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

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

**MPA103T**

**1st Semester Regular Examination 2019-20**

**PHARMACEUTICAL VALIDATION**

**BRANCH : ANALYSIS & QUALITY ASSURANCE, PHARMACEUTICAL ANALYSIS**

**Max Marks: 75**

**Time : 3 Hours**

**Q.CODE : HR717**

**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)** Define Calibration? Mention its significance.
**b)** What is the meaning of Qualification?
**c)** Differentiate copy right and related rights with suitable examples.
**d)** Write down the advantages of Validation?
**e)** What is Clean in place. Mention the advantages.
**f)** Which phase is called as “valley of death” in technology transfer and why?
**g)** What is Change control?
**h)** Enlist four compressed air used in pharmaceutical industries..
**i)** What do you mean by GI. Mention its significance.
**j)** What is pH meter and its range?

**Part-B**

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

**a)** Explain Validation Master Plan.
**b)** Give and account Qualification of Electronic Balance.
**c)** Write short note on technology Transfer.
**d)** Give An Account On HVAC System.
**e)** Differentiate between calibration and validation with examples.
**f)** Illustrate the significance of 21 CFR.
**g)** Explain Types of Patent application.
**h)** Analyze qualification of GC?
**i)** Justify the penalties for Violation of IP Protection?

**Part-C**

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

**Q3** Describe Qualification of HPLC with its Applications. **(10)**

**Q4** Write in detail about validation of analytical method as per ICH Guidelines. **(10)**

**Q5** What is IPR and factors affecting IP protection? Add a note on types of IPR. **(10)**

**Q6** Explain Pharmaceutical waters and Pure Steam with examples? **(10)**