Exam Seat No:_____ **Enrollment No:**_____

C.U.SHAH UNIVERSITY

WADHWAN CITY

University (Winter) Examination -2013

Course Name :M.Pharm Sem-I **Subject Name: - Method of Drug Evaluation & Clinical Research**

Duration :- 3:00 Hours **Date : 10/01/2014**

Instructions:-

(1) Attempt all Questions of both sections in same answer book / Supplementary.
(2) Use of Programmable calculator & any other electronic instrument is prohibited.
(3) Instructions written on main answer Book are strictly to be obeyed.
(4) Draw neat diagrams & figures (If necessary) at right places.
(5) Assume suitable & Perfect data if needed.

SECTION-I

Q-1 Define the following terms **(7)**

(1) AUC (2) Sterilization (3) Pyrogen

(4) Cmax (5) Good Clinical Practice (6) Bioequivalance (7) Pharmacokinetic

Q-2 (a) Describe Gel-Clot Technique For LAL Test. (5)

(b) Describe Membrane Filtration Method for Sterility Test. (5)

(c) Write informative note on microbial limit test. (4)

OR

Q-2(a) What do you understand regarding bioassay ? Explain its basic Principle. (5)

(b)What do you understand regarding toxicity study ? Discuss its parameters. (5)

(c) Write a short note on depyrogentation (4)

Q-3(a) Discuss the objectives and importance of bioavailability study (7)

(b)Discuss the importance of drug regulation (7)

OR

Q-3(a) Explain the various guidelines for bioequivalence study. (7)

(b) Discuss the various significance and importance of microbial limit test. (7)

SECTION-II

Q-4 Define and explain the following terms. **(7)**

(1) Pharmaceutical Equivalence
(2) Pharmaceutical alternative
(3) Tmax
(4) Investigator
(5) Teratogenecity
(6) Pharmacodynamic
(7) LD50 & ED50

Q-5 (a) What is drug development ? Explain the different stage involve in it. (5)

(b)Explain briefly ELISA and EMIT with their merits and demerits. (5)

(c)Write informative note on NDA (4)

OR

Q-5 (a) Discuss the importance of dissolution test study in contact with BA/BE Study. (5)

(b)Write detail note on Helsinki declaration. (5)

(c)Write short note on Rabbit pyrogen test. (4)

Q-6(a) Discuss the basic consideration in pharmacokinetic and various pharmacokinetic models used. (7)

(b) Explain the various objectives and consideration required for clinical trials of drugs (7)

OR

Q-6(a) Discuss the various phases in details for clinical trials. (7)

(b) Discuss Indian guidelines on biomedical research and clinical trials. (7)

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