Printed Pages:01 **Sub Code: MQA 204T**

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M. PHARM
(SEM-II) THEORY EXAMINATION 2018-19
PHARMACEUTICAL MANUFACTURING TECHNOLOGY

Time: 3 Hours ***Total Marks: 75***

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

SECTION A

1. Attempt *all* questions in brief. 10 x 2 = 20

a. State four major components of pharmaceutical sterile and aseptic area layout.

b. What do you mean by pharmaceutical production control?

c. State the principle of lyophilization.

d. Name four major in process quality control tests for small and large volume solutions.

e. State the working principle of marumerisers.

f. State the problems generally encountered during fluidized bed coating.

g. Mention the types of glass used to store pharmaceuticals.

h. State the uses of blister packs and tape seals.

i. Mention the advantages of QbD.

j. Write down the full forms of QTPP and RLD.

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SECTION B

2. Attempt any *two* parts of the following: 2 x 10 = 20

a. Describe the roles of the factors influencing pharmaceutical plant location.

b. Draw a neat manufacturing flowchart for pharmaceutical ointments.

c. Write a brief note on drug plastic interactions and how to overcome the problem.

SECTION C

3. Attempt any *five* parts of the following: 7 x 5 = 35

a. Write brief notes on the following:

(i) Legal requirements for API
(ii) Pharmaceutical aseptic area layout..

b. Write a brief note on the construction and applications of lyophilizer.

c. Describe the in process quality control tests for coated tablets.

d. Describe the evaluation methods for checking stability of pharmaceutical packaging material.

e. Write a brief note on different types of closures and closure liners.

f. Explain the FDA initiatives on process analytical technology.

g. State and explain the current approaches and limitations of QbD.