UKA TARSADIA UNIVERSITY
M. Pharm. (Quality Assurance) (2nd Semester)
040030202: Modern Pharmaceutical Analysis

Time : **2**:**30 p**m to **5**:**30** pm   Date : **30**/**11**/2013
Duration: 3 hours   Maximum marks: 70
Instructions:
1. Attempt all questions
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks allocated to that question.
5. Draw diagrams/figures wherever necessary.

SECTION 1

Q.1 a. What is impurity and impurity profile? Classify the impurities encountered in   (6)
pharmaceuticals. Describe origin of organic impurity during storage with
suitable example.

b. Discuss the applications of ICH guidelines in pharmaceutical analysis.   (5)

Q.2 a. What is pre-formulation? Describe pharmaceutical properties and their evaluation   (6)
in pre-formulation study.

b. Write brief review about the analytical techniques used in pre-formulation study.   (6)
OR
b. Describe principle of isoelectric focusing (IEF). Discuss gels used in IEF.   (6)

Q.3   Write notes on the following (**Any Two**)   (12)
a. Tryptic mapping
b. Methods of solubility determination of API
c. Methods of polymorphism study.

SECTION 2

Q.4 a. Give characteristics of parenteral dosage forms. Describe their analysis   (6)
during formulation and process development.

b. Write note on compendial testing   (5)

Q. 5   Give suitable classification of cosmetics. Discuss physical and chemical analysis   (12)
of cosmetics.
OR
Describe the different radiochemical methods of analysis with their applications.   (12)

Q. 6   What are the techniques used for analysis of solid oral dosage forms?   (12)
Describe application of near infra red (NIR) technique in analysis of solid oral
dosage form with examples.
OR
Q.6   Describe briefly quality control methods for medicinal plant material as per WHO.   (12)
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