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Total Number of Pages : 01

**B.Pharm
PH.8.4**

8th Semester Back Examination 2018-19

QUALITY ASSURANCE AND GMP

BRANCH : B.Pharma

Time : 3 Hours

Max Marks : 70

Q.CODE : F102

**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)**
- a) State the terms Quality control and Quality assurance?
 - b) Determine the various analytical validation parameters?
 - c) Write the criteria of Quality policy for an organization?
 - d) How the cleaning and sanitation maintenance of the premises and personnel is done?
 - e) Why warehousing practices are followed in the storage of materials and products?
 - f) Determine the role of HVAC system in the environment control?
 - g) State the terms Efficiency and Effectiveness?
 - h) Write the types of process validation and its importance?
 - i) Write the responsibilities and qualification of personnel?
 - j) State the terms MFR and BMR?
- Q2 a) Explain the role of drug regulatory authorities as per Indian constitution? (5)**
b) Design the various features and guidelines of ICH? Write its significance. (5)
- Q3 a) Explain in brief the product recall procedures? (5)**
b) Analyze the types of complaints? How the complaints can be handled? (5)
- Q4 a) Explain the guidelines for selection and procurement of equipments? (5)**
b) Analyze briefly the various features of production control? (5)
- Q5 a) Illustrate the process validation parameters for oral & liquid formulations? (5)**
b) Design the organizational layout of a pharmaceutical plant with various features? (5)
- Q6 Discuss the benefits, certification, elements and various standards of ISO? (10)**
- Q7 Describe the features of GMP and cGMP as per drugs and cosmetics act & rules? (10)**
- Q8 Write short answer on any TWO : (5 x 2)**
- a) Total Quality Management
 - b) Standard Operating Procedure
 - c) Quality Audit