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

[BPHARM 0422] **APRIL 2022** **Sub. Code: 2080**
(SEPTEMBER 2021 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)

PCI Regulation 2017 SEMESTER VIII
PAPER IV- PHARMACEUTICAL REGULATORY SCIENCES
Q.P. Code: 562080

Time: Three Hours **Maximum :75 marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain the approval process of timeline involved in Investigational New Drug.
2. Explain the procedure for export of pharmaceutical products.
3. Explain the design in developing clinical trial protocols.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain the roles and responsibilities of the regulatory authority.
2. Explain the Orange Book features.
3. Explain the informed consent process & procedure involved in clinical trials.
4. Explain the Drug Master File.
5. Explain the Common Technical Document.
6. Explain the approval process for implementing the changes to an approved NDA.
7. Explain the regulatory authorities of Australia.
8. Explain the preclinical studies involved in drug discovery.
9. Explain the concept of generics & Generic drug product development.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Phase 3 clinical trial.
2. CDSCO.
3. WHO.
4. Regulatory authorities of Canada.
5. Purple Book.
6. Phase 2 clinical trial.
7. EMA.
8. Functions of Ethics committee.
9. Investigational Product.
10. Three arm study.

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

[BPHARM 1022] OCTOBER 2022 Sub. Code: 2080
(MARCH 2022 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER IV- PHARMACEUTICAL REGULATORY SCIENCE
Q.P. Code: 562080

Time: Three Hours **Maximum :75 marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain the approval process and timeline involved in New Drug Application.
2. Describe ASEAN Common Technical Document (ACTD) research.
3. Explain ICH (International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for human use).

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain the non – clinical studies in the process of New Drug Application.
2. Explain the generic drug product development.
3. Describe the drug regulatory authority of India.
4. Explain the approval process for NDA.
5. Explain the technical documentation with an example.
6. Explain the role & responsibilities of sponsor and investigator in clinical trials.
7. Explain the purpose, importance & ethics of informed consent.
8. Explain the CFR, history, CFR in modern times of research tools in CFR.
9. Explain the Purple Book.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Explain the functions of US FDA.
2. EMA.
3. Phase 2 clinical trial.
4. Concept of Generics.
5. Regulatory Authorities of Japan.
6. Drug Master File.
7. eCTD.
8. Independent Ethics Committee.
9. Federal Register.
10. What is pharmacovigilance?

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

[B.PHARM 0323] MARCH 2023 Sub. Code: 2080
(SEPTEMBER 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER X- PHARMACEUTICAL REGULATORY SCIENCE

Q.P. Code: 562080

Time: Three Hours **Maximum: 75 marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain in detail about stages involved in drug discovery.
2. Discuss about Pharmaceutical policy 2002.
3. Explain about CTD and e CTD.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Write a note on organisation of ASEAN CTD format.
2. Compare innovator and generics.
3. Explain in detail about functions of CDSCO.
4. Write a note on procedure for obtaining No objection Certificate (NOC) for export of unapproved / approved new drugs / banned drugs.
5. Discuss obligations of investigators, sponsors and monitors.
6. Brief about the guidance documents for NDAs.
7. Explain the role of EMA and PDMA.
8. Write a note overview of regulatory authorities of USA.
9. Write about managing and monitoring clinical trials.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Define bioinformatics.
2. What is New drug Development?
3. What is placebo?
4. What is a 505(b)(2) application?
5. What do you mean by draft pharmaceutical policy 2006?
6. Define CTA.
7. Define Pharmacovigilance.
8. Define Orange book.
9. What is an investigational new drug (IND) application?
10. Name any five regulatory agencies and organisations established in countries.

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