Registration No: | | | | | | | | | | |

Total Number of Pages : 01 **M.Pharm**
MPA102T

1st Semester Regular Examination 2019-20
ADVANCED PHARMACEUTICAL ANALYSIS
BRANCH : ANALYSIS & QUALITY ASSURANCE, PHARMACEUTICAL ANALYSIS
Max Marks: 75
Time : 3 Hours
Q.CODE : HR638

Answer Question No.1 (Part-A) and 02 (Part-B) which are compulsory and any TWO from Part-C.
The figures in the right hand margin indicate marks.

Part-A

Q1 **Only Short Answer Type Questions (Answer All-10)** **(2 x 10)**

a) Classify impurities in residual solvent.
b) State basic principle of PCR?
c) State any two guidelines for photosensitivity testing.
d) How will you define the term accuracy and precision?
e) Explain shelf life of drug.
f) State common ICH guidelines.
g) How will you define Optical Immuno Assay?
h) What is sandwich assay?
i) What are overages? Write its role in drug stability.
j) Enlist sources of impurities in Pharmaceutical active ingredients.

Part-B

Q2 **Only Focused-Short Answer Type Questions- (Answer Any SEVEN out of NINE)** **(7 x 5)**

a) Describe the Enzyme Immuno Assay.
b) Write in detail about the regulatory requirements for Phyto-pharmaceuticals.
c) Describe the methods of C, H, N and S analysis with principle.
d) What is Heparin sodium I.P? Explain the tests and Assay.
e) Write the biological tests and assay procedure of oxytocin.
f) What are the Potential Sources of elemental Impurities?
g) How do you perform photo stability of formulations?
h) Write note on ICH stability guidelines for biological products.
i) Write note on listing of degradation products in specifications.

Part-C

Only Long Answer Type Questions (Answer Any TWO out of FOUR)

Q3 Describe the steps involved in preparation of validation Master Plan (VMP). **(10)**

Q4 Explain various techniques of Separation of bound and unbound drug in Radioimmunoassay. **(10)**

Q5 Write about HPTLC as finger printing tool in stability testing of phyto pharmaceuticals. **(10)**

Q6 Explain the factors affecting stability of drug substance and drug products. **(10)**