Code No. 13160 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar.Analysi.) I – Semester (PCI) (Main & Backlog) Examination,

January 2019

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 give the classification of impurities in new drug substances. 5

b) Explain the guidelines for reporting and control of elemental impurities in new drug products. 10

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 a) Explain the factors affecting stability of drug substance and drug products. 10

b) How do y perform photo stability of formulations? 5

4 a) Write abt differe nt analytical techniques used in characterization of degradants. 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 te sting of phytopharma ceuticals. 10

b) What are accelerated stability studies and how do y calculate shelf life of drug products. 5

6 Write abt the following

a) Enzyme immunoassay 8

b) Optical Immunoassay 7

7 a) Describe the principle and procedure involved in the biological assay of oxytocin. 8

b) What are antitoxins? Give biological assay of Tetanus antitoxin. 7

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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