

Exam 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 Quality Assurance

Date: 05-12-2018

Quality Control and Quality Assurance [PQA-MQA103T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Write a note on good warehousing practices. (10)
- 2) Discuss ICH Q3A guideline in detail. (10)
- 3) Write a note on Master Formula Record (MFR). (10)
- 4) How the expiry date of pharmaceutical product is calculated? (10)
- 5) Write a note on stability testing for new substance and product as per ICH guidelines. (10)

SECTION - B

Answer all the questions.

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

- 6) Enlist and explain IPQC tests for parenterals and ophthalmics. (5)
- 7) Write a note on Good Documentation Practices (GDP). (5)
- 8) Write a note on process deviations. (5)
- 9) Differentiate between inventions and discoveries. Enlist non-patentable inventions as per Indian Patent Act-1970. (5)
- 10) Differentiate between regulated and non-regulated markets. (5)

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