

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.

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.

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

[M.PHARM 0922]

**SEPTEMBER 2022
(APRIL 2022 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. Discuss about preclinical drug evaluation methods in animals. Add a note on teratogenicity and Genotoxicity tests.
2. Discuss the biological category of medicines used in the treatment of Autoimmune and Infectious diseases.

II. Write notes on:

(7 x 5= 35)

1. Methods of bioavailability measurement.
2. Methods for pyrogen detection.
3. Methods to overcome challenges in the delivery of biopharmaceuticals.
4. Principle and applications of microbiological assay.
5. Organ Transplantation.
6. In-vitro and In-vivo models for diseases.
7. Growth factors and Gene therapy in medicine.

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

[M.PHARM 0823]

**AUGUST 2023
(APRIL 2023 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. What are ED50 and LD50? Discuss about important aspects of acute and chronic toxicity testing of drugs.
2. Discuss the biological category of medicines used in management and treatment of cancer and related disorders.

II. Write notes on:

(7 × 5= 35)

1. Bioavailability concepts and bioequivalence.
2. Pyrogen and its importance.
3. Novel drug delivery of Biopharmaceuticals.
4. Microbiological assay of Vitamins.
5. Regulatory considerations related to approval and clinical testing of biopharmaceuticals.
6. Screening In-vitro models for diseases.
7. Interferon and RNA interference as biological medicine.
