

Code No: PAQA32C/R13

M. Pharmacy II Semester Regular/ Supplementary Examinations, July-2016

QUALITY ASSURANCE OF PHARMACEUTICALS-I

(Common to PA & QA, QA & RA, PA & AC and PA)

Time: 3 Hours

Max. Marks: 60

*Answer any FIVE Questions
All Questions Carry Equal Marks*

1. a Explain briefly about Indian GMP guidelines for the manufacturing of sterile dosage forms as per schedule M. 8
b Distinguish between GMP and CGMP. 4
2. a Discuss quality assurance procedure for maintenance and cleaning validation of tablet punching machine. 8
b Write quality assurance procedure for maintenance of raw materials in stores. 4
3. a Explain GMP guidelines for manufacturing and controls on solid oral dosage forms. 8
b Write a short note on good documentation practice guidelines. 4
4. a Discuss quality assurance procedure for finished products release. 6
b Write a note on GLP. 6
5. a Explain various quality assurance guidelines for handling of return goods. 8
b Write a short note on packaging and labeling controls. 4
6. a Write the GMP guidelines for the manufacturing and control of biological products. 8
b Write a short note on TQM. 4
7. Explain standard operating procedures for operation of the following:
a Drying equipment 6
b Membrane filtration 6
8. a Write a short note on personnel hygiene and training in sterile area. 8
b Write a note on line clearance. 4

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