School of Medical and Allied Sciences

Pharmacy

ETE - May 2023

Time : 3 Hours **Marks : 75**

Sem VIII - BP804ET - Pharmaceutical Regulatory Science

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

1.	Define clinical studies?	K1 CO1 (2)
2.	Interpret Drug discovery.	K2 CO1 (2)
3.	Name the regulatory authorities of: i. India iii. EU ii. US iv. Australia.	K1 CO2 (2)
4.	Illustrate the term IND and NDA.	K2 CO2 (2)
5.	What is the Certificate of Pharmaceutical Product?	K1 CO3 (2)
6.	Outline modules of CTD	K2 CO3 (2)
7.	Define the term Pharmacovigilance.	K1 CO4 (2)
8.	Explain the role of “Pharmacovigilance” in clinical research.	K2 CO4 (2)
9.	Define regulatory affairs	K1 CO5 (2)
10.	Summarize briefly “Market Authorization Application(MAA)”.	K2 CO5 (2)
11.	Model of “Stages of drug discovery”. **OR** Organize a note on “Concept of generics”.	K3 CO1 (5)
12.	Contrast the procedure for the export of generic formulations.	K4 CO1 (5)
13.	Choose the application and approval process for New Drug Application.	K3 CO2 (5)
14.	List about Organization structure and Overview of regulatory authorities of India. **OR** Motive of NDA and ANDA.	K4 CO2 (5)
15.	Identify the various types of technical documentation.	K3 CO3 (5)
16.	Write down the function of ASEAN Common Technical Document. OR Examine the procedure for export of Pharmaceutical products.	K4 CO3 (5)
17.	Elaborate cGMP (Current Good Manufacturing Process).	K6 CO5 (5)
18.	Evaluate the “Pharmacovigilance-safety monitoring” in clinical trials.	K5 CO4 (10)
19.	Discuss code of federal regulation with respect to Part 2. **OR** Elaborate in detail about the content of “Orange Book”.	K6 CO5 (10)