* P - M Q A 2 0 2 - T - 5 0 - 2 *

P-MQA202-T Seat No. _____

M. Pharm. (Sem. II) (CBCS)
(Quality Assurance External) Examination
July - 2018
Pharmaceutical Validation (Theory) : MQA202-T

Time : **3** Hours] [Total Marks : **75**

Instruction :

(1) Figure to the right indicates marks.

(2) Draw neat and clean diagrams as required.

1 Answer the following questions : **10×2=20**

1. Define Validation Master plan.
2. What is the importance of intellectual property right ?
3. Enumerate the validation parameter for the Assay as per ICH guideline.
4. What is the Retrospective Validation ? Explain importance of its.
5. Explain the term : Copyright, Trademark.
6. What is HVAC system ?
7. What is Factory Acceptance Test ?
8. How will you perform the water system validation ?
9. What do you mean by Electronic records ?
10. Give full form of: IPP, USFDA, SAT, CFR.

2 Answer any two out of following : **2×10=20**

1. What is qualification of analytical instruments ? Write short note on calibration of HPLC, HPTLC and UV.
2. What is process validation ? Briefly discuss the USFDA guideline for process validation. Write short note on Process Validation of tablet coating.
3. Write brief note on the Validation of analytical method as per ICH guidelines.

3 Answer any **seven** out of following : **7×5=35**

1. Briefly explain the Technology transfer. Draw the blank format for the TOT.
2. Draw the blank format for the Qualification, Disintegration tester, Dissolution test apparatus.
3. What is the difference between the calibration and validation ? Explain the advantage of the validations.
4 What is the cleaning method development and validation ? Explain the main requirements (Objective) for the method development.
5. Enumerate the different step for patent filling. Explain the provisional and non provisional patent.
6. Write short note on the validation of facilities in sterile plant.
7. Write note on qualification of Fluid Bed and Tray dryers
8. What is importance of Re-Qualification ?
9. Explain the Factors affecting choice of IP protection.
