

School: SOMAHS	Level: Bachelor	Invigilator's Sign: .....
Program: B. Pharmacy	Year/Part: III/II	Superintendent's Sign: .....
<b>Subject: Pharmaceutics -III (BP 601)</b>		Code No. ....

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<b>GROUP A (Multiple-Choice Questions)</b>	<b>[10x1=10]</b>	<b>Time: 20 Minutes</b>
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- i This group contains 10 multiple-choice questions (MCQs).
- ii Answers must be marked on the MCQ Answer Sheet. Code No.:
- iii You may use the main answer sheet for rough work.
- iv Marks will not be awarded for answers with cutting, erasing, overwriting, or multiple shaded options.
- v The MCQ question paper must be returned along with the MCQ answer sheet.

1. The primary objective of preformulation studies is to:
  - A. Increase drug price
  - B. Reduce manufacturing cost
  - C. Improve packaging
  - D. Gather information for dosage form development
2. According to the Biopharmaceutical Classification System (BCS), Class I drugs possess:
  - A. Low solubility and low permeability
  - B. High solubility and high permeability
  - C. High solubility and low permeability
  - D. Low solubility and high permeability
3. Which of the following is a principle of Total Quality Management (TQM)?
  - A. Customer satisfaction
  - B. Product recall
  - C. Advertising
  - D. Outsourcing
4. Accelerated stability studies are generally conducted to:
  - A. Predict shelf life
  - B. Predict half life
  - C. define stability profile
  - D. Test packaging
5. Cleaning validation is mainly performed to:
  - A. Improve appearance
  - B. provide line clearance
  - C. Ensure product safety
  - D. Prevent cross-contamination
6. Which microencapsulation technique uses atomization of a solution into hot air?
  - A. Pan coating
  - B. Coacervation
  - C. Spray drying
  - D. Air suspension
7. An ideal controlled-release dosage form should follow:
  - A. First-order release
  - B. Zero-order release
  - C. Random release
  - D. Biphasic release
8. The Higuchi model describes drug release primarily by:
  - A. Osmosis
  - B. Polymerization
  - C. Erosion
  - D. Diffusion
9. Good Warehouse Practice primarily ensures:
  - A. Proper storage of materials
  - B. workers safety
  - C. Area cleanliness
  - D. Product pricing
10. Amber-colored containers are used mainly to protect products from:
  - A. Heat
  - B. Moisture
  - C. Light
  - D. Dust

**Multiple Choice Questions' Answer Sheet**

Marks Secured: \_\_\_\_\_

In Words: \_\_\_\_\_

Examiner's Sign: \_\_\_\_\_ Date: \_\_\_\_\_

Scrutinizer's Marks: \_\_\_\_\_

In Words: \_\_\_\_\_

Scrutinizer's Sign: \_\_\_\_\_ Date: \_\_\_\_\_

Corrected Fill

A    B    C    D

Incorrected Fill

A    B    C    D

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Manmohan Technical University  
Office of the Controller of Examinations

**Exam Year: 2083, Ashar**

School: SOMAHS	Level: Bachelor	Time: 3 Hours
Program: B.Pharmacy (M0del Questions)	Year/Part: III/II	Full Marks: 50
<b>Subject: : Pharmaceutics -III (BP 601)</b>		

- ✓ Candidates are required to give their answers in their own words as far as practicable.
- ✓ The figures in the margin indicate **Full Marks**.
- ✓ Assume suitable data if necessary.

**GROUP A (Multiple-Choice Questions are provided on separate sheet)**

**[10\*1=10]**

**GROUP B (Problem Based Questions)**

**[2\*5=10]**

1. A pharmaceutical company develops a controlled-release tablet intended to release the drug over 24 hours. During dissolution testing, 80% of the drug is released within the first 4 hours.
  - a. What formulation problem is indicated by this result? [2]
  - b. Mention two possible causes of rapid drug release. [1]
  - c. Suggest suitable formulation approaches to achieve controlled release with a suitable representative formula . [2]
2. A syrup formulation stored in a transparent bottle develops discoloration and loses potency after six months of storage.
  - a. Which degradation process is likely responsible? [2]
  - b. How can packaging contribute to this problem? [1]
  - c. Suggest suitable packaging modifications to improve stability. [2]

**[4\*5=20]**

**GROUP C (Long Answer Questions – Attempt Any four Questions)**

1. Explain the concepts of Quality Management, Total Quality Management (TQM), Quality by Design (QbD), and Six Sigma in pharmaceutical industries.
2. Discuss ICH guidelines for stability testing. Explain stress testing, accelerated stability testing, and long-term stability testing.
3. Define pharmaceutical validation. Describe various types of validation and explain the importance of cleaning validation.
4. Define microencapsulation. Discuss various microencapsulation techniques with suitable examples.
5. Discuss controlled-release drug delivery systems. Explain factors influencing the design and performance of controlled-release products and describe various oral controlled-release systems.

**GROUP D (Short Answer Questions – Attempt any Five )**

**[5\*2 = 10]**

1. Define preformulation studies and state any two objectives.
2. Differentiate between SOP and BMR.
3. What is accelerated stability testing? Mention its significance.
4. Define pharmaceutical validation. State any two advantages.
5. Write any four pharmaceutical applications of microencapsulation.
6. Write down the pharmaceutical application of polymers.

\*\*\*\*\* All the Best \*\*\*\*\*