PAPER ID-420850

Subject Code: BP804ET

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-olinical 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.

QP22EP1_290 | 20-06-2022 13:29:11 | 117.55.242.131

https://www.aktuonline.com

QP22EP1 290 | 20 06 2022 13:29:11 117.55.242.131