

June
25/6/2022

Roll Number ----- (Total Number of Questions 13) (Total number of Printed Pages 01)

Programme	B. Pharmacy
Semester	8 th
Subject	Pharmaceutical Regulatory Science
Subject Code	BP804ET
Paper ID	79767
Time	3Hours
Maximum Marks	75

Instructions to Candidates: No supplementary/continuation sheet will be issued to the candidates. Answer the questions precisely.

*Section A consists of Ten parts of 2 marks each (Objective Type); Attempt **ALL**.

Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO.

***Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.

Section A

(10 X 2 = 20)

1. Give very short answers to the followings (2 marks each):

i.	What is meant by HIPPA?
ii.	Define Investigator brochure.
iii.	What is Generic drug development?
iv.	Who is responsible for drug regulation?
v.	Define Orange book.
vi.	What is the role of regulatory affairs in pharma industry?
vii.	Define e-CTD.
viii.	What do you mean by Proprietary medicines?
ix.	What documents are required for pharmaceutical export?
x.	What is clinical trial?

Section B

(2 X 10 = 20)

2.	Describe exhaustively drug development process, preclinical studies and clinical studies.
3.	Describe in detail the procedure for export of Pharmaceutical product.
4.	Discuss GCP obligations of investigators, sponsors and monitors.

Section C

(7 X 5 = 35)

5.	Write a short note on NDA and ANDA.
6.	Discuss organization structure and applications of FDA.
7.	What is the role of CRO in clinical trials?
8.	Briefly discuss Hatch-Waxman act and amendments.
9.	Explain in detail the federal register and code of federal regulatory.
10.	Write a note on drug master files.
11.	Write a note on Pharmacovigilance.
12.	Write a short note on scale up process after approval.
13.	Difference between innovator and generics.

Note: Disclosure of identity by writing mobile number or making request for passing on any page of answer-sheet will lead to UMC against the candidate.

(Evening)

240523

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Section- A

(10 X 2 = 20)

1.	Give very short answers to the followings:
i.	What is meant by HIPPA?
ii.	Define investigator brochure.
iii.	What is generic drug development?
iv.	Who is responsible for drug regulation?
v.	Define orange book.
vi.	What is the role of regulatory affairs in pharma industry?
vii.	Define e-CTD.
viii.	What do you mean by proprietary medicines?
ix.	What documents are required for pharmaceutical export?
x.	What is clinical trial?

Section- B

(2 X 10 = 20)

2.	Write clinical trial protocol for new anticancer drug.
3.	Discuss various aspects of common technical documents (CTD).
4.	Mention the composition and functions of institutional review board.

Section- C

(7 X 5 = 35)

5.	Write a short note on NDA and ANDA.
6.	Enlist regulatory requirement of European union.
7.	What is the role of CRO in clinical trials?
8.	Briefly discuss Hatch-Waxman act and amendments.
9.	Write down the various stages of drug discovery.
10.	Write a note on drug master files.
11.	Write a note on pharmacovigilance.
12.	Write a short note on scale up process after approval.
13.	Difference between innovator and generics.

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(evening)
300-24

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*** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.

Section- A (10 X 2 = 20)

1.	Give a very short answers to the followings:
i.	What is an innovator drug?
ii.	Define a generic drug.
iii.	What is a Drug Master File (DMF)?
iv.	What is the Electronic Common Technical Document (eCTD)?
v.	Define ACTD.
vi.	What is a clinical trial?
vii.	Define Good Clinical Practice (GCP).
viii.	What is the Orange Book?
ix.	What is the Purple Book?
x.	Define pharmacovigilance.

Section- B (2 X 10 = 20)

2.	Explain in detail the different stages of drug discovery.
3.	Discuss in detail the approval process of New Drug Application (NDA) and Abbreviated New Drug Application (ANDA).
4.	Write in detail the different types of clinical trials and add a note on the informed consent process.

Section- C (7 X 5 = 35)

5.	Discuss the approval processes and timeline involved in an Investigational New Drug (IND) application.
6.	Write in detail about the regulatory authorities of India and the United States.
7.	Explain in detail the Common Technical Document (CTD).
8.	Discuss the procedure for the export of pharmaceutical products.
9.	Explain in detail the procedure for the development of a clinical trial protocol.
10.	Write the Good Clinical Practice (GCP) obligations of investigators and sponsors.
11.	Discuss the role of pharmacovigilance in safety monitoring during clinical trials.
12.	Explain in detail the Federal Register and Code of Federal Regulations (CFR).
13.	Discuss in detail the generic drug product development process.

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- ***Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.

Section- A (10X2=20)

1.	Give very short answers to the followings:
i.	Define generic drugs.
ii.	What is e- CTD?
iii.	What are clinical trials?
iv.	Define drug development.
v.	Why do we need pre-clinical studies?
vi.	What is the role of regulatory affairs in pharma industry?
vii.	Define drug discovery.
viii.	What is DMF?
ix.	What is investigator brochure?
x.	Define orange book.

Section- B (2X10=20)

2.	Explain in detail about different stages of drug discovery.
3.	Write a note on procedure for export of pharmaceutical products.
4.	Explain formation and working procedure of IRB.

Section- C (7X5=35)

5.	Explain laws and acts of regulatory concepts.
6.	Give format of DMF given by FDA.
7.	Write a detail note on development of clinical trial protocol.
8.	Differentiate between innovator and generic drug.
9.	Describe about generic drug product development.
10.	Explain the overview of regulatory authority of Canada.
11.	Write a note on types of DMF.
12.	Explain the approval procedure of INDA.
13.	Explain code of federal regulatory.

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***Section- C consists of nine questions, each carrying 5 marks (Short Answer Type); Attempt any seven.

Section-A (10X2=20)

1.	Give very short answers to the followings:
i.	Why does a generic drug look different from a branded drug?
ii.	Summarize the purpose of Good Clinical Practice (GCP).
iii.	What is the Informed Consent Form?
iv.	Outline the Investigator's Brochure.
v.	What is the FDA Orange Book?
vi.	Outline the preclinical studies.
vii.	Write about accelerated development.
viii.	Summarize the importance of electronic Common Technical Documents (eCTD).
ix.	What is the centralized procedure for drug approval as per the European Union (EU)?
x.	Enlist the types of Drug Master Files (DMF).

Section-B (2X10=20)

2.	Briefly discuss the benefits and contents of the Orange Book.
3.	Explain the types and review process of a New Drug Application (NDA).
4.	Discuss the generic drug approval process in the United States.

Section-C (7X5=35)

5.	State the role of the Hatch-Waxman Act in the development of generic drug industries.
6.	Outline the review process of an Abbreviated New Drug Application (ANDA).
7.	Provide a brief note on the decentralized procedure for drug approval in Europe.
8.	Differentiate between CTD and eCTD.
9.	Mention the constitution and functions of an Institutional Review Board (IRB).
10.	Write a short note on the Purple Book.
11.	List the key principles of Good Clinical Practice (GCP).
12.	Give an overview of the format of the ASEAN Common Technical Dossier (ACTD).
13.	Mention the procedure to export medicines from India.

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