

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

**[MPHARM 0921]**

**SEPTEMBER 2021  
(OCTOBER 2020 EXAM SESSION)**

**Sub. Code: 2968**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER-II (PCI New regulations 2016)  
PHARMACEUTICAL BIOTECHNOLOGY - MPB  
PAPER IV – BIOLOGICAL EVALUATION OF DRUG THERAPY  
*Q.P. Code : 262968***

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Regulatory considerations for pre-clinical & clinical testing of biologicals.
2. Insulin & Antibiotics Assays.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Gene Therapy.
2. Evaluation tests of pyrogens.
3. Guidelines of toxicity studies.
4. Applications of pharmacokinetic principles in monoclonal antibodies.
5. Assay of Vitamins.
6. 'Bioequivalence studies of biopharmaceuticals.
7. Gene Therapy in treatment of various diseases.

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