

Question Paper

Exam Date & Time: 06-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 Analysis

MPharm Second Semester- End-Semester Examination- May-2019

Date : 06/05/2019

Quality Control and Quality Assurance [PCH-MPA203T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain in detail about packaging of sterile products. How will you calculate percentage yield? Explain. (10)
- 2) What is SOP? What are its benefits? Explain the method of preparation and maintenance of SOP. (10)
- 3) Explain specifications, verification of specifications and shelf life of finished products as per WHO guidelines. (10)
- 4) What is pharmaceutical quality system? Mention the objectives of GMP. How do you prepare Master plan? (10)
- 5) Mention the contents and specifications for the purchase of raw material. (10)

SECTION - B

Answer all the questions.

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

- 6) How will you calculate expiry date? Discuss accelerated stability testing (5)
- 7) Explain the In process quality control tests for suppositories (5)
- 8) Discuss packaging operations. (5)
- 9) What is the difference between routine and periodic test for finished products? Explain. (5)
- 10) What are the secondary packaging materials used? Enlist various transport packaging tests (5)

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