Enroll No. _____

Shree Manibhai Virani and Smt. Navalben Virani Science College (Autonomous)

Affiliated to Saurashtra University, Rajkot

SEMESTER END EXAMINATION NOVEMBER – 2016

M.Sc. Microbiology / M.Sc. Biotechnology

16PMBDC02 / 16PBTDC02 - GOOD LABORATORY PRACTICES

Duration of Exam – 3 hrs ***Semester – I*** ***Max. Marks – 70***

***Part A** (5x2= 10 marks)*

Answer **ALL** questions

1. 21 CFR part 11 and part 111 codes for?
2. What is FIFO?
3. Define the term "Deviation" in Industry
4. What is OOS?
5. What are the functions of HSE department in industry?

***Part B** (5X5 = 25 marks)*

Answer **ALL** questions

6a. Enlist regulatory authorities of Industry. State the role of any one regulatory authority.

OR

6b. Which functions of industry are included in GLP? Discuss aseptic techniques in detail.

7a. What is the need for Calibration of instrument? Discuss calibration process of any one instrument in detail.

OR

7b. Write a brief note on Validation of the instrument. State the phases of Validation.

8a. What is the need of SOP? Discuss with one microbiological example.

OR

8b. What are the functions of Quality control department in industry?

9a. Which parameters are kept into consideration while developing methods in QC? Discuss any one in detail.

OR

9b. Write a brief note on Reporting documents with respect to its procedure and significance.

10a. Write a brief note on Quality audits.

OR

10b. Write a brief note on Waste disposal management.

<u>Part C</u> (5X7 = 35 marks)

Answer **<u>ALL</u>** questions

11a. State the need and function of Quality assurance and Quality management system in Industry.

OR

11b. Write the full form of HACCP and FSSAI. Discuss any one with suitable example.

12a. Write a brief note on IQ, OQ and PQ of the instrumentation.

OR

12b. State the significance of Approval of protocols, Analysis test protocols and Preventive maintenance of equipments.

13a. Enlist various techniques of GLP in Microbiological works. Discuss any two in brief.

OR

13b. Discuss entry exit procedures and the working practices in sterile area of an individual.

14a. What is Reference standard? Discuss about its need, maintenance and reporting.

OR

14b. Write a detail note on Media & Reagent preparation and their storage.

15a. Which regulatory agencies are looking for Health safety and Environment in Industry? Discuss their role in detail.

OR

15b. What is the need of self inspection? State the significance of Record keeping and Labeling in GMP.