Printed Pages: 01 **Sub Code: MPC 204**

Paper Id: 900156 **Roll No.** | | | | | | | | | | |

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_2 and B_{12}

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

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