Reg.No. \_\_\_\_\_\_\_\_\_\_\_\_

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**End Semester Examination – Nov/Dec – 2018**

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| --- | --- | --- | --- |
| **Code :** | **14BI2031** | **Duration :** | **3hrs** |
| **Sub. Name :** | **CLINICAL DATABASE MANAGEMENT** | **Max. marks :** | **100** |

**ANSWER ALL QUESTIONS (5 x 20 = 100 Marks)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Q. No.** | **Sub Div.** | **Questions** | **Course**  **Outcome** | **Marks** |
| 1. |  | Describe the workflow of a Clinical Data Management Process. | CO1 | 20 |
| (OR) | | | | |  |  | (OR) |
| 2. |  | Explain the types of insilico computer based drug design processes | CO1 | 20 |
|  |  |  |  |  |
| 3. |  | Describe the importance and the contents of an investigator’s brochure. | CO1 | 20 |
| (OR) | | | | |  |  | (OR) |
| 4. |  | Describe the drug disasters that led to Pharmacovigilance and the FDA. | CO2 | 20 |
|  |  |  |  |  |
| 5. |  | Explain the drug discovery cycle using a flowchart. | CO2 | 20 |
| (OR) | | | | |
| 6. |  | Illustrate the drug regulatory structure in India and its states. | CO2 | 20 |
|  |  |  |  |  |
| 7. | a. | Describe adverse events and the types of adverse events observed during clinical trials. | CO3 | 10 |
| b. | Develop a SAE CRF form for a Cardiovascular Drug trial. | CO3 | 10 |
| (OR) | | | | |
| 8. |  | Describe process mapping in an SOP with examples. | CO3 | 20 |
|  | |  |  |  |
|  | | **Compulsory**: |  |  |
| 9. |  | Design a Physical Examination form, for a trial involving testing of an anti-diabetic formulation, | CO3 | 20 |