Pramukh Swami Science & H.D. Patel Arts College, Kadi

Bachelor of Vocation Pharmaceutical Chemistry Semester- III

Internal Examination, October- 2017, November

(PC 314) Indian Drug Regulatory Guideline

Time: 2 hours 2/11/2017 **Total Marks: 60**

Que-1. Answer any 12 questions. Each question carries 1 mark [

1) Define: Robustness.

2) True/false; SOP is required for handling machine only.

3) Give full form of CANAD, CFR

4) Write a Purpose of IND.

5) _____ give idea about closest value f result to actual value. (precision, accuracy)

6) Certificate of analysis is generally provided by_____. (manufacturer, trader, supplier)

7) What is TQM?

8) Define Investigator brochure.

9) Write a purpose of NAD.

10) Enlist type of SOP/

11) COA is issued only for finished product. True/ false

12) What is Validation?

13)IRB stand for_____

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

1) Discuss certificate of Analysis.

2) Write a brief about precision of analytical method.

3) Write a Note on GMP.

4) Discuss about limit of quantification.

5) What is Robustness & Repeatability?

6) Enumerate & Discuss about five fundamental point of GLP.

Que.3. Answer any four questions. Each question carries 7 marks [28]

1) Write note on Validation Parameter.

2) Write a principle of ISO Guideline.

3) Note on Content of IND.

4) Brief on format & submission of NAD.

5) write about elements of Total Quality management.