

School of Basic and Applied Sciences

BioScience
ETE - Jun 2023

Time : 3 Hours

Marks : 50

Sem II - MBACRT2004 - Drug Discovery And Development

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

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| 1. | Define Inspection in clinical trials. | K2 CO4 (2) |
| 2. | Describe Quality assurance in clinical trials. | K2 CO5 (2) |
| 3. | Define adverse drug reaction. | K1 CO1 (2) |
| 4. | Describe monitoring in clinical studies. | K1 CO3 (2) |
| 5. | Define serious adverse event. | K2 CO2 (2) |
| 6. | Evaluate chronic toxicity testing in rodent and non rodent regarding toxicity testing study. | K3 CO1 (5) |
| 7. | Demonstrate the Quantitative structure activity relationship. | K4 CO6 (6) |
| 8. | Demonstrate the importance of S1A guideline in clinical trials.. | K4 CO2 (5) |
| 9. | Define Investigational new drug application and new drug application in clinical research studies. | K4 CO4 (8) |
| 10. | Define global regulations which were applicable for cosmetics act. | K3 CO3 (8) |
| 11. | Demonstrate the composition of imdrf. | K4 CO5 (8) |