

Total No. of Questions : 5]

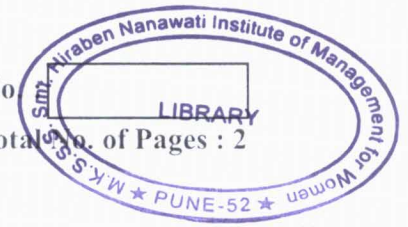
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SEAT No.

[Total No. of Pages : 2



**308 PHM-614-MJ : PHARMACEUTICAL PRODUCTION MANAGEMENT
(2024 Pattern) (Semester - III)**

Time : 2½ Hours]

[Max. Marks : 50

Instructions to the candidates:

- 1) *All questions are compulsory.*
- 2) *Each question has an internal options.*
- 3) *Your answer should be specific and to the point.*

Q1) Answer any 5 out of 8. (2 marks each)

[10]

- a) State any two objectives of production management in the pharma industry.
- b) What are the 6Ms of production management?
- c) Define GMP and State its purpose.
- d) What is meant by process validation?
- e) Define RRP (Resource Requirement Planning)
- f) List any two basic requirements of cGMP.
- g) What is facility layout in pharmaceutical production?
- h) What is manufacturing operations control?

Q2) Answer any 2 out of 3 questions. (5 marks each)

[10]

- a) Explain the importance of inventory management and the concept of Just-In-Time (JIT) in pharma production.
- b) Explain the key functions of production management in the pharmaceutical industry.
- c) Describe traditional vs modern pharma manufacturing techniques with suitable examples.

P.T.O.

Q3) Answer 3 (a) or 3 (b)

[10]

- a) Discuss the role of Quality Assurance and Quality Control in ensuring compliance with GMP/cGMP in pharmaceutical production.
- b) Discuss how environmental and safety considerations influence the design and operations of a pharmaceutical plant.

Q4) Answer 4 (a) or 4 (b)

[10]

- a) Discuss the stages and importance of process validation. Explain with examples relevant to pharmaceutical production.
- b) Analyze the factors affecting production scalability in the pharmaceutical industry with suitable examples.

Q5) Answer 5 (a) or 5 (b)

[10]

- a) Critically evaluate the challenges and risk factors associated with implementing continuous manufacturing in pharmaceutical facility.
- b) Examine how digital transformation is reshaping pharmaceutical production planning and resource management.

