Hemchandracharya North Gujarat University, Patan

Bachelor of Vocation Pharmaceutical Chemistry Semester- III

End term Examination, December 2018

(PC 314) Indian Drug Regulatory Guideline

Time: 2 hours 13/12/2018 **Total Marks: 50**

Que-1. Answer any 9 questions. Each question carries 1 mark [9]

1) Define: Linearity
2) Give full form of IND,NDA,
3) Write a Purpose of NDA.
4) Define: TQM
5) _____ give idea about closest value f result to actual value. (precision, accuracy)
6) COA is issued only for finished product. True/ false
7) What is Validation?
8)Define: Sop
9) IRB stand for_____
10)Write full form of CFR, CANDA
11) GMP is
    a) Good MarkettinfPractice
    b) Good Manufacture Practice
    c) Good Manufacturing Practical

Que.2. Answer any 5 questions. Each question carries 4marks [20]

1) Write a note on Certificate of Analysis.
2) Brief On GLP.
3) What is Accuracy & Precision?
4) Note on TQM
5) Write a Note on GMP.
6) Discuss about Detection limit.

Que.3. Answer any 3 questions. Each question carries 7 marks [21]

1) Note on Content of NDA
2) Write note on Analytical method parameter.
3) Explain IND.
4) Write a principle of ISO Guideline.