118 SEAT No._____ No. of printed pages : 02

SARDAR PATEL UNIVERSITY

M.Sc. Pharmaceutical Chemistry, Fourth Semester Examination
Wednesday, 20th March
2019
2.00 a.m. to 5.00 p.m.
Validation and cGMP: PS04CPCH22

Total Marks : 70

Note : (i) All questions are to be attempted. (ii) Figures to the right indicate marks.

Q.1 **Choose the correct option for the following:** **8x1= 08**

(i) Prospective validation occurs .....
(a) Before production (b) After production
(c) Simultaneously during process (d) All

(ii) Validation is the most recognized and important parameter of.....
(a) QA (b) GMP (c) QC (d) All of the above

(iii) CFR means .....
(a) cost of freight (b) cost for right (c) both 'a' & 'b' (d) None

(iv) HVAC stands for .....
(a) Heating, ventilation and air conditioning
(b) Heating, ventilation and air compression
(c) Both 'a' & 'b'
(d) None

(v) Process validation includes .....
(a) Process design (b) Process qualification (c) Process verification (d) All

(vi) ..... should be maintained for shipment of labels and packaging materials.
(a) Record (b) production (c) Rejection (d) both 'a' & 'c'

(vii) Contamination can be cause by .....
(a) poor hygiene practice (b) residual cleaning agent (c) both 'a' & 'b' (d) none

(viii) In cGMP labeling operation should be designed.
(a) to prevent mix up (b) to provide name
(c) to store material (d) for examination.

Q.2 **Answer the following : (Attempt any seven)** **7x2= 14**

(i) Explain: Validation is an important for pharmaceuticals.
(ii) What is meant by PQ and DQ ?
(iii) Define retro septic validation.
(iv) Write the Installation qualification for HVAC.
(v) Define basic concept of cGMP.
(vi) Distinguish unit dose packaging and device packaging.

(P.T.O.)

(vii) Define finished dosage form.

(viii) Draw basic plant layout.

(ix) What type of specification is necessary for raw material purchase in Industry?

Q.3 **Answer the following :**

A Discuss in detail about various types of validation methods. **06**

B What are the essential elements for retrospective validation? **06**

OR

B. Discuss the function of packaging in detail. **06**

Q.4 **Answer the following :**

A. Describe the process validation protocol. When the process validation is required? **06**

B. Discuss about purified water system validation process. **06**

OR

B. Write a note on: Sterilization process. **06**

Q.5

A. Discuss the basic concepts and philosophy of cGMP in manufacturing. **06**

B. Explain the main responsibilities of organization for good manufacturing practices. **06**

OR

B. Explain in detail about Training and Hygiene of person in pharmaceutical industry. **06**

Q.6 **Answer the following:**

A. What are the basic facilities required to control quality of raw materials. **06**

B Describes various utility area and services required as part of GMP in industry **06**

OR

B Discuss in detail about design and construction features of industry. **06**