

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LO 974]

MAY 2019

Sub. Code: 2974

**M.PHARM. DEGREE EXAMINATION**  
**(PCI New regulations 2016)**  
**SEMESTER-I**  
**BRANCH V – PHARMACY PRACTICE - MPP**  
**PAPER IV – CLINICAL RESEARCH**

*Q.P. Code : 262974*

**Time : Three hours**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Define clinical trials. Discuss in detail five various phases involved in drug development process.
2. a) Define investigational new drug application and describes the component and categories of investigational new drug application.  
b) What are the essential documents for the conducting of clinical trials and its purpose?

**II. Write notes on:**

**(7 x 5 = 35)**

1. Significance of post marketing surveillance.
2. Study designs in a clinical trial.
3. Vulnerable subjects.
4. Define the followings:  
a) Blinding      b) Comparator      c) Good clinical practice
5. Data migration and archiving.
6. Write a note on schedule Y.
7. Good clinical practice and its principles.

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