

Total No. of Pages : 1

Total No. of Questions : 06

M.Pharmacy(Pharmaceutical Analysis) (2017 Batch) (Sem.-2)

QUALITY CONTROL & QUALITY ASSURANCE

Subject Code : MPA-203T

Paper ID : [74927]

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Briefly discuss : (3×5)
 - a) Difference between QA and QC.
 - b) Difference between GMP and cGMP.
 - c) Protocols and reports.
2. Discuss Q series of ICH guidelines. (15)
3. Discuss the protocol for conduct of non clinical testing. (15)
4. Discuss WHO guidelines regarding drug industry location, design and construction of plant and its maintenance *w.r.t.* sanitation and environmental control. (15)
5.
 - a) Discuss IPQC pertaining to finished products. (8)
 - b) Discuss the CPCSEA guidelines. (7)
6.
 - a) Discuss the Master Formula Record. (7)
 - b) Briefly discuss about SOP. (8)