Printed Pages: 01 **Sub Code:MRA205**

Paper Id: | 2 | 8 | 3 | 2 | 0 | 7 | **Roll No.** | | | | | | | | | | |

M. PHARM

(SEM II) THEORY EXAMINATION 2017-18

CLINICAL RESEARCH REGULATIONS

Time: 3 Hours ***Total Marks: 70***

Note: Attempt all Sections.

SECTION A

1. Attempt *all* questions in brief. 2 x 7 = 14

a. Define Clinical trial Protocol?
b. Diffrentiate ethics and Law.
c. Mention the role of placebo in clinical trials.
d. What is the purpose of ICH guidelines?
e. What is the full form of CDSCO? Mention its function.
f. What are the requirements for INDA submission.
g. What are the benefits of post marketing surveillance?

SECTION B

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

a. Discuss in detail about various phases of clinical trial.
b. Write in detail about Good clinical practice (ICH-GCP) guidelines.
c. Discuss FDA Guidance to industry for acceptance of foreign clinical studies.
d. Write about ICH GCP guidelines for Clinical investigation of medicinal products in the pediatric population.
e. Describe EU Directives on Pharmacovigilance for medicinal products for human use.

SECTION C

3. Attempt any *one* part of the following: 7 x 1 = 7

(a) Discuss the principles governing informed consent process.
(b) Discuss the composition, roles, responsibilities, review and approval process of institutional review board

4. Attempt any *one* part of the following: 7 x 1 = 7

(a) What are the responsibilities of sponsor in ethical conduct of clinical research? discuss in detail.
(b) Write about US-FDA regulations to conduct clinical trials.

5. Attempt any *one* part of the following: 7 x 1 = 7

(a) Describe clinical research regulations in European Union.
(b) Discuss clinical research regulations in India.

6. Attempt any *one* part of the following: 7 x 1 = 7

(a) Write a note on Indian GCP guidelines.
(b) Discuss about Good clinical practice guidelines (ICH GCP E10): Choice of control groups and related issues in clinical trials.

7. Attempt any *one* part of the following: 7 x 1 = 7

(a) Discuss about FDA Safety reporting requirements for INDs and and BA/BE studies.
(b) Discuss the formate and content of IND application.