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Total Number of Pages:01

B.PHARM
PH.8.4**8th Semester Regular / Back Examination 2015-16****QUALITY ASSURANCE & GMP****BRANCH(S): B.PHARM****Time: 3 Hours****Max Marks: 70****Q.CODE: W221****Answer Question No.1 which is compulsory and any five from the rest.****The figures in the right hand margin indicate marks.****Q1** Answer the following questions:- **(2 x 10)**

- What is the importance of Q.A in Pharmacy?
- What do you mean by Process validation?
- What is Quality audit?
- What is MFR & BMR?
- Name some analytical validation parameters as per validation protocol?
- What is Quality control & Quality assurance?
- Differentiate between efficiency & effectiveness?
- Define TQM & QMS?
- What is product recall?
- How complaints can be handled?

Q2 a) What are the guidelines for validation of cleaning procedures? **(5)**b) Write in brief about the features of process validation? **(5)****Q3** a) Describe about the quality assurance features with reference to organization? **(5)**b) What are the responsibilities & qualifications of personnel? **(5)****Q4** Describe briefly about the salient features of GMP with reference to manufacture of drugs in India? **(10)****Q5** a) Write in brief about the features of production control? **(5)**b) What are the guidelines for selection & purchase specification of equipments? **(5)****Q6** a) Write about the salient features of regulatory authorities of India? **(5)**b) Write in brief about the role of regulatory affairs department? **(5)****Q7** a) What are the guidelines for stability testing protocol of drug products? **(5)**b) Describe about the ware housing operations with reference to quality assurance? **(5)****Q8** Write short notes on:- **(5 x 2)**

- ISO
- TQM
- Documentation
- Quality review