

**PS04CPCH03: Validation, Documentation and cGMP (CBCS)**

**Total Marks - 70**  
**[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

[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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