Subject Code: BP804ET

PAPER ID-420850

Roll No: | | | | | | | | | | | | |

BPHARMA
(SEM VIII) THEORY EXAMINATION 2021-22
PHARMACEUTICAL REGULATORY SCIENCE

Time: 3 Hours *Total Marks: 75*

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define innovator drug product.
b.	Mention the various modules of CTD format.
c.	Enumerate the GCP obligations of the investigators.
d.	Define Pharmacovigilance.
e.	What is the significance of drug discovery?
f.	What is purple book? Give its importance.
g.	Mention the different stages of clinical trials.
h.	How will you define generic products?
i.	Define non-clinical trials.
j.	What is the importance of informed consent form?

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Describe in detail the timelines involved in Investigational New Drug application
b.	How will you define drug master file? Discuss its significance in detail.
c.	.Discuss the development of clinical trial protocols in detail.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Discuss the drug developmental process in detail.
b.	Write a detailed note on regulatory approval process of ANDA.
c.	Explain in detail the procedure for export of pharmaceutical products in India.
d.	What do you mean by orange book? Describe in detail.
e.	Give an overview of the regulatory authorities of India.
f.	Give the detailed process of generic drug product development.
g.	What is Institutional Review Board? Describeits formation and working procedures.

Printed Pages:01 Sub Code: BP 804ET

Paper Id: 231064 Roll No. | | | | | | | | | | |

B PHARM
(SEM VIII) THEORY EXAMINATION 2022-23
PHARMACEUTICAL REGULATORY SCIENCE

Time: 3Hours *Total Marks: 75*

Note: Attemptall Sections.

SECTION A

1. Attempt *all* questions in brief. **2 x 10 = 20**

(a) Differentiate NDA and ANDA.

(b) What is placebo trial?

(c) What do you mean by a randomized design?

(d) Define clinical trial and explain Phase II.

(e) Write about Timeline and types of IND.

(f) How many people will be selected for Phase-I trial?

(g) What is the significance of pharmacovigilance?

(h) Importance of DMF.

(i) Write a brief note on 21 CFR.

(j) Differentiate Generic vs Innovator.

SECTION B

2. Attempt any *two* parts of the following: **10 x 2 = 20**

(a) Discuss the various modules and requirements of electronic CommonTechnical Document (eCTD)? Compare it with ASEAN common technical documents (ACTD).

(b) Write the various stages of Development of new drugs.

(c) Discuss the application and approval process of ANDA.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

(a) Explain organizationstructure and functions of USFDA.

(b) What are various GCP obligations of investigator and sponsor?

(c) Explain the salient features of orange book and purple book.

(d) Explain the organization and functions of CDSCO.

(e) Discuss the organization structure and functions of Australian drug regulatory body.

(f) Explain the safety monitoring in clinical trials.

(g) Discuss the importance of pharmaceutical regulatory affairs in industry.

PAPER ID-410764

Roll No: | | | | | | | | | | | | | |

BPHARM
(SEM VIII) THEORY EXAMINATION 2023-24
PHARMACEUTICAL REGULATORY SCIENCE

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Definegeneric drugs.
b.	Why preclinical studies are not required for ANDA?
c.	Describe the Nonclinical drug development process.
d.	Define post marketing surveillance.
e.	Describe typical difference between CTD and eCTD.
f.	Enlist different clinical trial phases.
g.	Discuss investigator brochure.
h.	Explain the need of independent ethics committee.
i.	Discuss the GCP obligations of Investigators.
j.	Discuss Orange book.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Discuss the organizationstructure of European Union and types of applications.
b.	Discuss in detail about Investigational New Drug (IND).
c.	Discuss in detail about New Drug Application (NDA).

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Illustrate the different Stages of drug discovery.
b.	Write an overview of regulatory authorities of India.
c.	Explain the Drug Master Files (DMF).
d.	Illustrate the procedure for export of pharmaceutical products.
e.	Elaborate the clinical trial protocol development.
f.	Discuss the Federal Register and CFR.
g.	Describe the formation and working procedure of Institutional Review Board.

Paper ID : 250355

Roll No: | | | | | | | | | | | | | |

BPHARM
(SEM VIII) THEORY EXAMINATION 2024-25
PHARMACEUTICAL REGULATORY SCIENCE

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	What is the purpose of IND filing?
b.	How will you define generic product?
c.	What is ASEAN common technical document?
d.	What do you mean by post marketing surveillance?
e.	Enumerate the GCP obligations of the investigators.
f.	What is Investigator brochure?
g.	Summarize different phases of clinical trials.
h.	Write down the importance of regulatory affairs.
i.	Describe the term 'Pharmacovigilance'.
j.	Give the importance of purple book.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Discuss the various stages of new drug development.
b.	Explain the organization structure and functions of CDSCO.
c.	Discuss the clinical trial protocol development in detail.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Explain the regulatory approval process of ANDA.
b.	What do you mean by CFR? Discuss Federal Register.
c.	Write a note on 'CTD' and 'eCTD'.
d.	How pharmacovigilance safety monitoring done in clinical trials?
e.	Write a detailed note on drug master file.
f.	What is Institutional review board? Discuss formation and working procedure.
g.	Write a note on Orange book.

Paper ID : 261259

Subject Code: BP804ET

Roll No:													

BPHARM

(SEM. VIII) THEORY EXAMINATION 2025-26

PHARMACEUTICAL REGULATORY SCIENCE

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10x2 = 20**

(a)	Define drug discovery and drug development. Give one example.
(b)	What is the importance of pre-clinical studies?
(c)	What is an Investigational New Drug (IND)?
(d)	What is the purpose of a New Drug Application (NDA)?
(e)	What do you mean by generic drugs?
(f)	What is a Drug Master File (DMF)?
(g)	Name the phases of clinical trials.
(h)	What is informed consent?
(i)	Define pharmacovigilance.
(j)	What is the Orange Book?

SECTION B

2. Attempt any *two* of the following: **2 x 10 = 20**

(a)	Explain the stages of drug discovery and development in simple terms.
(b)	Describe the IND and NDA approval process briefly.
(c)	Write a short note on drug regulatory authorities in India, USA and Europe.

SECTION C

3. Attempt any five part of the following: **5 x 7 = 35**

(a)	Explain the concept of generic drug product development.
(b)	Describe the ANDA approval process in simple terms.
(c)	What are DMF and CTD? Explain their importance.
(d)	Explain the procedure for export of pharmaceutical products.
(e)	What is an Institutional Ethics Committee (IEC)? State its functions.
(f)	Write a note on Good Clinical Practice (GCP).
(g)	Explain pharmacovigilance and its importance in drug safety.