

Question Paper

Exam Date & Time: 04-May-2019 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

MPharm - Pharmaceutical Quality assurance

MPharm Semester II - End-Semester Examination May 2019

Date : 04/05/2019

Pharmaceutical Validation [PQA-MQA202T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Describe important factors to be considered for tablet process validation. (10)
- 2) Explain mechanical calibration and performance verification test for type 1 dissolution apparatus. (10)
- 3) Describe operational qualification and performance qualification of HPLC (10)
- 4) What is Validation master file? Explain its principle and contents for a pharmaceutical industry (10)
- 5) Analyse the parameters of "validation of analytical methods for cleaning". Discuss the keys to method validation. (10)

SECTION - B

Answer all the questions.

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

- 6) What are LOD and LOQ? Explain its determination methods. (5)
- 7) Explain objective and advantages of factory acceptance test (5)
- 8) Explain the pharmaceutical water system validation life cycle. (5)
- 9) Explain the types of validation. (5)
- 10) Explain the computer system life cycle approach for a pharmaceutical industry (5)

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