

Enrollment No. _____



NAVVRACHANA UNIVERSITY
a UGC recognized University

School: School of Science
Program/s: BMS
Year: 2nd **Semester:** 3
Examination: End Semester Examination
Examination year: December - 2021

Course Code: BM206 **Course Name:** Good Laboratory Practices
Date: 10/12/2021
Time: 8:30 am to 10:30 pm

Total Marks: 40
Total Pages: 2

Instructions:

- Write each answer on a new page
- Draw neat and well-labelled diagrams wherever required
- * COs=Course Outcome mapping. # BTL=Bloom's Taxonomy Level mapping

Q. No.	Details	Marks	COs	BTL#
Q.1	<p>A. Choose the correct option (4M)</p> <p>1. GLP includes _____</p> <p>a. Stringent operating procedures b. Principles for planning, performing, monitoring and reporting of studies c. Proper management of data d. Management of scientific resources</p> <p>2. The purpose of the corrective and preventive action subsystem is _____</p> <p>a. To prepare SOPs b. To manage logbooks c. To collect and analyze information to identify product and quality problems d. To give training to personnel for better output</p> <p>3. _____ is submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed for a license to market the drug for a specified indication.</p> <p>a. New drug application b. Investigational new drug c. Institutional Review Board d. Rational drug design</p> <p>4. Which of the following statements is true about clinical studies</p> <p>a. Phase IIA is specifically designed to assess dosing requirements while Phase IIB is specifically designed to study efficacy b. Phase IIA is specifically designed to study efficacy while Phase IIB is specifically designed to assess dosing requirements c. Phase II A and B studies are done to study the efficacy of the drug d. Phase II A and B studies are done to assess dosing requirements</p> <p>B. Fill in the blanks (5M)</p> <p>6. A _____ design is a design in which each patient receives one and only one treatment in a random fashion.</p> <p>7. The drug that blocks the activity of its target is known as _____</p> <p>8. In _____ cell lines, cells have infinite lifespan</p>	13	CO 1,2, 3,4, 5	BTL1, 2,3

	<p>9. The use of the drug _____ created by Massengil caused kidney failure, stoppage of urine, severe abdominal pain, nausea, vomiting, stupor, and convulsions in patients</p> <p>10. A spare parts _____ gives information about the stock, cost and ordering information</p> <p>C. State whether true or false <u>with justification</u> (4M)</p> <ol style="list-style-type: none"> 1. Anchorage dependency means that cells have finite life span 2. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, vaccines, biopharmaceuticals, animal foods & feed and veterinary products. 3. IND approval filing is followed by establishment of the effective and toxic doses. 4. Methods of synthesis, fabrication, or derivation of test and control articles should be documented for FDA inspection. 			
Q.2	<p>Answer the following in one or two sentences <u>ANY FIVE</u> (5 questions X 2 Marks=10 Marks)</p> <ol style="list-style-type: none"> 1. What are the features of a good log book? 2. What is the difference between direct and indirect drug design? 3. How do diagnostic trials differ from prevention trials? 4. What are the roles of an Institutional Review Board? 5. Why are bioassays important? 6. If you are given the task of equipment management, what will be your responsibilities? 	10	CO 1,2, 3,4, 5	BTL1, 2,3
Q.3	<p>Answer the following in detail (4 questions X 3 marks=12 Marks)</p> <ol style="list-style-type: none"> 1. Discuss the different phases of clinical trials. 2. Discuss the seven subsystems of a quality system 3. What are lean labs? What are the advantages of a lean lab? 4. You have received a product which has issues with its quality. What steps will you take? 	12	CO 1,2, 3,4, 5	BTL1, 2,3
Q.4	<p>Q4. What does the given image depict? Write the benefits of the wash-out period (5 Marks)</p> <p style="text-align: center;"> Treatment A Active Drug Treatment B Active Drug Randomization Treatment B Placebo Treatment A Placebo → → → <u>Period 1</u> <u>Wash Out</u> <u>Period 2</u> 1 week 1 week 1 week </p>	5	CO 5	BTL1, 2,3