III. Short type questions (Answer any seven) 5x7=35

a. Enlist the responsibilities of quality assurance department in pharmaceutical industry. 5

b. Enlist the responsibilities of quality control department in pharmaceutical industry. 5

c. Highlight the evaluation tests for containers. 5

d. Highlight the evaluation tests for closures. 5

e. Write a brief note on total quality management. 5

f. What is analytical method validation? Write a brief note on the significance of analytical method validation. 2+3

g. What is process validation? Write a note on the various types of process validation. 2+3

h. What are the salient features of ISO 9000 and ISO 14000. 5

i. Write a brief note on NABL certification process. 5

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B.Pharm Even Semester Examination, May, 2025

PHARMACEUTICAL SCIENCES

(6th Semester)

Course No: BP-606T

(Pharmaceutical Quality Assurance)

FM: 75

Time: 3 Hours

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

I. A. MCQ's (Answer all questions) 1x10=10

a. Current Good Manufacturing Practice regulations are enforced by the_____

i. CDSCO ii. MHRA

iii. US FDA iv. EMA

b. What refers to "degree of excellence"?

i. Quality ii. Management

iii. Efficacy iv. Finished product

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

i. SOP ii. TQM

iii. Documentation iv. Warehouse

d. 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.

e. Why security is essential component of good warehousing practise?

i. Prevents theft

ii. Avoids unauthorized entry

iii. Both

iv. None

f. 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

g. UV-VIS spectrophotometer works on the principle of _____ nm.

i. Daltons law ii. Ficks law

iii. Newtons law iv. Beer-Lamberts law

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

i. High ii. Low

iii. Adequate iv. None

i. Self sealability test is performed for quality control of _____

i. Plastic container ii. Glass container

iii. Rubber closure iv. Metal container

j. Products are recalled from the market based on their batch number.

i. True ii. Ii. False

iii. Iii. Biased iv. Iv. None

I. B. Very short objective type questions (Answer all) 2x5=10

a. What is NP glass?

b. What is personnel?

c. Define BMR.

d. Define SOP.

e. What is CFR 21? 1+1=2

II. Long type questions (Answer any two) 10x2=20

a. i. What is UV radiation range?

ii. Discuss the qualification of UV-VIS spectrophotometer. 2+8

b. Discuss in brief about the following-

i. Premise

ii. Raw materials 5+5

c. Discuss the significance of various Q-series guidelines of ICH QSEM.