2. Discuss in brief about the following-

   i. Facility equipment

   ii. Personnel 5+5

3. Discuss in details the key features of good warehousing practices.

III. Short answers (Answer seven out of nine questions) 5x7=35

1. Enlist the various "Q" series guidelines of ICH-QSEM. 5

2. Write any five fundamental differences between QA and QC.

3. Highlight the evaluation tests for containers. 5

4. Highlight the evaluation tests for closures.

5. Discuss the significance of master manufacturing record.

6. Discuss the product recall procedure.

7. Discuss the various sources of complains and procedure for complaint redressal. 2+3

8. What are the salient features of QbD.

9. What are the roles and responsibilities of NABL.

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B Pharm Even Semester Examination, September, 2023

PHARMACEUTICAL SCIENCES

(6th Semester)

Course No: BP-606T

(Pharmaceutical Quality Assurance- Theory)

FM: 75
Time: 3 Hours

The figures in the right margin indicate full marks for the question

I. A. Multiple Choice questions 1x10=10

1. Current Good Manufacturing Practice regulations are enforced by the_____

   i. CDSCO ii. MHRA

   iii. US FDA iv. EU

2. What refers to "degree of excellence"?

   i. Quality ii. Management

   iii. Efficacy iv. Finished product

3. _____ is the key to GMP compliance and ensures traceability of all development, manufacturing, and testing activities.

   i. SOP ii. TQM

   iii. Documentation iv. Warehouse

4. Which one of the following is the storage solution for a calibrated pH meter?

   i. Acid phthalate buffer

   ii. Phosphate buffer

   iii. Distilled water

   iv. 3 M KCl solution.

5. Why security is essential component of GWP?

   i. Prevents theft

   ` ii. Avoids unauthorized entry

   iii. Both

   ` iv. None

6. Test facility management, quality assurance program, meeting the requirements of the test facility, equipment, receipt, handling, sampling and storage, standard operating procedures, performance of the study, reporting of study results, storage and retention of records and materials are the basic components and principles of _____

   i. GMP ii. CGMP

   iii. GCP iv. GLP

7. UV-VIS spectrophotometer works on the wavelength of light ranging from_____ nm.

   i. 100-400 ii. 400-800

   iii. Both iv. None

8. Inventory in case of material management should be always _____

   i. High ii. Low

   iii. Adequate iv. None

9. Where do we find VSR and VMP?

   i. TQM

   ii. QbD

   iii. Material management

   iv. Validation

10. Which of the following is/are type of audit?

   i. Product audit ii. Process audit

   iii. System audit iv. All of the above

I. B. Objective type 2x5=10

1. Write any two differences between quality review and quality documentation.

2. What is distribution record?

3. Define BMR.

4. Define a calibration.

5. Who is the current DCGI? What is the full form of CDSCO? 1+1

II. Long answers (Answer two out of three questions) 10x2=20

1. i. What are buffered tablets?

   ii. Write about two-point method for the calibration of pH meter. 2+8