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SARDAR PATEL UNIVERSITY

M. Sc. Pharmaceutical Chemistry (Semester-IV) Examination

Friday, 13/04/2018; Time-2:00 PM to 5:00 PM

SUBJECT CODE: PS04CPCH03

SUBJECT TITLE: Validation, Documentation and cGMP

Maximum Marks: 70

Note: (1) All questions are compulsory.
(2) Figure to right indicates total marks of question.

Q-1 **Choose the correct option for the following:** 1× 8

1. **Prospective validation is done _____**
   a. Before the process b. During the process
   c. After the process d. All
2. **For content uniformity, a normal range would cover**
   a. 70-90% b. 10-20%
   c. 40-60% d. 60-70%
3. **FDA stands for.**
   a. Food & Drug Administration b. Food & Drug Analysis
   c. Factory Data Administration d. Factory Data Analysis
4. **Pump flow accuracy can be checked at a flow rate of_____**
   a. 10 mL/min b. 1 mL/min
   c. 4 mL/min d. 15 mL/min
5. **An material substance or energy that adversely affects the product or process is:**
   a. Bacteria b. Disinfectant
   c. Virus d. Contamination
6. **Cleansing agent must be**
   a. Product compatible b. Process compatible
   c. Disinfectant compatible d. All the above
7. **Literary and artistic work can be covered by:**
   a. Patent b. Trade-mark
   c. Copyright d. None of above
8. **The term of patent in India is:**
   a. Life time b. 40 yrs
   c. 60 yrs d. 20 yrs

Q-2 **Answer the following (Any Seven).** 2 × 7

1. Differentiate retrospective and concurrent validation
2. What is master validation plan?
3. Describe Factors acceptance test?
4. Define Accuracy.
5. Give the importance of documentation in process validation.

PTO....

6. Why process should be validated?

7. Describe the life cycle of analytical method?

8. What is geographical indication? Give an example?

9. Write the Eligibility conditions for registration as patent agent.

Q-3 A. Write the concept, philosophy and importance of cGMP with Its effect over manufacturing? 6

B. Enlist the desirable qualities of analyst. 6

OR

B. Write the concept, philosophy and importance of camps, what is its effect on manufacturing. 6

Q-4 A. Write a brief account on validation of HPLC instrumentation Qualification. 6

B. Write an essay on analytical method validation. 6

OR

B. Explain the terms LOD, LOQ and Range. 6

Q-5 A. Write an essay on pharmaceutical clean room technology. 6

B. Describe retrospective and concurrent validation. 6

OR

B. Explain the statutory and regulatory requirements for Process validation. 6

Q-6 A. Write the procedure for registration of a work under the Copy-Right registration act. 1957 and add a note on the power of the copyright board. 6

B. Write an essay on the patent system in India and a note on the rights of a patentee 6

OR

B. What is trademark? Write a note on key features and Administrative procedure of registration of trademark. 6