

Shree Manibhai Virani and Smt. Navalben Virani Science College (Autonomous), Rajkot
Affiliated to Saurashtra University, Rajkot

SEMESTER END EXAMINATION APRIL - 2018

M.Sc. Chemistry (Analytical Chemistry)

16PCEAC06 - REGULATORY AFFAIRS & IPR

Duration of Exam – 3 hrs

Semester – IV

Max. Marks – 70

Part A (5x2= 10 marks)

Answer **ALL** questions

1. What is included in Schedule Y?
2. What is Sampling in QC Lab?
3. Explain TQM in brief.
4. Write a brief note on UPOV for protection of plant varieties.
5. What are Intellectual Property Rights (IPR)?

Part B (5x5= 25 marks)

Answer **ALL** questions

- 6a. Explain GLP.

OR

- 6b. Describe the role of BMR and BPR in QA.

- 7a. Give Regulations given by ANVISA

OR

- 7b. Explain Intellectual Property Rights in brief. Name any 5 Intellectual Property Rights.

- 8a. What is IND & NDA filing?

OR

- 8b. Write a note on SUPAC and level of changes in SUPAC.

- 9a. Note on Personnel, Premises in GMP.

OR

- 9b. What are the legislations covering IPRs in India?

- 10a. What is important of QA/QC and GMP?

OR

- 10b. Write a note on role and benefits of Paris Convention.

Part C (5x7= 35 marks)

Answer **ALL** questions

11a. Explain Raw materials, Equipment's in GMP.

OR

11b. Explain New Drug Approval Process.

12a. Write a detailed note on WHO.

OR

12b. Describe role of Quality Audits in GMP

13a. Explain types of ICH guidelines.

OR

13b. Explain in detail GMP guidelines.

14a. Note on USFDA.

OR

14b. Write a note on Patent Cooperation Treaty (PCT).

15a. Explain Quality Guidelines.

OR

15b. Enlist conditions for Patentability. Enlist types of inventions which are not patentable in India.
