

**M. PHARM.**  
**(SEM-II) THEORY EXAMINATION 2018-19**  
**PHARMACEUTICAL PROCESS CHEMISTRY**

Time: 3 Hours

Total Marks: 70

**Note:** 1. Attempt all Sections. If require any missing data; then choose suitably.

**SECTION A**

1. Attempt *all* questions in brief. 2 x 7 = 14
- a. What is API? Give example.
  - b. Define the term "In process control".
  - c. What is genotoxic impurity? Give examples.
  - d. Define nitrating agents with examples.
  - e. What do you mean by cost effective route?
  - f. Define In-process control.
  - g. Write down the structures of Vitamin B<sub>2</sub> and B<sub>12</sub>

**SECTION B**

2. Attempt any *three* of the following: 7 x 3 = 21
- a. Describe stages of scale up process in detail.
  - b. Discuss in detail about validation of large scale process.
  - c. Discuss the detailed account of oxidative reactions and non oxidative agents in unit process.
  - d. Describe the role fermentation process in the production of antibiotics.
  - e. Describe the isolation, characterization and profiling of impurities in API.

**SECTION C**

3. Attempt any *one* part of the following: 7 x 1 = 7
- (a) Write a note on "Reaction progress kinetic analysis".
  - (b) Define impurities of API. Explain their types with suitable examples.
4. Attempt any *one* part of the following: 7 x 1 = 7
- (a) What is industrial safety? Explain types of hazards with special reference of chemical hazard.
  - (b) Discuss the role of fermentation in the production of Vitamins
5. Attempt any *one* part of the following: 7 x 1 = 7
- (a) Explain the mechanism of reduction reactions used in unit process.
  - (b) Discuss the mechanism of halogenation and nitration reaction of unit process.
6. Attempt any *one* part of the following: 7 x 1 = 7
- (a) Write a note on Hazard labels of chemicals with examples.
  - (b) Discuss in detail about 14001(Environmental Management System).
7. Attempt any *one* part of the following: 7 x 1 = 7
- (a) Discuss in detail about material safety data sheet (MSDS) ISO
  - (b) Describe Occupational health and safety health series 1800