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

Day : Friday
Date : 22-07-2022

S-20685-2022

Time : 10:00 AM-01:00 PM
Max. Marks : 75

N.B.:

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

SECTION – I

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

i) Enlist different responsibilities of quality assurance.
ii) What is the importance of quality management for pharma industry?
iii) What are types of stability studies and enlist various climatic zones used for ICH stability study?
iv) Enlist the different advantages of quality by design approach.
v) What are various personnel responsibilities to be carried out in the pharmaceutical industry?
vi) Write a note on contamination.
vii) Describe steps involved in the purchase procedure.
viii) Explain importance of packaging of pharmaceuticals.
ix) Enlist various chemical tests conducted on glass containers.
x) Write a short note on good laboratory practices.

Q. 2 Attempt **ANY TWO** from following **(20)**

i) Explain in brief approach stating "To identify quality cannot be tested in products, that is quality should be built into product by design."
ii) Describe in brief good laboratory practices.
iii) Write a note on NABL and explain how organization and personnel playing important role in developing quality product.

SECTION - II

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

i) Explain types of complaints and its evaluation parameters.
ii) Elaborate on Standard Operating Process (SOP).
iii) Differentiate between calibration and validation with suitable examples?
iv) Illustrate on analytical method validation as per ICH guidelines.
v) What are Quality Audits? Explain in detail?
vi) Justify documentation as an integral part of pharmaceutical industry.
vii) Explain about waste disposal in pharmaceutical industry.
viii) What is Batch Formula Record and master Formula Record? Explain in brief batch formula record?
ix) What is qualification? Explain qualification of UV visible spectrophotometer?

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