BACHELOR OF PHARMACY (B. PHARM.) (CBCS-2019 COURSE)
B. Pharm. Sem-VI : WINTER- 2022
SUBJECT : PHARMACEUTICAL QUALITY ASSURANCE

Day : Thursday | Time : 10:00 AM-01:00 PM

Date : 19-01-2023 | **W-20685-2022** | Max. Marks : 75

N. B. :

1) All questions are **COMPULSORY**.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer books.

SECTION – I

Q. 1 Answer all the questions: **(20)**

a) Enlist different components of quality assurance.

b) What are responsibilities of quality control in pharma industry?

c) Write a short note on Good Manufacturing Practices (GMP).

d) What is importance of TQM in pharma industry?

e) Write a note on stability study.

f) Differentiate between traditional and quality by design approach of product development.

g) What are the principles of ISO?

i) Explain different measures to prevent cross contamination.

j) Enlist different quality control tests for paper and board.

k) What is the classification of the pharmaceutical packaging?

Q.2 Attempt **ANY TWO** of the following: **(20)**

a) Describe in brief good laboratory practices.

b) Explain in brief quality by design approach of product development.

c) Write a note on NABL accreditation and explain organization and personnel role in developing quality product.

Q. 3 Answer **ANY SEVEN** of the following: **(35)**

a) Explain validation master plan.

b) Explain about ICH Q2 R1 guideline.

c) Give importance and scope of validation.

d) Correlate handling of market complaints and recalls.

e) How will you perform qualification of UV-Visible spectrophotometer?

f) Explain about Quality Review.

g) Describe the importance of documentation in pharmaceutical industry.

i) Write in detail about waste disposal in pharmaceutical industry.

j) What is Batch Formula Record and Master Formula Record? Explain in detail BFR.

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