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Number of printed pages: 02

[A-87]

SARDAR PATEL UNIVERSITY

M. Sc Pharmaceutical Chemistry (Semester-IV) Examination

Saturday, 25/04/2015; Time-2:30 PM to 5:30 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. **Simplified drug validation path contains**
   a. R&D new drug b. FDA approval
   c. Clinical trials d. All
2. **For content uniformity, a normal range would cover**
   a. 70-130% b. 10-20%
   c. 40-60% d. 60-70%
3. **Limit test is applicable to**
   a. Mirror test b. Limit of detection
   c. Concentration d. accuracy
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. **Frequency of changing tacky mats in clean room 1000 is**
   a. 1 time in month b. 1 time per week
   c. Every 2 hours d. 2 times per shift
6. **Re-validation becomes necessary in case of**
   a. Change in raw material b. Change in process
   c. Both a and b d. none
7. **Renewable fee for patent application during 2 nd year to 6th year is**
   a. 1500 Rs b. 3000 Rs
   c. 500 Rs d. 5000 Rs
8. **The term of copy right in case of photographs is**
   a. 30 years b. 60 years
   c. 5 years d. 10 years

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

1. Describe the scope validation.
2. Define analytical method validation.
3. Define the term of cGMP.
4. Why process should be validated?
5. What is importance of documentation in process validation?
6. Define clean room.
7. Enlist examples of geographical indications.
8. What is meant by complete specifications?
9. What is meant by design?

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Q-3	A.	Describe various protocols of validation.	6
	B.	Enlist the desirable qualities of analyst.	6
		OR	
	B.	Write note on USFDA and EMEA.	
Q-4	A.	Explain the terms LOD, LOQ and range.	6
	B.	Write note on phase appropriate method validation.	6
		OR	
	B.	Describe the procedure for validation of dissolution test apparatus.	
Q-5	A.	Describe the key elements of contamination control.	6
	B.	Write not on retrospective and concurrent validation.	6
		OR	
	B.	Give the comparison of ISO and federal clean room classifications.	
Q-6	A.	Discuss in detail about copy right.	6
	B.	What is opposition and what are the grounds for opposition?	6
		OR	
	B.	Write a note on Paris convention.	

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