

M. Pharm. First Semester (Quality Assurance) (New Course)
35330 : MQA 102 T - Quality Management Systems

P. Pages : 1

Time : Three Hours



AU - 0773

Max. Marks : 75

- Notes :
1. All question carry equal marks.
 2. Answer **five** question.
 3. Illustrate your answer necessary with the help of neat sketches.
 4. Use of pen Blue/Black ink/refill only for writing the answer book.

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| 1. | a) Define the following terms. | 3 |
| | i) Quality
ii) Customer focus.
iii) Cost of Quality. | |
| | b) How the Quality is evaluated? Give their dimensions. | 6 |
| | c) Classify the customers, discuss various factors affecting customer perception. | 6 |
| 2. | a) Discuss in detail Total Quality Management (TQM). | 10 |
| | b) Write a note on NABL certification and accreditation. | 5 |
| 3. | Discuss regarding Quality Management System and packaging & labeling system of six inspection system model. | 15 |
| 4. | What is Quality risk management? Explain ICH guidelines for stability testing of drug substances and drug products. | 15 |
| 5. | a) Define and discuss the importance of Statistical Process Control (SPC). | 5 |
| | b) Explain the Quality measurement in manufacturing with statistical control charts. | 10 |
| 6. | a) Discuss the term development of Quality culture with reference to Regulatory compliance. | 5 |
| | b) Explain in detail Benchmarking? | 10 |
| 7. | Write a note on any three . | 15 |
| | a) Models of cost of Quality. | |
| | b) WHO-GMP requirements. | |
| | c) HACCP. | |
| | d) IPQC. | |
