

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

[LP 968]

NOVEMBER 2019

Sub. Code: 2968

M.PHARM. DEGREE EXAMINATION

(PCI New regulations 2016)

SEMESTER-II

BRANCH-IV – PHARMACEUTICAL BIOTECHNOLOGY – MPB

PAPER IV – BIOLOGICAL EVALUATION OF DRUG THERAPY

Q.P. Code : 262968

Time : Three hours

Maximum : 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Explain in detail about Regulatory aspects of drugs, biologicals and medical devices.
2. Microbiological assay of Antibiotics and Vitamins.

II. Write notes on:

(7 x 5 = 35)

1. Special toxicity studies.
2. Describe various guidelines of toxicity studies.
3. Neurologic disorders.
4. Interferons.
5. Official pyrogen tests.
6. Novel drug delivery system of biopharmaceuticals.
7. Growth factors.

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[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.
