

**Branch- BIOTECHNOLOGY**

**MAJOR ELECTIVE COURSE - I PHARMACEUTICAL BIOTECHNOLOGY**

Time: Three Hours

Maximum: 75 Marks

**SECTION-A (10 Marks)**

Answer **ALL** questions

**ALL** questions carry **EQUAL** marks

(10 × 1 = 10)

| Module No. | Question No. | Question                                                                                                                                                                                                                                                                                                                                                            | K Level | CO  |
|------------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-----|
| 1          | 1            | Which one of the following is not a route of drug administration?<br>(i) Intravenous (ii) Oral<br>(iii) Dissolution (iv) Nasal drug Delivery                                                                                                                                                                                                                        | K1      | CO1 |
|            | 2            | Which method is most suitable for extracting thermo-labile components from herbs?<br>(i) Decoction (ii) Soxhlet Extraction<br>(iii) Maceration (iv) Steam Distillation                                                                                                                                                                                              | K2      | CO1 |
| 2          | 3            | Drugs interact with their receptors sites by forming _____.<br>(i) Ionic bonds (ii) Hydrogen bonds<br>(iii) Van der Waals bond (iv) All the above                                                                                                                                                                                                                   | K1      | CO2 |
|            | 4            | _____ is not a neurotransmitter.<br>(i) Acetylcholine (ii) Cyclic AMP<br>(iii) Adrenalin (iv) Dopamine                                                                                                                                                                                                                                                              | K2      | CO2 |
| 3          | 5            | Which phase of clinical trials focuses on testing safety and dosage in a small group of healthy volunteers?<br>(i) Phase I (ii) Phase II (iii) Phase III (iv) Phase IV                                                                                                                                                                                              | K1      | CO3 |
|            | 6            | The ICH (International Council for Harmonisation) provides guidelines for _____.<br>(i) Drug marketing<br>(ii) Technical requirements for pharmaceutical registration<br>(iii) Price control<br>(iv) Laboratory equipment procurement                                                                                                                               | K2      | CO3 |
| 4          | 7            | Which system utilizes osmotic pressure to control drug release?<br>(i) Liposomes (ii) Osmotic pumps<br>(iii) Niosomes (iv) Microspheres                                                                                                                                                                                                                             | K1      | CO4 |
|            | 8            | Bio-availability of a drug is _____.<br>(i) The percentage of drug released from a formulation that becomes available for biological effect<br>(ii) The percentage of drug that is ionized from a formulation<br>(iii) The net amount of actual therapeutic agent present in the formulation<br>(iv) The dose of a drug by which 50% animals show signs of toxicity | K2      | CO4 |

Cont...

|   |    |                                                                                                                                                                                                      |    |     |
|---|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|-----|
| 5 | 9  | and purity of a produced protein.<br>(i) PCR (ii) Western blotting<br>(iii) Mass spectrometry (iv) Restriction mapping                                                                               | K1 | CO5 |
|   | 10 | What type of vaccines uses recombinant DNA technology to express specific antigen proteins?<br>(i) Live attenuated vaccines (ii) Subunit vaccines<br>(iii) Inactivated vaccines (iv) Toxoid vaccines | K2 | CO5 |

### **SECTION - B (35 Marks)**

Answer **ALL** questions

**ALL** questions carry **EQUAL** Marks (5 × 7 = 35)

| Module No. | Question No. | Question                                                                                                                                            | K Level | CO  |
|------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------|-----|
| 1          | 11.a.        | Identify the various routes of drug administration.                                                                                                 | K3      | CO1 |
|            |              | (OR)                                                                                                                                                |         |     |
|            | 11.b.        | Explain about the steam distillation process for compound extraction.                                                                               |         |     |
| 2          | 12.a.        | Examine how blood brain barrier affects drug distribution.                                                                                          | K4      | CO2 |
|            |              | (OR)                                                                                                                                                |         |     |
|            | 12.b.        | Explain in detail how CNS responds to drug.                                                                                                         |         |     |
| 3          | 13.a.        | Analyse how drug toxicity testing is done.                                                                                                          | K4      | CO3 |
|            |              | (OR)                                                                                                                                                |         |     |
|            | 13.b.        | Illustrate the core components of OECD 423 guidelines-based animal handling.                                                                        |         |     |
| 4          | 14.a.        | Determine the mechanism of controlled release system in drug delivery.                                                                              | K5      | CO4 |
|            |              | (OR)                                                                                                                                                |         |     |
|            | 14.b.        | Explain in detail the key concepts of CDSCO Guidelines for novel drug delivery system.                                                              |         |     |
| 5          | 15.a.        | Elaborate the key components of GMP.                                                                                                                | K6      | CO5 |
|            |              | (OR)                                                                                                                                                |         |     |
|            | 15.b.        | Elucidate the application, advantage and disadvantages of using CHO cell and Pichia pastoris host system for the production of recombinant protein. |         |     |

### **SECTION - C (30 Marks)**

Answer **ANY THREE** questions

**ALL** questions carry **EQUAL** Marks (3 × 10 = 30)

| Module No. | Question No. | Question                                                                                                       | K Level | CO  |
|------------|--------------|----------------------------------------------------------------------------------------------------------------|---------|-----|
| 1          | 16           | Elucidate the various kinds of drugs based on ATC system in details with examples.                             | K3      | CO1 |
| 2          | 17           | Distinguish the various stages involved in detoxification mechanism of drugs in liver.                         | K4      | CO2 |
| 3          | 18           | Expound a note on drug discovery and development process in detail.                                            | K4      | CO3 |
| 4          | 19           | Explain how liposomal drug delivery system is been executed?                                                   | K5      | CO4 |
| 5          | 20           | Discuss the concept of therapeutic protein production in detail. Add a note on its application and challenges. | K6      | CO5 |

Z-Z-Z

END