Pramukh Swami Science and H D Patel Arts College

Bachelor of Vocation

Pharmaceutical Chemistry Semester III

Mid SEM Examination, November 2015

Subject: Indian Drugs Regulatory Guidelines (PC314)

Time: 2 hrs | Date: 05/11/2015 | Marks: 60

Q.1 Answer any 12 questions. (Each question carries 1 mark) [12*1=12]

1. What is the full form of ICH
2. What is the full form of ISO
3. Define precision
4. Define accuracy
5. Define validation
6. _____ is the full name of IND.
7. _____ is the full name of GLP.
8. _____ gives idea about closeness of the results to the actual value. (Precision/Accuracy/ISO/ICH)
9. Certificate of analysis is generally provided by _____. (Manufacturer/Trader/Supplier/Customer)
10. State True or False: Certificate of analysis is issued for finished product only
11. State True or False: SOP is required for handling of machine only
12. State True or False: SOP is developed by Organisation for Economic Co-operation and Development (OECD)
13. SOPs may be written for any ____ technical activity, as well as for any administrative or functional programmatic procedure, that is being followed within an organization. (repetitive/competitive/analytical/valedictory).

Q.2 Answer any 5 questions. (Each question carries 04 marks) [5*4=20]

1. Discuss various Parts of a CERTIFICATE OF ANALYSIS
2. Discuss benefits of using SOP
3. Write in general about "GOODS RECEIVED NOTE"
4. Enumerate & discuss in brief about five fundamental points of GLP
5. Write in brief about precision of analytical method.
6. Discuss about limit of detection or limit of quantification of analytical method.

Q.3 Answer any 4 questions. (Each question carries 07 marks) [4*7=28]

1. Discuss in detail about Specificity
2. Discuss principles of ISO
3. Discuss general format of Standard Operation Procedure
4. Write in detail about Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs
5. Discuss in detail about analytical method validation.
