

Code: 17S04101

M.Pharm I Semester Regular Examinations February 2018

QUALITY MANAGEMENT SYSTEM

(Pharmaceutical Analysis & Quality Assurance)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

- 1 Classify customers. What are the factors affecting customer perception.
- OR**
- 2 Write the categories and models based on quality of cost.
- 3 Differentiate the three ISO standards 9001:2008, 9001:2015 and 14001:2004 based on quality management.
- OR**
- 4 Explain ICH Q10 with respect to quality management and CFR-21 WHO-GMP requirements.
- 5 Discuss about root cause determination methods and the methods adopted in corrective and preventive action.
- OR**
- 6 Specify the requirements for Vendor qualification. State the procedures followed in product returns and recalls.
- 7 Mention the concept and importance of statistical process control with the merits.
- OR**
- 8 How to measure process control and potential capability using control chart analysis?
- 9 Write the merits and limitations of benchmarking.
- OR**
- 10 How to develop quality benchmarking as per regulatory compliance guidelines.
