

Date & Time: 05-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: 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.

(5)

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