(108)

SARDAR PATEL UNIVERSITY

M. Sc. Pharmaceutical Chemistry, Semester- IV

Saturday, 9th April, 2016

Time: 02:30 pm to 05:30 pm

PS04CPCH03: Validation, Documentation and cGMP (CBCS)

Note: (i) Figures to the right indicate marks. **Total Marks - 70**

Q-1 Choose the correct option and answer. **[08]**

(1) Prospective validation is done .....
a. before the process **b.** during the process
c. after the process **d.** All of these

(2) FDA means _____.
a. Factory Data Analysis **b.** Food and Drug Administration
c. Food and Drug Data **d.** Food and Drug Analysis

(3) A temperature accuracy test of column oven is carried out by_____.
a. Sensitized probe **b.** Detector
c. Using a calibrated thermal probe **d.** all of the above

(4) Full name of ICH is _____.
a. International Chemical Harmonization
b. International Convention on Harmonization
c. Indian Convention on Harmonization
d. None of the above

(5) Which of the following is not comes under the process of analytical method validation?
a. Writing and approval of method validation
b. Reporting the analytical method validation
c. Planning and deciding on the method validation experiments
d. None of the above

(6) A class 100 clean room is designed to never allow more than _____.
a. 100 particles (0.5 microns or larger) / cubic foot of Air
b. 100 particles (0.5 microns or larger) / 4 cubic foot of Air
c. 100 particles (10 microns or larger) / cubic foot of Air
d. None of the above

(7) Trade mark is a recognizable _____.
a. Sign **b.** Design **c.** Unique expression **d.** All of these.

(8) Copyright generally lasts for a period of _____.
a. Sixty years. **b.** Twenty years **c.** Ten years **d.** Five years

Q-2 Answer the following. (Any seven) **[14]**

(1) Define the terms purity, efficacy and quality in validation process.

(2) Write a note on factory acceptance tests.

(3) Why validation of analytical procedures is required?

(4) Define Accuracy.

(5) Give a note on life cycle of analytical method.

(6) What is contamination?

(7) Enlist the types of cleaning materials can be used in the clean room.

(8) Write the eligibility conditions for registration as patent agent.

(9) Enlist the classes of works for which copyright protection is available.

Q-3	(A)	Write an essay on validation protocols and the qualifications required for an effective validation process.	[6]
	(B)	Give an account on the concept of cGMP. What is its effect on manufacturing?	[6]
		OR	
	(B)	Write a note on the responsibilities under GLP. Why should we follow GLPs?	[6]
Q-4	(A)	Enlist the characteristics of analytical method validation. Explain any two in detail.	[6]
	(B)	Write detail account on method precision and reproducibility.	[6]
		OR	
	(B)	Write brief account on validation of HPLC instrumentation qualification.	[6]
Q-5	(A)	Enlist Key elements of contamination control. Discuss any two in detail.	[6]
	(B)	Write brief account on pharmaceutical clean room classification and testing	[6]
		OR	
	(B)	Write note on guideline on sterile drug products produced by Aseptic processing	[6]
Q-6	(A)	What is patent? Write a brief note on Patent system in India, types of patent application and the role of international organizations in patent practice.	[6]
	(B)	Give a detail note on copyright and the procedure for registration of a work under the Copyright Registration act, 1957.	[6]
		OR	
	(B)	Write a note on publication and examination of patent application. Add a note on the rights of the patentee.	[6]

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