparin IP? Give the procedure (5)
- 7) write a note on accelerated stability studies of drugs (5)
- 8) What are biologicals? Write the sampling guidelines for the same (5)

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

- 9) Define (2)
  - A) Identified impurity
  - B) qualification of impurity
- B) Differentiate HPLC with HPTLC in applications. (2)
- C) Define Photostability of pharmaceuticals (2)
- D) What are the steps in PCR studies (2)
- E) What are monoclonal and polyclonal antibodies (2)

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END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017  
PROGRAM : MPHARM SEMESTER I**

**DATE :01-12-2017**

**TIME : 2:00PM - 5:00PM**

**Pharmaceutical Validation [PCH-MPA103T]**

**Duration: 180 mins.**

**Marks: 50**

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

- 1) What is specificity and accuracy of an analytical method? How specificity and accuracy studies are carried out for a chromatographic method. (5)
- 2) What are the different computerized operations associated with a pharmaceutical industry? Write a note on fundamental task and supporting procedures involved in the validation of computer systems? (5)
- 3) What is a complete specification? Explain the contents and format of a complete specification (5)
- 4) What is Patent Cooperation Treaty? Discuss the objectives and benefits of PCT and explain the PCT filing system (5)
- 5) List out the advantages of validation. (5)
- 6) Discuss in detail about Prospective validation. (5)
- 7) Name the parameters that must be checked during qualification of IR spectrophotometers (5)
- 8) Write about level 3 and level 4 qualification of pH meters. (5)

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

- 9) What is peak purity? How it is established for a chromatographic method? (2)
  - A) What are the various mechanisms (source) of contamination in pharmaceutical operations and enlist the factors to be considered for setting acceptable limits for cleaning process. (2)
  - B) Under what circumstances revalidation is required? Explain (2)
  - C) Explain Design qualification (2)
  - D) Explain the difference between validation and qualification. (2)
  - E)

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# Question Paper

Date & 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**

**Food Analysis [PCH-MPA104T]**

**Duration: 180 mins.**

**Marks: 50**

**Answer all the questions.**

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

- 1) Explain the method used for determination of, iodine value and saponification value of oils/fats and add a note on their significance. (5)
- 2) A. Write the principle and procedure involved in the bioassay of Vitamin D. (5)  
B. Discuss the methods used for the detection of any two natural colours in food. (3+2=5)
- 3) Classify the methods used for assay of vitamins. Write the principle and procedure involved in the microbiological assay of Vitamin B2. (5)
- 4) A. Discuss the methods involved in the extraction, qualitative and quantitative analysis of any two antioxidants present in oils or fats. (5)  
B. Write the molybdate test for detection of castor oil in other oils. (4+1=5)
- 5) Explain the method of determination of salt content in butter. (5)
- 6) Explain the methods of analysis of vinegar. (5)
- 7) Write the principle and procedure involved in the Biuret method. (5)  
What are the advantages and disadvantages?
- 8) Explain the method of determination of organophosphorus pesticide residues in food grains. (5)

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

- 9) Write the ferric chloride test and modified Mohler's test used for identification of benzoic acid in food. (2)
  - A) (2)
  - B) Discuss the method used for estimation of MSG in food. (2)
  - C) How will you detect the presence of ammonium compounds in (2)



milk?

What is gelatinization and retrogradation of starch? Explain. (2)

How will you determine total ash on dry basis in milk powder? (2)

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## Question Paper

Exam Date & Time: 28-Dec-2017 (09:30 AM - 12:30 PM)



### MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal University, Manipal MPharm Theory End-Semester Examinations.  
MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES  
END SEMESTER THEORY EXAMINATIONS- DECEMBER 2017 - JANUARY 2018  
PROGRAM: MPharm SEMESTER 1  
DATE: 28/12/2017  
TIME: 9:30AM - 12:30PM

### Pharmaceutical Validation [PCH-MPA103T]

Marks: 50

Duration: 180 mins.

a

#### Answer all the questions.

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

- 1) What is linearity, range and precision of an analytical method? Explain how linearity, range and precision studies are carried out for a chromatographic methods. (5)
- 2) What is CIP and discuss its importance? Explain the cleaning parameters that makeup cleaning process. (5)
- 3) What are non-patentable inventions under section 3 of Indian Patent Act 1970? Discuss on the different types of patent applications. (5)
- 4) 4A. Discuss the V-model which illustrates the key lifecycle activities of computer system validation. (2 mark)  
4B. What is system suitability testing? Explain how system suitability parameters are established for a chromatographic method. (3 mark)
- 5) Discuss about Validation Master Plan including its advantage and the information that must be included in validation master plan (5)
- 6) Explain retrospective validation. List out the essential elements for Retrospective Validation. (5)
- 7) Name the parameters that must be checked during qualification of UV-Visible spectrophotometers (5)
- 8) Explain the regulatory requirements for receiving of samples and their storage. (5)

b

#### Answer all the questions.

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

- 9) What is robustness of an analytical method and how it is established? (2)  
A)  
B) What are trademarks and copyrights and discuss their benefits? (2)  
C) Write a note on cleaning validation master plan (2)  
D) Explain Change control (2)  
E) Name any four parameters that are checked during qualification of dissolution apparatus (2)

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Exam Date & Time: 30-Dec-2017 (09:30 AM - 12:30 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal University, Manipal MPharm Theory End-Semester Examinations.  
MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES  
END SEMESTER THEORY EXAMINATIONS- DECEMBER 2017 - JANUARY 2018  
PROGRAM: MPharm SEMESTER 1  
DATE: 30/12/2017  
TIME: 9:30AM - 12:30PM

### Food Analysis [PCH-MPA104T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

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

- 1) Discuss the principle and procedure involved in Babcock and Gerber method for milk fat determination (5)
- 2) 2A. 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. (3 mark)  
2B. What are the reasons for adding colour additives in food products? Classify food colours with examples. (2 mark)
- 3) Classify the methods used for assay of vitamins. Write the principle and procedure involved in the microbiological assay of Vitamin B<sub>2</sub> (5)
- 4) Discuss the principle and procedure involved in the determination of monosodium glutamate and saccharine in food (5)
- 5) How will you determine the total solids and over-run in ice cream? Explain. (5)
- 6) Explain the procedure involved in the analysis of spirits. (5)
- 7) Write the principle and procedure involved in Somogyi-Nelson method of analysis of reducing sugar content. (5)
- 8) Explain the enzymatic methods of carbohydrate analysis (5)

b

Answer all the questions.

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

- 9) What is peroxide value and what is its significance? Write the principle involved in the determination of peroxide value (2)
  - A)
  - B) What is BIS? Discuss the salient features and importance of BIS (2)
  - C) What is Maillard reaction? (2)
  - D) Describe pesticide cycle (2)
  - E) How will you test for sulphates in milk? (2)

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