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SARDAR PATEL UNIVERSITY

M. Sc. Pharmaceutical Chemistry (Semester - III) Examination
Saturday, 29/10/2016; Time - 2:00 PM to 5:00 PM
SUBJECT CODE : PS03EPCH01
SUBJECT TITLE : Advance Pharmaceutical Chemistry

Maximum Marks: 70

Note: (1) All questions are compulsory. (2) Figure to right indicates total marks of question.

Q-1 **Choose the correct option for the following:** 1× 8

i. The rate and amount of absorption of unchanged drug from its dosage form, term as .....
   a. Systemic availability
   b. Bioequivalence
   c. Bioavailability
   d. Relative availability

ii. Dissolution rate can be enhance by .....
   a. Molecular inclusion complex
   b. Precipitation
   c. Microionization
   d. All

iii. Ozone disinfection .....
   a. Promotes pyrogen
   b . Filtration process
   c. Kills waterborne organism
   d. None

iv Removal of minerals in water treatment is known as:
   a. Sedimentation
   b. Coagulation
   c. Demineralization
   d. None

v. Pilot plant design consideration includes :
   a. Formulation and process development
   b. a flexible highly trained staff
   c. GMP Compliance
   d. all of these

vi. A validation master plan should be develop that addresses
   a. The design specifications
   b. Installation qualification
   c. a & b both
   d. none

vii AQL means
   a. Accurate quality limit
   b. Acceptance quality limit
   c. a & b both
   d. none

viii Which materials can be used as packaging material ?
   a. Glass
   b. Cotton
   c. Plastics
   d. All

Q-2 **Answer the following (Attempt any seven).** 2 × 7

i. Write main objective of bioavailability studies.

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ii Write advantages of multiple dose studies.

iii. Write limitation of randomized study design for bioequivalence study.

iv. Enlist main elements of bioequivalence study protocol.

v. What is the importance of chlorination ?

vi. Give the theory of electro-dialysis.

vii. Give the reason to conduct Pilot plant studies.

viii. What is the Transfer of analytical methods to quality assurance ?

ix. Write basic requirements for pharmaceutical packaging.

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Q-3 A. Discuss in detail about objective and type of bioequivalence studies. 6

B. Describe various methods used for bioavailability measurement. 6

OR

B. Discuss various methods used for drug permeability enhancement. 6

Q-4 A. Describe the role of ion-exchange in the purification of water with advantage and limitation of the process. 6

B. Write a note on Reverse osmosis. 6

OR

B. Write a note on WFI (water for Injection). 6

Q-5 A. Discuss the steps for Pilot Plant design for Tablets. 6

B. Write a note on Scale-up for parenterals. 6

OR

B. Describe the consideration for Dry Compaction. 6

Q-6 A. Discuss in detail about various parameter for the selection of packaging material. 6

B. Write main objective and functions of QC/ and QA departments in industry. 6

OR

B. Write main composition of glass containers. Also discuss type of glasses used in pharmaceutical packaging, its advantages and disadvantages. 6

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