

M. Sc. CLINICAL RESEARCH
SEMESTER - II EXAMINATION, JUNE – 2026
(2025 Batch)

(CMCR518) BASICS OF PHARMACEUTICS

[Time Allotted: 3:00 Hours]**[Max. Marks: 100]****Note:** Read all the instructions carefully

Answer all questions in serial order, Draw suitable diagrams wherever necessary

Q. 1. Objective type questions: (Attempt All) **(10 x 02 = 20)**

(Very short/ Short answer/ MCQ/ One liners/ Fill in the blanks/ True/False)

- a. Define pharmaceuticals. [CO1, PO1]
- b. Explain the relationship between solubility and dissolution. [CO2, PO1]
- c. Define polypharmacy with example. [CO2, PO1]
- d. Write two demerits of oral route of drug administration. [CO1, PO1]
- e. Differentiate between toxic and nontoxic impurities with examples. [CO4, PO2]
- f. Write two situations when a COPP (Certificate of Pharmaceutical Product) is required. [CO5, PO3]
- g. Define fixed dose combinations & give example (FDCs). [CO2, PO1]
- h. Differentiate between dry binders and wet binders. [CO2, PO1]
- i. Define multidisciplinary guidelines. [CO5, PO4]
- j. Differentiate between elixirs and syrups. Also, give examples [CO1, PO1]

Q. 2. Short notes / Short Answer Type (Attempt any **five out of **seven**)** **(5 × 4 = 20)**

- a. Discuss the importance of a regulatory body in Clinical Research. [CO5, PO4]
- b. Differentiate between QC and QA [CO4, PO2]
- c. Write down the methods of particle size measurement. [CO4, PO1]
- d. Enlist the factors affecting the dose of a drug in humans. [CO2, PO1]
- e. Define posology. [CO4, PO2]
- f. What are the eight dimensions of quality? [CO4, PO3]
- g. Differentiate between sustained release and controlled release tablets with examples. [CO2, PO1]

Q. 3. Structured Question (Attempt any **three out of **four**)** **(3 × 10 = 30)**

- a. Elaborate the 10 principles of GMP. [CO5, PO3]
- b. Discuss the parts of a prescription with example. What are common source of errors in a prescription. [CO1, PO4]
- c. Write the limit test for heavy metals. [CO4, PO2]
- d. Elaborate the types of stability testing in pharmaceuticals. [CO4, PO1]

Q. 4. Long Answer/Essay type (Attempt any **two out of **three**)** **(2 × 15 = 30)**

- a. Discuss the parts and functioning of any five instruments observed in the instrumentation room. [CO2, PO1]
- b. Discuss the entire process of approval of new drugs in India. [CO5, PO3]
- c. Elaborate the steps involved in process of ICH harmonization. [CO5, PO4]