

# Question Paper

Exam Date & Time: 29-Nov-2017 (02:00 PM - 05:00 PM)



**MANIPAL ACADEMY OF HIGHER EDUCATION**

**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) 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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