

04/01/24

Seat Number

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DADU-32

MQA 102 T : Quality Management System-I
(161102)

Total Page : 1]**Time: 3 Hours****Max. Marks : 75****Instruction to candidates:**

- 1 Do not write anything on question paper except Seat number.
- 2 Graph or diagram should be drawn with black ink pen being used for writing paper or black HB pencil.
- 3 Students should note, no supplement will be provided.
- 4 Solve any FIVE questions.
- 5 Figures to the right indicates Full Marks.

1. Describe Cost of Poor Quality (COPQ) with its categories? Write any two models of Cost of Quality. **15**
2. Explain the salient features of ISO 9001:2008 in pharmaceutical quality management. Comment on WHO GMP requirements for quality management. **15**
3. Define TQM and discuss the key element of TQM approach. Comment on McKinsey 7s model in quality management **15**
4. Define benchmarking. Discuss in detail the benchmarking process. Write the advantages and limitation of benchmarking. **15**
5. Describe in detail knowledge management techniques in organizations and discuss CFR 21 part 11 **15**
6. (A) Discuss Corrective and preventive actions (CAPA) as a part of Quality System. **08**
(B) Discuss the role of management in commitment to quality as per quality as a strategic decision. **07**
7. (A) Write your views on importance of the Concept of internal and external customers. **08**
(B) Discuss the significance of Customer satisfaction and customer delight in QMS. **07**
8. (A) Describe Shewhart Control Chart with an example. **08**
(B) Discuss the importance of Westgard rules in SPC. **07**