

Code: 17S11103

M.Pharm I Semester Regular Examinations February 2018

**CLINICAL RESEARCH REGULATIONS**

(Pharmaceutical Regulatory Affairs)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

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- 1 Explain about various phases of clinical trials.  
**OR**
- 2 What is new drug development process? Discuss about regulatory process in approving the new drug in to market.
- 3 Explain the composition, roles and responsibilities of institutional ethics committee.  
**OR**
- 4 What is patient information sheet? Explain the process of informed consent.
- 5 Explain about the Indian regulations governing clinical trials in India.  
**OR**
- 6 Explain the procedure in getting the approval of generic drug product as per USFDA.
- 7 Explain about the CDSCO guides pertaining to the conduct of clinical trials.  
**OR**
- 8 Explain about the clinical investigation of medicinal products in pediatric population.
- 9 (a) Explain the USFDA guidelines on financial disclosure by clinical investigators.  
(b) Write about EU guidance on animal safety reports.  
**OR**
- 10 What are good pharmacovigilance practices? Explain in detail.

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