NAME..... ROLLNO.....

2008 JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY

III B.TECH II SEMESTER SUPPLIMENTARY EXAMINATIONS
REGULATORY AFFAIRS AND CLINICAL TRIALS
(BIO-TECHNOLOGY)

AUG/SEP 2008

TIME-3 HOUR
MARK-80

ANSWER ANY FIVE QUESTIONS.ALL QUESTIONS CARRY EQUAL MARKS

1. Write in detail about Clinical trial directives made by European Union.

2. Write short notes on:

(a) Negleigence in clinical trails

(b) Informed consent

(c) Mental competence.

3. Write the roles of GCP auditor in Quality assurance unit.

4. What are the essential documents needed during the clinical conduct of the study.

5. (a) What is clinical audit and explain various types of audits.

(b) Explain how an invertigator should prepare for audits.

(c) Explain the purpose of Audits.

6. Explain. Medicine Health care Research Agency-QSE.

7. What are the requirements for gaining approval by FDA?

8. Write short notes on

(a) ICH principles

(b) Inspection policy.