

**FACULTY OF PHARMACY****M. Pharmacy (Pharm.Analysis) II-Semester (PCI) (Main) Examination, August 2018****Subject: Quality Controls and Quality Assurance****Time: 3 Hrs****Max. Marks: 75****Note: Answer any five questions. All questions carry equal marks.**

- 1 Describe concept, components of Quality Assurance and Quality control. (15)
- 2 What are the requirements of an organization and personnel as per USFDA? (15)
- 3 Describe the in process quality control and finished products quality control of tablet according to Indian pharmacopeia. (15)
- 4 Write a brief notes on a) Quality audit plan (8)  
b) Batch formula record (7)
- 5 Write the detail notes on the following  
(a) Expiry date calculation (5)  
(b) Limitations of production (5)  
(c) Calculation of yields (5)
- 6 a) Describe the overview of ICH Guidelines with Q series (8)  
b) Write notes on SOP. (7)
- 7 a) Write note on the aseptic process control. (8)  
b) Write abt the organization and personnel responsibilities as per WHO. (7)
8. a) Describe the onsite sanitation of manufacturing premises (8)  
b) Write note on finished product (7)

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