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

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

M.PH.1.5C

1st Semester Back Examination 2019-20

STABILITY OF DRUGS AND DRUG PRODUCTS

BRANCH : ANALYSIS & QUALITY ASSURANCE

Time : 3 Hours

Max Marks : 70

Q.CODE : HB568

Answer Question No.1 which is compulsory and any FIVE from the rest.

The figures in the right hand margin indicate marks.

Q1 **Answer the following questions :** **(2 x 10)**

a) Discuss the effect of pH on degradation rate constant.

b) Discuss the importance of addition of antimicrobial agents to pharmaceutical products.

c) Define order and molecularity with suitable examples.

d) Discuss the technique to prevent hydrolytic degradation.

e) Discuss the techniques to protect photosensitive drugs and formulation.

f) Discuss the role of solvent in the drug degradation process.

g) Give the equation for Q_{10} method of shelf life estimation.

h) Give the storage condition and importance of accelerated stability testing for solid dosage forms.

i) Name the potential adverse effects of instability.

j) Give the parameters to be studied in the physical stability testing of pharmaceutical powders.

Q2 Discuss briefly different order of reactions and describe the Pseudo and complex order reaction with suitable examples. **(10)**

Q3 What is Arrhenius equation? Discuss its importance in establishing the expiry date of a dosage form. How it is useful to calculate activation energy? **(10)**

Q4 What are the different types of drug decomposition mechanism? Discuss the mechanism of drug decomposition by oxidation. How oxidation can be prevented in a dosage form for a drug prone to oxidative degradation with suitable examples? **(10)**

Q5 Discuss drug-drug and drug-excipient interactions with suitable examples. **(10)**

Q6 Discuss the stability protocol for the physical stability testing of Novel Drug Delivery system and briefly describe the importance of the parameters to be studied in the physical stability testing of disperse system. **(10)**

Q7 Describe the protocol and parameters for the physical stability testing of the tablets in the formulation development stage. **(10)**

Q8 Describe the different Regulatory requirements for stability studies for pharmaceutical products for the approval. **(10)**