HEMCHANDRACHARYA NORTH GUJARAT UNIVERSITY, PATAN

Bachelor of Vocation

Pharmaceutical Chemistry Semester III

SEMESTER END Examination, February 2016

Subject: Indian Drugs Regulatory Guidelines

Subject code: PC314

Time: 2 hrs Marks: 50

Q.1 Answer any 9 questions. (Each question carries 1 mark) [09*1=09]

1. State True or False: Certificate of analysis is issued for raw material only
2. State True or False: All machine handling requires proper SOP
3. State True or False: Certificate of analysis is always provided by Trader
4. What is the full Name of OECD
5. What is ISO
6. What is precision of method.
7. Define IND.
8. What is validation?
9. _____ gives idea about closeness of the results to the **repetitive value**. (Precision/Accuracy/Limit of detection/Limit of Quantification)
10. SOPs should be written for any _____ type of technical activity. (repetitive / competitive / analytical / valedictory).

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

1. What is SOP? Discuss advantages of using SOP.
2. Give detailed note on concept of "Specificity" in analytical method validation.
3. What is "certificate of analysis"? Why is it required? Discuss in detail.
4. What is "goods received note"? Discuss its various components.
5. Enumerate & discuss in detail about five fundamental principles of GLP
6. Discuss in detail about precision of analytical method.

Q.3 Answer any 3 questions. (Each question carries 07 marks) [3*7=21]

1. Write in detail about Content and Format of investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs.
2. What is ISO? Discuss principles involved in certification of ISO.
3. Write a note on analytical method validation.
4. Discuss general format of Standard Operation Procedure
