IIHMR UNIVERSITY

School of Pharmaceutical Management

Master of Business Administration

Pharmaceutical Management

Batch-8th (2016-2018) Second Year

Clinical Research and Development

Term Examination

Time - 3 Hour **MM-70**

The question paper contains 1 printed page.
Each question carries equal marks
Attempt any five questions.

Q. 1. What do you mean by drug development process (DDP). Describe the role of Clinical Research in DDP with its different phases of trials.

Q.2. Enumerate 13 ethical principles of ICH-GCP essential for evaluation of drugs in humans.

Q.3. What are adverse drug reactions? Describe periodic safety update reporting (PSUR).

Q.4. Why bioavailability/bioequivalence studies are needed for approval of generic drugs. How parallel designs differs from cross-over designs.

Q.5. What are source documentation and give examples of different source documents for clinical trials. Enumerate the list of essential documents required before the trial start.

Q. 6. How Pharmacovigilance is important in clinical research. Describe about the role of Pharmacovigilance Program in India (PvPi).

Q.7. Write short note on any two.

1. **Monitoring of clinical trials**
2. **Analysis of clinical data**
3. **Models and Theory of clinical research**