

B.Sc.-M.Sc. INTEGRATED PROGRAMME (TOXICOLOGY)
SEMESTER V, ONLINE EXAMINATION 2020
PAPER CODE - BTX-CC16TH

PAPER TITLE: DRUG REGULATORY AFFAIRS

Time : Three Hours

Maximum Marks : 75

Attempt all questions. All parts of a question must be attempted in continuation. Start answer of a fresh question on a new page. Cite examples and draw labeled diagrams wherever necessary

Q.1. A) Write at least one difference between given below: (2x5=10)

- i. DCGI and DI
- ii. DEC and DCC
- iii. PATENT and Copyright
- iv. AICTE and PCI
- v. Schedule C and Schedule N

B) Complete the following sentence:

(5x1=5)

- vi. Expand cGMP
- vii. Rules of Drug and Cosmetic act was passed in
- viii. Cruelty to animal act was passed in
- ix. Expand DGHS
- x. Schedule J is for

Q.2 Write a short note on ANY THREE of the following

(5x3=15)

- A). Objectives of Pharmacy act
- B). Objectives of Bhore committee
- C). objectives of drug and cosmetics act
- D). Objectives of animal cruelty act
- E). DPCO

Q.3 Describe shortly about ANY THREE of the following

(5x3=15)

- A). Functions of Drug analyst
- B). Functions of central drug laboratoryC).
- Powers of Narcotics Inspector
- D). Process patenting
- E). Bonded manufacturing of alcohol

Q.4. Discuss about ANY THREE of following

(5x3=15)

- A) National Pharmaceutical pricing authority
- B) Essential Medicines list