Code No: 6131/PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar. Analysis) I-Semester (PCI) (Main & Backlog) Examination, February 2019

Subject: Advanced Pharmaceutical analysis

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

Note: Answer any five Questions. All Questions carry Equal Marks

1 a) Explain the guidelines for reporting and control of degradation products in new drug products. 10
b) Explain the classifications of residual solvents and their limits in substances and drug products. 5

2 a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. 10
b) Write short note on qualification of degradation products. 5

3 Write abt :
a) Control of elemental impurities 8
b) Potential srces of elemental impurities. 7

4 a) Write abt different analytical techniques used in characterization of degradan ts. 10
b) What is impurity profiling and give its importance in testing of pharmaceutical products. 5

5 a) Write abt HPTLC as finger printing tool in stability testing of phytopharmaceuticals. 10
b) What are accelerated stability studies and how do y calculate shelf life of drug products. 5

6 a) Write the principle and procedure and applications of radioimmunoassay. 10
b) Write short note on optical Immunoassay. 5

7 a) Discuss the biological assay of diphtheria vaccine. 7
b) Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine. 8

8 a) Discuss the different polymerase chain reaction studies for gene expression. 8
b) Explain the different steps involved in production of antibodies. 7

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