Printed Pages : 1 **Roll No.** | | | | | | | | | | | **MPH-205**

M. PHARMA.

THEORY EXAMINATION (SEM–II) 2016-17

PHARMACEUTICAL DESIGN & DEVELOPMENT

Time : 3 Hours ***Max. Marks : 70***

Note : *Be precise in your answer. In case of numerical problem assume data wherever not provided.*

SECTION- A

1. Attempt all parts of this Section : **7×2=14**

(a) Mention the scopes of preformulation studies.

(b) Classify drug-excipients interactions.

(c) Mention the parameters used for optimization of a pharmaceutical formulation.

(d) Mention the significance of factorial design.

(e) What do you mean by 'pilot plant scale-up'?

(f) What are the various types of recalls in pharmaceutical product disposal?

(g) What do you mean by technology transfer?

SECTION- B

2. Attempt any three parts of the following : **3×7=21**

(a) Describe various solubility enhancement techniques used for poorly soluble drugs.

(b) Describe the methods to be used for drug-excipients interactions.

(c) Mention the application of statistical design in optimization of a pharmaceutical formulation.

(d) Write down the protocols for technology transfer in pharmaceutical manufacturing.

(e) What are the methods for safe disposal of unwanted pharmaceuticals?

SECTION- C

3. Attempt all questions in this section : **5×7=35**

(a) State the preformulation worksheet for solid dosage forms.

OR

Write down the stability testing protocols for various dosage forms as per ICH guidelines.

(b) **Write brief note on any one of the following:**

(i) Selection of excipients

(ii) GRAS excipients

(c) **Write short notes on any one:**

(i) Response surface method

(ii) Contour design.

(d) Write brief note on PAT.

OR

Describe the term 'post approval changes'.

(e) Write brief note on 'finished product reprocessing and salvaging'.

OR

Mention the strategy for effective recall.