

78

SVKM'S NMIMS

Shobhaben Pratapbhai Patel / School of Pharmacy & Technology Management

Programme: M. Pharm / M. Pharm + MBA (PQA)

Year: I

Semester: I

Academic Year: 2019-20

Marks: 75

Subject: Quality Management Systems

Time: 2.00 pm to 5.00 pm

Date: 20 November 2019

Duration: 3 hrs.

No. of Pages : 2

FINAL EXAMINATION

Instructions: Candidates should read carefully the instructions printed on the question paper and on the cover of the Answer Book, which is provided for their use.

- 1) Question No. 1 is compulsory.
- 2) Out of remaining questions, attempt **any 4** questions.
- 3) **In all 5 questions to be attempted.**
- 4) All questions carry equal marks.
- 5) Answer to each new question to be started on a fresh page.
- 6) Figures in brackets on the right hand side indicate full marks.
- 7) Assume suitable data if necessary

Section A

Q.1 Answer all the questions.

[3X5=
15 M]

- A. Briefly state
 - ISO 9001:2015
 - Design space
 - Control charts
- B. State true or false with justification.
 1. 'Strategy' is one of the soft 'S' of McKinsey 7S Framework.
 2. Fault tree analysis (FTA) is primarily used risk methodology to manage hazards.
- C. How do you perform photostability testing?
- D. What do you mean by SWOT Analysis?
- E. State brief procedure to conduct NABL certification.

Section B

- Q.2 A. What do you mean by Customer perception? What are the factors affecting customer perception? Suggest different approaches to satisfy customer needs. [8M]
- B. What is process capability? Describe the process capability indices. [7 M]
- Q.3 A. You are asked to perform benchmarking in your company. What are the reasons for benchmarking? How will you carry out the process? [8M]
- B. What is product life cycle? Describe application 'Corrective Action and Preventive Action System' throughout the Product Lifecycle. [7 M]
- Q.4 A. Discuss quality by design approach by taking example of immediate release tablet dosage form. [8M]
- B. What is six system inspection model? Give two examples of inspector's observations for each system. [7 M]
- Q.5 A. What are categories of cost of quality? Describe any 4 models for COQ. [8M]
- B. What are requirements for 'personnel' and 'Equipment' as per good manufacturing practices? [7 M]
- Q.6 A. How ICH Q8, Q9 and Q10 work together for maintaining quality of pharmaceutical products? [10 M]
- B. Explain IPQC tests for tablet dosage form. [5 M]
- Q.7 A. The average percentage of defectives in 27 samples of size 1500 each was found to be 13.7%. Construct a suitable control chart for the situation. [5 M]
- B. Write a note on HACCP. [5 M]
- C. Describe various quality metrics. [5 M]
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