



# AJEENKYA

## D Y PATIL UNIVERSITY

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### End Term Examinations (December 2018)

**School :** School Of Management

**Program:** M.Sc.Clinical Research

**Course:** Introduction To Clinical Research

**Course Code:** MGT549

**Semester:** Semester I

**Max Marks:** 50

**Duration(mins) :** 2 Hrs(120 mins)

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Note: 1. Figures to the right indicates full marks.

Q.1 Define Clinical research. Discuss in detail the various phases of clinical trial (10)

OR

Q.1 Discuss in detail the need and importance of Post Marketing Surveillance. (10)

Q .2 What is investigational new drug? Discuss the drug development process and data to be submitted along with the application to conduct clinical trials as per schedule Y. (10)

OR

Q. 2 Discuss the importance and contents of Investigator Brochure. (10)

Q. 3 Define Ethics. Give detailed account of ICH-GCP guidelines (10)

OR

Q. 3 Write down General principles and General ethical issues as per ICMR guidelines (10)

Q.4. Define Bioavailability & Bioequivalence. Factors affecting in Bioavailability, Significance of BA-BE studies in Clinical Trial. (10)

OR

Q.4 Write a short note on of the following (10)

- a. Human Equivalent Dose (HED)
- b. Mutagenicity and carcinogenicity

Q.5 Write a short note on Any Two of the following (10)

- a. Belmont Report
- b. Pharmacokinetics
- c. Declaration of Helsinki
- d. Institutional Review Board/Independent Ethics Committee (IRB/IEC)