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JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT

END SEMESTER EXAMINATION-2015

B.Pharm VI Semester

COURSE CODE: 10B11PY613 MAX. MARKS: 45

COURSE NAME: Industrial Pharmacy-II

COURSE CREDITS: 03 MAX. TIME: 3 HRS

Note: *All questions are compulsory. Carrying of mobile phone during examinations will be treated as case of unfair means.*

Section A **(6 *1.5 = 9 Marks)**

1. How the design of chemical weighing room is crucial for high potency drugs (such as steroids)?
2. How can one prevent cross-contamination of chemicals?
3. Explain the concept of EOQ and ABS analysis.
4. What does 'Ruggedness test' describes?
5. According to FDA what is "A validated manufacturing process'?
6. What is the role of GMP in production management?

Section B **(13.5 Marks)**

1. What does inventories stands for? What is the significance of EOQ formulae in the inventory control? How it is helpful in the good materials management? **(1+1.5+2)**
2. How inadequate cleaning of floors and equipments can be a problem for coating operation? Provide various parameters to avoid these problems for large operations. **(4.5)**
3. Why sampling process is considered as one of the crucial parameters of quality control? What should be the characteristics of a good statistical sampling plan? **(4.5)**

Section C (22.5 Marks)

1. Explain the effects of following additives on to the plastic containers. Also explain the strategy to overcome the problem associated with it: **(5 M)**

   (a) Oils, (b) Surfactants, (c) Plasticizers, (d) Antioxidants and (e) Stabilizers

   (b) (b) Testing of finished products is a crucial factor for quality control and quality assurance, why? **(2.5 M)**

2. If you are supposed to design a formulation (Liquid dosage form containing volatile oils), which type of packaging materials you want to use and why? Give your answer with suitable examples. **(7.5 M)**

3. In the development of containers specification, what are the major features that have to be considered during packaging of material controls? Also explain the quality test standards used to measure accurately the characteristics properties of a drug with suitable examples. **(3.5+4.0 M)**

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