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

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2080
(MARCH 2023 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 the stages of drug discovery.
2. Explain the GCP obligations of investigators sponsors and monitors.
3. Explain the Code of Federal Regulatory and purple book.

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

1. Explain the generic drug product development.
2. Illustrate the pre-clinical studies.
3. Explain the timelines involved in Investigational New Drug (IND).
4. Explain the Abbreviated New Drug Application (ANDA).
5. Explain the overview of regulatory authorities of India.
6. Explain the procedure for export of pharmaceutical products.
7. Explain the Electronic Common Technical Document.
8. Explain Orange Book.
9. Elaborate on Federal Register.

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

1. Regulatory authorities of Canada.
2. Generic drug.
3. EMA.
4. Timelines involved in NDA.
5. Drug Master File.
6. Pharmacovigilance.
7. Institutional Review Board.
8. GCP.
9. Name the regulatory authority of Australia and USA.
10. Clinical Trials.

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

[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2080
(SEPTEMBER 2023 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. Define Investigational New Drug. Explain about its types and category.
2. Write a note on role and responsibilities of lead investigator and Node principal investigator.
3. Explain in detail about regulatory bodies govern the pharmaceutical sector in India.

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

1. Write a brief note on resources of IND applications.
2. Explain the changes to an approved ANDA and assessing the effect of manufacturing changes.
3. Write a note on advance technologies in drug discovery.
4. Explain in detail about drug price control order (DPCO) 1995.
5. Write a note overview of regulatory authorities of Japan.
6. Write a note on module and benefits of e CTD.
7. Explain about institutional review board / Independent ethics committees (IECS).
8. Describe the importance of Hatch Waxman act.
9. Discuss in detail the contents of orange book.

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

1. Define regulatory affairs.
2. What is generic drug product?
3. What is marketing authorization application?
4. What is 180 day exclusivity?
5. What do you mean by good clinical practice?
6. Which ANDA process is applicable for 21 CFR Part 320?
7. Give the full form of following abbreviated terms: a) QMS, b) GPSP.
8. What is branded drug?
9. Give the task of post marketing drug safety unity.
10. Write about e CTD management software.

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