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

**[M.PHARM 0823] AUGUST 2023 Sub. Code: 3006**
**(APRIL 2023 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICAL REGULATORY AFFAIRS - MRA**
**PAPER II – REGULATORY ASPECTS OF HERBAL & BIOLOGICALS**

***Q.P. Code: 263006***

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

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

1. Explain the process of BLA submission and approval in the US.

2. Explain regulatory guidelines for blood and its components including blood products in India.

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

1. Write the GMP requirements for biologics in India.
2. Write about the advertising and labeling aspects of biologics in EU.
3. Write about the TSE/BSE evaluation.
4. Pharmacovigilance for vaccines in India.
5. United States regulations and guidelines for herbal medicine.
6. Legislative guidelines for herbal medicine in India.
7. Explain the safety and packaging system of herbal products in US.

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

**[M.PHARM 1223] DECEMBER 2023 Sub. Code: 3006**
**(OCTOBER 2023 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICAL REGULATORY AFFAIRS - MRA**
**PAPER II – REGULATORY ASPECTS OF HERBAL & BIOLOGICALS**

***Q.P. Code: 263006***

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

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

1. Write the premarket approval (PMA) data to be submitted for biologicals as per the US FDA.

2. Elaborate on vaccine regulations in India for marketing authorization registration.

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

1. Revised guidelines on similar biologics in India.
2. Advertising guidelines for biologics in EU.
3. Importance of 510(K) application.
4. Role of International Society for Blood Transfusion (ISBT).
5. Explain International Haemovigilance Network (IHN).
6. What are the safety requirements of herbal drugs under AYUSH in India?
7. Indian regulatory guidelines for herbal product quality.

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

**[M.PHARM 0524] MAY 2024 Sub. Code: 3006**
**(APRIL 2024 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICAL REGULATORY AFFAIRS - MRA**
**PAPER II – REGULATORY ASPECTS OF HERBAL & BIOLOGICALS**

***Q.P. Code: 263006***

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

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

1. Discuss in general the regulatory requirements of similar biologics for market authorization.

2. Explain on the quality, safety and regulatory guidance of herbals for USA.

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

1. Write notes on pharmacovigilance for biologics.
2. Differentiate generic and biosimilars concept.
3. What is plasma master profile?
4. Write a note on GMP and GDP.
5. Write in brief about International Society of Blood Transfusion (ISBT).
6. Write a note on labeling and packaging of biologics.
7. Write in brief the stability issues for biologics products.

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

**[M.PHARM 1124]** **NOVEMBER 2024** **Sub. Code: 3006**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICAL REGULATORY AFFAIRS - MRA**
**PAPER II – REGULATORY ASPECTS OF HERBAL & BIOLOGICALS**

***Q.P. Code: 263006***

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

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

1. Discuss the preclinical and clinical development in EU of biologics for market authorization.

2. Explain on the quality, safety and regulatory guidance of herbals for India.

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

1. Write notes on International Hemovigilance Network (IHN).
2. Differentiate NDA and BLA.
3. What is INA and 510(k)?
4. Write a note on TSE and BSE in processing biologics application.
5. Write in brief about post market data for similar biologics.
6. Write a note on labeling and packaging of herbals.
7. Write in brief the advertising biologics products.

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

**[M.PHARM 1025]** **OCTOBER 2025** **Sub. Code: 3006**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICAL REGULATORY AFFAIRS - MRA**
**PAPER II – REGULATORY ASPECTS OF HERBAL & BIOLOGICALS**

***Q.P. Code: 263006***

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

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

1. Elaborate the contents and regulatory approval process of biological license applications as per USFDA.

2. Explain the data requirements for preclinical studies, clinical trial application and market authorization application of biologicals in India.

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

1. Write the difference between biological and Biosimilars.
2. Write short notes on labelling and packing of biologics as per USFDA.
3. Write briefly about stability requirement of biologics as per EMEA.
4. Discuss the Principle involved in the development of similar biologics in India.
5. Write an account on Pharmacovigilance of Vaccines.
6. Write briefly legislation requirements of herbal products in India.
7. Write a note on Plasma Master File.

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