Code No. 1151/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018

Subject: Advanced Pharmaceutical Analysis

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

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

1 (a) Explain in-detail abt impurity profiling of new drug product. (10)
(b) Write classification and identification of elemental impurities. (5)

2 (a) Explain briefly protocol adopted for stability testing of drugs. (8)
(b) Describe briefly accelerated stability studies and determination of shelf-life. (7)

3 (a) Explain varis pri nciples and testing procedures involved in degradant characterization. (8)
(b) Describe ICH stability guidelines for biological products. (7)

4 (a) Write an accnt on requirements for stability testing of phytopharmaceuticals. (7)
(b) Describe the principle and methods involved in HPLC finger printing with suitable examples. (8)

5 (a) Mention different types of tetanus vaccine. Explain bioassay of adsorbed tetanus vaccine. (8)
(b) Describe the principle and procedure involved in bioassay of any one biological product. (7)

6 (a) Describe the principle, instrumentation and applications of radio immune assay. (8)
(b) Describe procedures for separation of bnd and unbnd drug during immunoassay. (7)

7 (a) Write an accnt on elemental impurities and their determination. (10)
(b) Explain basic principle and applications of PCR studies. (5)

8 (a) Write classification, potential srces, control and identification of residual solvent impurities. (10)
(b) Describe the production of antibodies. (5)

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