

**Hemchandracharya North Gujarat University, Patan**  
**Bachelor of Vocation**

**Pharmaceutical Chemistry Semester - III**  
**End Term Examination, December, 2016**

**(PC 314) Indian Drug Regulatory Guideline**

**Time: 2 hrs**

**Date: 22/12/2016**

**Maximum marks: 50**

**Q.1 Answer all questions. Each question carries 1 mark.**

**(9\*1=9Marks)**

1. Write a Purpose of IND
2. What is TQM?
3. Certificate of analysis is generally provided by \_\_\_\_\_. (manufacturer, trader, supplier)
4. Give full form of CANAD, CFR.
5. What is ICH Guideline?
6. COA is issued only for finished product. True/ false
7. Define GMP.
8. Give full form ISO.
9. True/false; SOP is required for handling machine only
10. Define: Validation

**Q. 2 Answer any 5 questions. Each question carries 4 marks.**

**(5\*4=20Marks)**

1. What is Audit? Write Type of Audit.
2. write fundamental point of GLP.
3. What is Robustness & Repeatability?
4. Write benefits of SOP.
5. What is Good received note? Discuss its Components.
6. Discuss certificate of Analysis

**Q.3 Answer any 3 question. Each question carries 7 marks.**

**(3\*7=21Marks)**

1. Write note on Analytical method Validation Parameter.
2. Write a note on content of New Drug Application.
3. Write a general format of SOP.
4. What is ISO? Discuss Eight Principle of ISO.