Code No. 1302/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supple.) Examination, August 2018

Subject: Advanced Pharmaceutical Analysis

Time: 3 Hrs **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1 (a) Define impurity and write classification of impurities in drug substances with examples. (5)
(b) Describe analytical procedures for quantification of impurities in drug products As per ICH guidelines and mention their threshold limits. (10)

2 (a) Classify and write the potential srces of elemental impurities. (5)
(b) Describe instrumentation and analytical procedures for analysis of carbon, hydrogen, nitrogen and sulphur impurities. (10)

3 (a) Write the systematic approach to stability evaluation of drug substances. (8)
(b) Explain the influence of temperature, pH buffering species ionic strength and dielectric constant on drug stability. (7)

4 Write an accnt on WHO and ICH guidelines for stability testing. (15)

5 (a) Explain the role of analytical instruments (HPTLC & HPLC) in interaction and complexity studies of phytopharmaceuticals. (10)
(b) Write a note on stability testing protocols for herbal drugs. (5)

6 (a) Define bioassay. Describe the principle and method involved in bioassay of any one biological product. (8)
(b) What are antitoxins? Give biological assay of tetanus antitoxin. (7)

7 (a) Describe basic principles of radio immune assay. Enumerate its applications and limitations. (10)
(b) Describe the production of antibodies. (5)

8 (a) Write an accnt on Impurity profi ling and degradation product characterization studies for gene regulation. (10)
(b) Classify residual solvents by risk assessment and describe their limits. (5)

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