

C.U.SHAH UNIVERSITY

WADHWAN CITY

University (Winter) Examination -2013

Subject Name: - Method of Drug Evaluation & Clinical Research

Course Name :M.Pharm Sem-I

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.

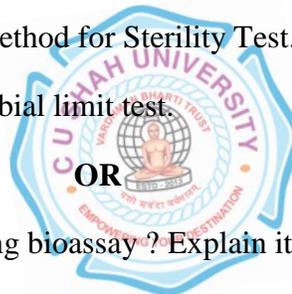
SECTION-I**Q-1 Define the following terms (7)**

- (1) AUC (2) Sterilization (3) Pyrogen
(4) Cmax (5) Good Clinical Practice (6) Bioequivalence (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 depyrogenation (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) T_{max}
- (4) Investigator
- (5) Teratogenicity
- (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)

*******10***14*****

