

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]

Marks: 75

Duration: 180 mins.

### 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:  
i) new drug substance                      ii) new drug product  
iii) identification threshold                iv) qualification threshold (5)
- 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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