

Hemchandracharya North Gujarat University, Patan  
Master of Vocation

'Pharmaceutical Chemistry' Semester - I  
END TERM Examination, January, 2019

Subject: GMP and Pharmaceutical Process Validation (MPC-103)

Time: 2 hrs

Date: 29/01/2019

Maximum marks: 50

**Q.1 Answer any 9 questions. Each question carries 1 mark (9\*1=9Marks)**

1. What is VMP?
2. What is CIP - SIP?
3. Full form of SUPAC?
4. Define sterilization Process?
5. Assertion: GMP is followed by QMS.

Reason: - It is maintained for production of consistently high quality products.

- (a) If both assertion and reason are true and the reason is the correct explanation of the assertion.
- (b) If both assertion and reason are true but reason is not the correct explanation of the assertion.
- (c) If assertion is true but reason is false.
- (d) If the assertion and reason both are false.

6. Match the following: -

I

(a) S1

(b) S5

(c) S2

II

(p) Reproductive Toxicology

(q) Carcinogenicity Studies

(r) Genotoxicity Studies

7. \_\_\_\_\_ is the full form of QSEM.

8. SUPAC IR: - For Modified Release Solid Oral Dosage Form. (True/False).

9. Match the following: -

I

(a) M

(b) E

(c) Q

II

(P) GMP

(Q) Electronic standards.

(R) Clinical trials

10. Define Process validation.

**Q.2 Answer any 5 questions. Each question carries 4 marks (5\*4=20 Marks)**

1. Short note on the FDA principles of QA.
2. List out any 05 principles involved in GLP.
3. What is SOP? List out various parts involved in it.
4. What is process validation? Explain any two types of it in detail.
5. What kinds of good practice system are used other than GMP and GLP.
6. Short note on any 05 ICH Guideline regarding Safety purpose.

**Q.3 Answer any 3 questions. The question carries 07 marks (3\*7=21 Marks)**

1. Full form of ICH Guidelines? Explain about Quality and Multidisciplinary Guidelines.
2. Give the definition of following: -
  - (a) SUPAC
  - (b) GLP
  - (c) GMP
  - (d) CSV
  - (e) QMS
  - (f) SME
3. Detail note on SUPAC.
4. Detail note on GMP.