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

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 3005**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – REGULATORY ASPECTS OF DRUGS & COSMETICS

Q.P. Code: 263005

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

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

1. Explain the organization and functions of US FDA.

2. Explain the regulations for manufacture, distribution and sale of cosmetic in European Union.

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

1. Regulatory requirement for orphan drugs in US.
2. Supplement New Drug Application (SNDA)
3. Eudralex directives for human medicines.
4. Post marketing surveillance in Japan.
5. Distribution and sale of cosmetics in ASEAN countries.
6. Marketing authorization procedure in Kazakhstan.
7. Post approval requirement in Singapore.

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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 3005
(OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – REGULATORY ASPECTS OF DRUGS & COSMETICS

Q.P. Code: 263005

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

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

1. Explain the regulatory considerations for manufacture, packaging and labeling of pharmaceuticals in USA.

2. Discuss the regulatory requirements for registration of drugs and post approval requirements in WHO through prequalification programme.

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

1. Drug Master File (DMF) in US.
2. Hatch Waxman act and orange book.
3. Import and regulation for import of cosmetics in Australia.
4. Certificate of pharmaceutical product for Egypt and Nigeria.
5. Requirements for registration of drugs in China.
6. Regulatory committee in ASEAN and SADC.
7. Legislation and regulations for distribution and sale of cosmetics in Brazil.

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

[M.PHARM 0524] MAY 2024 Sub. Code: 3005
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – REGULATORY ASPECTS OF DRUGS & COSMETICS

Q.P. Code: 263005

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

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

1. Describe the history and evolution of United States Federal Food Drug and Cosmetics Act (FFDCA).

2. Explain the regulatory considerations for manufacture, packaging and labeling of pharmaceuticals in Japan.

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

1. Regulatory approval process for Investigational New Drug (IND).
2. Decentralized marketing authorization procedures in EU.
3. Explain Active Substance Master Files (ASMF)
4. Different types of registration applications in Japan.
5. Regulatory pre-requisites related to marketing authorization requirement for drugs in UAE.
6. Regulatory pre-requisites related to marketing authorization requirement related to drugs in Commonwealth of Independent States (CIS).
7. Post approval requirement in Gulf Cooperation council (GCC).

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

[M.PHARM 1124] **NOVEMBER 2024** **Sub. Code: 3005**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – REGULATORY ASPECTS OF DRUGS & COSMETICS

Q.P. Code: 263005

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

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

1. Elaborate the content and regulatory approval process of Pre –IND and IND in USA.

2. Discuss in detail the WHO –GMP certification in pharma industry.

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

1. Give a note on marketing authorization transfer.
2. Write down the benefits of orange book.
3. Explain sale and distribution of cosmetics in Japan.
4. Write the salient features of Japanese laws and regulations.
5. Differentiate between generic and brand products.
6. Write the salient features of ACTD.
7. Explain the needs of prequalification programme.

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

[M.PHARM 1025] **OCTOBER 2025** **Sub. Code: 3005**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – REGULATORY ASPECTS OF DRUGS & COSMETICS

Q.P. Code: 263005

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

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

1. Elaborate on Purple book and its significance. Describe the historical evolution of the United States federal, Food, Drug and Cosmetic act.

2. Discuss the key legislative and regulatory requirements for the import, manufacture distribution and sale of cosmetics in EU.

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

1. Code of Federal Register.
2. Regulatory requirements for import and manufacture of cosmetics in Canada.
3. Certificate of suitability and market authorization transfers.
4. Sale of Cosmetics in Brazil.
5. Regulatory considerations for packaging and labelling of drugs in Japan.
6. Marketing authorization requirements in Saudi Arabia and UAE.
7. Certificate of Pharmaceutical product (COPP) for Kenya and Botswana.

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