

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

SEMESTER END EXAMINATION NOVEMBER 2018

B.Sc. Biotechnology

16UBTDC03 – PHARMACEUTICAL BIOTECHNOLOGY

Duration of Exam – 3 hrs

Semester – V

Max. Marks – 70

Part A (10x1= 10 marks)

Answer **ALL** questions

1. What is Granulation?
2. According to Biopharmaceutical Classification System (BCS) drugs having high solubility & high permeability belongs to class_____?
3. Which organization produced the principle of GLP considered as international standard?
4. Planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality is called_____?
5. According to WHO write the name of any two cell line used in vaccine production?
6. What is the function of Recombinant factor VIII?
7. Write the function of pyrometer?
8. Which is considering living documents that detail written instructions describing specific steps to follow in all activities under defined conditions?
9. Which cell act as regenerative medicine?
10. Which viral vector is used to production of pharma protein by using insect cell?

Part B (5x5= 25 marks)

Answer **ALL** questions

- 11a. Write five application of Biotechnology in pharmaceutical industry?
OR
- 11b. Define in short - i) Agglomeration ii) D-value iii) Generic drug iv) Therapeutic index
v) Orange Book.
- 12a. Explain the principles of Good Laboratory Practices?
OR
- 12b. Why total quality management (TQM) is important in pharmaceuticals? Write important features of TQM?
- 13a. Define Biopharma? Write the name and function of any five Biopharma products?
OR
- 13b. Give the detail account of Recombinant Vaccine?
- 14a. What are the causes of contamination in clean room? Discuss any one category of classification system of clean room?
OR
- 14b. What is Walk-in-incubator? Explain the specification and qualification of walk-in-incubator?

15a. Enumerate any two DNA based molecular diagnostic techniques for disease diagnosis?

OR

15b. Discuss any five advancements in Pharma Biotechnology sector?

Part C (5x7= 35 marks)

Answer **ALL** questions

16a. Discuss the structural organization and function of CDSCO? What is the role of State Licensing Authorities?

OR

16b. Write the name of various departments in pharmaceutical industry? Discuss about any five Common components in Pharmaceutical Manufacturing Operations?

17a. Write are the responsibilities of Quality Control? Discuss the source of quality variation in pharma industry?

OR

17b. Briefly write the objective of quality assurance (QA)? Discuss the important highlights of quality assurance?

18a. Explain various microbiological tests for pharmaceutical products?

OR

18b. Write name of two important protein purification techniques? Explain the production of Recombinant Hormone and antibodies?

19a. Define SOP (Standard operating procedure)? Write important benefits of SOP?

OR

19b. Briefly write the name of seven major instruments and equipments and its role in pharma industry?

20a. What kind of selection systems are used for animal cell transformation? Discuss the production of any two recombinant Biopharma products through animal cell culture?

OR

20b. Describe the principle and application of Molecular diagnosis?
