



**JAZ-1603120602030200** Seat No. \_\_\_\_\_

**M. Sc. (Biochemistry) (Sem. III) (CBCS) Examination**

**December - 2019**

**EBC - 2 : Pharmaceutical Biochemistry &  
Regulatory Affairs**

Time :  $2\frac{1}{2}$  Hours]

[Total Marks : 70

**1** Answer briefly any **seven** of the following questions : **14**

- (1) Draw the detailed graph of dose-effect relationship.
- (2) What is Ld50 and Mec ?
- (3) What is Pharmacopae ?
- (4) Define the term Non-infringing patent ability.
- (5) What is Drug excretion? Enlist its types.
- (6) Enlist the difference between Antagonists and Partial agonist.
- (7) What are the functions of FDA ?
- (8) Enlist the various aspects of pharmaceutical product management.
- (9) Enlist the various side effects of drugs.
- (10) What is Data Mining ?

**2** Answer any **two** of the following questions : **14**

- (1) What is renal clearance? Explain the relationship between renal clearance values and mechanism of clearance.
- (2) Write a detailed notes on drug receptor interaction theories.
- (3) Write a note on cGMP.

- 3 (1) Enlist the various factors affecting Drug metabolism and elimination and explain any two in detail. 7
- (2) Mention any two treatment of diseases by enzyme stimulation along with significance. 7

**OR**

- 3 (1) Write a note on GATT-WTO scenarios. 7
- (2) Write the guidelines of International Council for Harmonisation. 7

4 Answer the following questions : 14

- (1) Write a detailed note on soft drug
- (2) Enlist the various governing Law of Intellectual Property Rights in India . Give details of procedure for grant of patent.

5 Answer the following questions : (any two) 14

- (1) Enlist differences of Phase I and Phase II in biotransformation reactions.
- (2) Describes the methods for analytical aspects of pharmaceutical products.
- (3) Write Short note on drug delivery system by liposome.
- (4) Case report form development, purpose and importance in clinical data documentation.