Pramukh Swami Science & H.D. Patel Arts College, Kadi
Master of Vocation Pharmaceutical Chemistry Semester- I
Internal Examination, January-2019,
(MPC-103)GMP AND PHARMACEUTICAL PROCESS VALIDATION

Time: 2 hours 03/01/2019 Total Marks: 60

Que-1.Answer any 12 questions. Each question carries 1 mark[12]

1. Define Process validation.
2. What is GMP?
3. Full form of CIP & SIP.
4. Full form of QMS.
5. ICH prevents duplication of clinical trials in humans. (True/False)
6. What are Q_7 and Q_{10}?
7. Enlist steps involved in CSV.
8. Level of changes _____ : - Likely to have significant impact.
   (a) Level 1 (b) Level 3
   (c) Level 2 (d) None of above
9. SUPAC IR: - For Modified Release Solid Oral Dosage Form. (True/False)
10. Define ICH?
11. What is role of QMS?
12. What is Validation master plan?
13. With what kind of purpose GMP is maintained?

Que-2.Answer any fivequestions. Each question carries 4marks [20]

1. Give the definition of following: -
   (a) SMF (b) CSV
   (c) GLP (d)SUPAC
2. Write a short note on Process design.
3. Explain about GLP.

4. Short not on SUPAC.
5. Explain about any 05 principles involved in GLP.
6. Short note on Retrospective Process Validation.
7. Brief note on the FDA principles of QA.

Que-3.Answer any fourquestions. Each question carries7 marks [28]

1. What is ICH? Give detail note on Safety and Efficacy Guidelines.
2. Define and explain principles involved in GMP.
3. Explain in detail about CSV.
4. What is SUPAC? Explain in detail about SUPAC-IR.
5. What is process validation? Explain any 02 types in detail.
6. What kinds of good practice system are used other than GMP and GLP.