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

[M.PHARM 0423] APRIL 2023 Sub. Code: 3004
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS – MRA
PAPER IV – REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Q.P. Code: 263004

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. The regulatory requirements and approval procedures for Food and Nutraceuticals in India.

2. The organization, responsibilities and registration procedure for drugs under CDCSO.

II. Write notes on: **(7 x 5 = 35)**

1. The guidelines for approval of medical devices in India.
2. Drug Price Control Order.
3. Biopharmaceutic Classification System (BCS) and its importance.
4. The categories of research on stem cell as per DST-ICMR Guidelines.
5. CPCSEA Guidelines.
6. The regulatory requirements for carrying out BA/BE (Bioavailability and bioequivalence) studies in India.
7. Stability studies and the stability requirements as per WHO (World Health Organization).

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

[M.PHARM 0823] AUGUST 2023 Sub. Code: 3004
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER IV – REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Q.P. Code: 263004

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Describe in detail regulatory requirements and approval procedure for biologicals in India.

2. Write elaborately on ICMR-DBT guidelines for stem cell research and add a note on stem cell classification.

II. Write notes on: **(7 x 5 = 35)**

1. Write a brief procedure for obtaining patent in India.
2. Discuss in brief about Bureau of Indian Standard.
3. Write the functions of NPPA.
4. Explain the CPCSEA guidelines for conducting experiments in animals.
5. Write a note on WHO stability requirements of Pharmaceuticals.
6. Explain the regulatory requirements for bioequivalence studies in India.
7. Write a short note on Indian Pharmacopoeia and its standards.

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

[M.PHARM 0524] MAY 2024 Sub. Code: 3004
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER IV – REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Q.P. Code: 263004

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Regulatory requirements for carrying out BA/BE studies in India.

2. Intellectual property rights and Indian patent scenario.

II. Write notes on: **(7 x 5 = 35)**

1. Medicinal and Toilet Preparation Act.
2. International Organisation for standardisation (ISO).
3. The ethical guidelines for carrying out stem cell research in India.
4. Prevention of Cruelty to Animals Act.
5. The regulatory guidelines and authorities for narcotic biologics in India.
6. ICH stability guidelines.
7. The Ayush guidelines and standards for herbals.

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 3004**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER IV – REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Q.P. Code: 263004

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Write in detail about regulatory requirements for conducting bioequivalence studies in India.

2. Explain the regulatory requirements for import of drugs and cosmetics as per D & C Act 1940 and Rules 1945.

II. Write notes on: **(7 x 5 = 35)**

1. Write the roles and responsibilities of DPCO.
2. Explain the process of medical device approval in India.
3. List the responsibilities of CDSCO.
4. Write a brief procedure for obtaining Patent in India.
5. Explain CPCSEA guidelines for conducting experiments in animals.
6. Write the function and role of DTAB and DCC.
7. Differentiate between IPR and Regulatory Affairs.

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