Graphic Era HILL UNIVERSITY
Established by an Act of the State Legislature of Uttarakhand (Adhiniyam Sankhya 12 of 2011)
University under section 2(f) of UGC Act, 1956

Sessional II (Even) Semester Examination, May 2025

Roll no.....

Name of the Course and semester: **B. Pharm.- VIII Sem**
Name of the Paper: **Pharmaceutical Regulatory Science**
Paper Code: **BP-804ET**
Time: 1.5-hour

Maximum Marks: 30

Note:
(i) This question paper contains three sections.
(ii) All the questions are compulsory.

Section-A

Q1. Multiple Choice Questions – Attempt all questions **(10 X 1 = 10 Marks)**

1. Module 4 of the Common Technical Document is related to **(CO3)**
a) Quality
b) Non-Clinical Study Reports
c) Clinical Study Reports
d) Administrative & Regional Information

2. The Content & structure of Module 5 is specified in ICH.....guidelines. **(CO3)**
a) M4Q
b) M4S
c) M4
d) M4E

3. Type II DMFs are meant for…….. **(CO3)**
a) Excipients
b) Packaging Material
c) Drug Substance/Drug Product
d) Manufacturing sites/facilities

4. For Export of Pharmaceuticals from India to the USA, NOC is provided by….**(CO3)**
a) CDSCO
b) USFDA
c) TGA
d) EMA

5. Common Technical Document is categorized into……..modules. (CO3)
a) 3
b) 7
c) 5
d) 4

6. IRB/IEC are committees for…… (CO4)
a) DMF preparation
b) Monitoring and managing clinical trials
c) Ethics and welfare of human participants in the clinical trials
d) Audit of the clinical research center

7. Pharmacovigilance is the pharmacological science of……. (CO4)
a. Detection of adverse effects
b. Evaluation of adverse effects
c. Prevention of adverse effects
d. All of the above

8. Phase III Clinical trials are also known as…….. (CO4)
a) Human pharmacology
b) Therapeutic confirmatory phase
c) Therapeutic Exploratory phase
d) Post marketing monitoring

9. As per the GCP obligations, preparation of the Clinical trial protocol is done by…. (CO4)
a. Investigator
b. Sponsor
c. Monitor
d. None of the above

10. ICH stands for…….. (CO4)
a) International Conference on Harmonization
b) International Council for Harmonization
c) International Council for harmonization of technical Requirements for Pharmaceuticals for Human use
d) International Conference for harmonization of technical Requirements for Pharmaceuticals

Section B

Q. 2 Short Questions: Attempt any two questions **(2X 5 = 10 Marks)**

a. Discuss the procedure for the export of pharmaceutical products. (CO3)
b. What are the Informed Consent process and procedures, and their content? (CO4)
c. Write a note on "Pharmacovigilance-safety monitoring in clinical trials". (CO4)

Section C

Q. 3 Long questions: Attempt any one question **(1X10 = 10 Marks)**

a. Explain in detail the structure of the Common Technical Document (CTD). **(CO3)**

b. Describe the GCP obligations of Investigators, Sponsors & Monitors. **(CO4)**