



Subject: Good Lab Practices- BET2BT11208

Type of course: Professional Core

Prerequisite: Students should have a basic understanding of laboratory techniques in Sciences. Familiarity with laboratory equipment, safety practices, and basic experimental procedures is recommended. Basic knowledge of chemical handling, measurement, and documentation will be beneficial.

Rationale: This course provides a are essential to ensure the accuracy, reliability, and integrity of laboratory data. This course is designed to train students in standardized laboratory procedures, safety regulations, documentation practices, and quality assurance systems. It prepares students for professional laboratory environments in research, industry, pharmaceuticals, food technology, and biotechnology sectors. The course emphasizes compliance, reproducibility, and ethical scientific practices.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks		Total Marks
CI	T	P	C	SEE	CCE	
0	0	4	2	50	50	100

Legends: CI-Classroom Instructions; T-Tutorial; P -Practical; C –Credit; SSE -Semester End Evaluation; CCE-Continuous Class Evaluation; V–Viva; CA-Continuous Assessment; ALA-Active Learning Activities.



Course Content:

Sr.No.	Course Content	Hrs.	% Weightage
1	Introduction to GLP <u>Topics</u> • Definition and history of GLP • Importance of GLP in research and industry • GLP principles and guidelines • Regulatory bodies and standards <u>Practical:</u> 1. Prepare a timeline chart showing the development of GLP ➤ To understand the historical evolution and significance of Good Laboratory Practices (GLP) in ensuring laboratory quality and compliance. 2. Understanding Basic lab instrumentation ➤ To familiarize students with commonly used laboratory instruments and their functions in scientific analysis. 3. Discuss a historical laboratory error or failure ➤ To analyze laboratory mistakes and understand the importance of adhering to quality and safety standards. 4. Presentation on "Importance of GLP in Pharmaceutical, Food, and Biotechnology Industries." ➤ To develop awareness of the role of GLP in maintaining data integrity, product quality, and regulatory compliance. 5. Prepare an SOP for a simple experiment ➤ To learn the preparation of standardized procedures for ensuring consistency, accuracy, and reproducibility in laboratory work. 6. Identification and classification of laboratory hazards and preparation of laboratory safety guidelines. ➤ To recognize potential laboratory hazards and establish safe working practices for accident prevention. 7. Calibration and verification of basic laboratory instruments (pH meter, weighing balance, thermometer, micropipette). ➤ To understand the importance of instrument calibration in obtaining accurate, reliable, and reproducible results. 8. Preparation and maintenance of sample labeling, storage	12	20 %



	records, and inventory management documentation. ➤ To develop skills in proper sample handling, documentation, traceability, and inventory control as per GLP requirements. 9. Conduct a mock GLP laboratory audit and prepare an audit observation report. ➤ To gain practical exposure to laboratory auditing procedures and identify areas for quality improvement and compliance. Evaluation Method: <table border="1"> <thead> <tr> <th>Sr. No.</th><th>Evaluation Methods</th><th>SEE</th><th>CCE</th></tr> </thead> <tbody> <tr> <td>1</td><td>Content and Understanding: Evaluation will be based on the student's understanding of GLP concepts, accuracy of the content, and ability to apply principles in activities such as SOP writing or checklist preparation.</td><td>10</td><td></td></tr> <tr> <td>2</td><td>Active Learning Assignment: Create a Mind Map: Prepare a mind map illustrating the importance of laboratory documentation, objectives of Good Laboratory Practices (GLP), key laboratory concepts, and the workflow of a scientific experiment. Include brief definitions and examples for each concept and upload it on the GMIU Web Portal.</td><td></td><td>10</td></tr> <tr> <td></td><td>Total</td><td>20</td><td>10</td></tr> </tbody> </table> Examination Style: Content and Understanding: (20 Marks) Students will be evaluated based on their ability to demonstrate understanding of Good Laboratory Practices (GLP) through activities such as SOP preparation, checklist design, and application of GLP principles in laboratory scenarios. Active Learning Assignment: Create a Mind Map: (10 Marks) A case-based role play activity was conducted to help students understand GLP principles through real laboratory scenarios and active participation and along with timely submission of the assignment on the GMIU Web Portal.	Sr. No.	Evaluation Methods	SEE	CCE	1	Content and Understanding: Evaluation will be based on the student's understanding of GLP concepts, accuracy of the content, and ability to apply principles in activities such as SOP writing or checklist preparation.	10		2	Active Learning Assignment: Create a Mind Map: Prepare a mind map illustrating the importance of laboratory documentation, objectives of Good Laboratory Practices (GLP), key laboratory concepts, and the workflow of a scientific experiment. Include brief definitions and examples for each concept and upload it on the GMIU Web Portal.		10		Total	20	10		
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2	Demonstration of Laboratory Safety <u>Topics</u> History, Scope, Fundamental points of GLP (Resources Characterization, Rules, Results).																		



	• General Rules/Protocols for Lab Safety measures, • Precaution and Safety in handling of chemicals, Laboratory tools, • Glassware and 10 instruments. <u>Practical:</u> 10. Prepare a flowchart or mind map covering History, Scope, and Fundamental Principles of GLP. ➤ To develop a clear understanding of the evolution, applications, and core principles of Good Laboratory Practices through visual representation. 11. Analyze a laboratory scenario and identify missing GLP practices and possible errors in results. ➤ To enhance critical thinking skills by identifying non-compliance issues and their impact on the reliability of laboratory data. 12. Prepare a daily lab safety checklist including PPE, cleanliness, labeling, and waste disposal ➤ To promote routine laboratory safety practices and ensure a safe and compliant working environment. 13. Lab Safety Demonstration ➤ To provide practical knowledge of laboratory safety procedures, emergency response, and accident prevention measures. 14. Chemical Label Reading Exercise ➤ To understand the interpretation of chemical labels, hazard symbols, and safety information for proper chemical handling. 15. Understanding and analyzing various basic safety lab-1 (To identify common laboratory hazards and implement appropriate preventive measures.) ➤ To recognize potential laboratory hazards and apply suitable preventive strategies to minimize risks and ensure safety. 16. Understanding and analyzing various basic safety lab-2 (To evaluate safe handling and storage practices for laboratory chemicals and reagents.) ➤ To understand proper chemical handling, storage requirements, and safety protocols for preventing accidents and contamination. 17. Understanding and analyzing various basic safety lab-3 (To understand biological, chemical, and physical risk assessment procedures in laboratories.) ➤ To develop the ability to assess laboratory risks and implement appropriate control measures for safe laboratory operations. 18. Understanding and analyzing various basic safety lab-4 (To gain practical knowledge of laboratory emergency preparedness and accident prevention.)	12	20 %
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- To familiarize students with emergency response procedures and preventive measures for managing laboratory incidents effectively.
- 19. Gain detailed knowledge about the precaution and safety of lab instruments and chemicals**
- To understand the safe operation of laboratory instruments and proper handling of chemicals to maintain safety and prevent accidents.

Evaluation Method:

Sr. No.	Evaluation Methods	SEE	CCE
1	Fundamentals of GLP and Laboratory Safety Management: Students will be evaluated based on their understanding and application of GLP concepts through activities such as flowchart preparation, safety checklist design, and analysis of laboratory scenarios, focusing on accuracy and completeness of content. Assessment will also be based on the clarity of presentation, proper documentation, and practical demonstration skills, including the ability to identify laboratory hazards and follow safety precautions.	10	
2	Active Learning Assignment: Look & Learn: Faculty will provide photographs of laboratory instruments. Students are required to identify the instrument, explain its function and working principle, and upload their assignment on the GMIU Web Portal before the due date.		10
	Total	20	10

Examination Style:**Fundamentals of GLP and Laboratory Safety Management (20 Marks)**

Students will develop accuracy, consistency, and reliability in laboratory practices by following Good Laboratory Practices (GLP), including proper documentation, sample labeling, use of Personal Protective Equipment (PPE), and adherence to Standard Operating Procedures (SOPs). Activities such as preparing flowcharts and mind maps will help students understand the principles and framework of GLP, while laboratory case studies will enable them to identify common errors and non-compliance issues. Practical exercises



	including safety checklists, laboratory safety demonstrations, and chemical label interpretation will enhance awareness of laboratory hazards and safe working practices. Understanding safety measures related to laboratory instruments and chemicals will help students minimize risks, prevent accidents, and ensure the generation of accurate, reliable, and reproducible experimental results. Look & Learn(10 Marks) Based on the laboratory instrument photographs provided, students are required to recognize the instruments and document their applications, structural features, and operating principles. The assignment must be uploaded on the designated platform before the submission deadline through GMIU Web Portal within the specified timeline		
3	Portfolio maintenance and Instrument maintenance <u>Topics</u> • Demo and Maintenance of Internal and External Portfolio • Calibration. of Basic Instruments such as pH meter, Water bath, colorimeter <u>Practical:</u> 20. Study and differentiate between internal and external laboratory portfolio ➤ To understand the purpose, components, and significance of internal and external laboratory documentation systems for quality assurance and compliance. 21. Understanding documentation structure and records ➤ To develop knowledge of proper documentation practices and record management as required under Good Laboratory Practices (GLP). 22. Writing proper lab notebook entries and Maintaining date, observation, and result format. ➤ To cultivate accurate scientific recording skills for ensuring data integrity, traceability, and reproducibility of laboratory work. 23. Draft an SOP for any laboratory instrument (e.g., pH meter) ➤ To learn the preparation of standardized operating procedures for the safe and consistent use of laboratory instruments. 24. Calibration using standard buffer solutions (pH 4, 7, 9/10) and Recording observations and accuracy ➤ To understand the importance of instrument calibration in maintaining measurement accuracy and reliability. 25. Measure pH of water, food samples, or solutions and interpret and record results ➤ To develop practical skills in pH measurement and data interpretation for quality assessment and analytical applications.	12	20%



	26. Determine concentration of a sample using colorimeter and plot basic observation and result ➤ To understand the principles of colorimetric analysis and apply them for quantitative determination of sample concentration. 27. Cleaning, handling, and storage of instruments and understanding preventive maintenance and safety measures ➤ To ensure proper care and maintenance of laboratory instruments for accurate performance, longevity, and safe operation. 28. Proper usage of water bath and Temperature control and safety precautions ➤ To gain practical knowledge of temperature-controlled laboratory operations and the safe handling of water bath equipment. Evaluation Method: <table border="1"> <thead> <tr> <th>Sr. No.</th><th>Evaluation Methods</th><th>SEE</th><th>CCE</th></tr> </thead> <tbody> <tr> <td>1</td><td>Performance Assessment in Laboratory Practices: Practical performance, accuracy of observations, proper maintenance of laboratory records, and adherence to GLP. Students will be evaluated on their ability to perform calibration, handle instruments correctly, and maintain SOPs and documentation with clarity and completeness.</td><td>10</td><td></td></tr> <tr> <td>2</td><td>Active Learning Assignment: Skill Development and Practical Competency: Students will simulate SOP drafting, data interpretation from colorimeter and pH analysis, and portfolio preparation. Emphasis will be given to critical thinking, problem-solving skills, and timely submission of assignments, ensuring students demonstrate both conceptual understanding and practical competency and , along with timely submission of the assignment on the GMIU Web Portal.</td><td></td><td>10</td></tr> <tr> <td></td><td>Total</td><td>20</td><td>10</td></tr> </tbody> </table> Examination Style:	Sr. No.	Evaluation Methods	SEE	CCE	1	Performance Assessment in Laboratory Practices: Practical performance, accuracy of observations, proper maintenance of laboratory records, and adherence to GLP. Students will be evaluated on their ability to perform calibration, handle instruments correctly, and maintain SOPs and documentation with clarity and completeness.	10		2	Active Learning Assignment: Skill Development and Practical Competency: Students will simulate SOP drafting, data interpretation from colorimeter and pH analysis, and portfolio preparation. Emphasis will be given to critical thinking, problem-solving skills, and timely submission of assignments, ensuring students demonstrate both conceptual understanding and practical competency and , along with timely submission of the assignment on the GMIU Web Portal.		10		Total	20	10		
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	Performance Assessment in Laboratory Practices(20 Marks) Students practical performance, accuracy of observations, maintenance of laboratory records, and adherence to GLP guidelines. Marks will be awarded for the ability to perform calibration procedures, handle laboratory instruments correctly, and maintain SOPs and documentation with clarity and completeness. Emphasis will be given to systematic work, precision, and compliance with standard laboratory practices. Skill Development and Practical Competency(10 Marks) Students will be evaluated based on activities such as SOP drafting, data interpretation using instruments like pH meter and colorimeter, and preparation of laboratory portfolios. Assessment will focus on critical thinking, problem-solving ability, conceptual understanding, and practical competency. Timely submission of assignments through the GMIU Web Portal will also be considered as an important evaluation criterion.		
4	Data maintenance and record <u>Topics</u> • Importance of data accuracy and integrity • Role of data in research and industry • Principles of proper documentation • ALCOA principles (Attributable, Legible, Contemporaneous, Original, Accurate) • Proper entry writing (date, aim, procedure, observation, result) and Corrections and error handling • Manual vs electronic data recording and Preparation of reports and result sheets <u>Practical:</u> 29. Analyze sample datasets and identify errors/inconsistencies and Suggest corrections based on GLP principles ➤ To develop the ability to identify data discrepancies and apply GLP principles to ensure data accuracy, reliability, and integrity. 30. Review a given experimental report and Identify importance of accurate data in decision-making ➤ To understand the role of accurate and reliable laboratory data in scientific interpretation, quality assurance, and decision-making processes. 31. Identify correct vs incorrect documentation samples and Rewrite improper entries into proper GLP format ➤ To enhance documentation skills by recognizing non-compliant records and converting them into GLP-compliant documentation.	12	20%



32. Evaluate a lab record based on ALCOA principles and Mark whether data is attributable, legible, etc.

- To understand and apply ALCOA principles for maintaining data integrity and regulatory compliance in laboratory records.

33. Demonstrate correct method of correcting errors in lab records and Avoid overwriting and maintain transparency

- To learn proper error correction practices that preserve data integrity, traceability, and transparency in laboratory documentation.

34. Convert raw data into a structured report and Include aim, method, observation, result, conclusion

- To develop scientific reporting skills by organizing experimental data into a standardized and meaningful laboratory report format.

35. Create result sheets from given experimental data and Ensure accuracy, neatness, and proper interpretation

- To acquire skills in preparing accurate and well-organized result sheets for effective data presentation and interpretation.

Evaluation Method:

Sr. No.	Evaluation Methods	SEE	CCE
1	Data Accuracy, Integrity, and Record Maintenance Task: Students will focus on ability to analyze datasets, identify errors, and maintain accurate and complete laboratory records in accordance with GLP and ALCOA principles. Assessment will be based on clarity of documentation, correctness of data interpretation, proper error correction methods, and structured report preparation.	10	
2	Data Analysis and GLP-Based Documentation Skills Task: Students will implement reviewing experimental reports, rewriting incorrect documentation, evaluating records based on ALCOA principles, and preparing result sheets. Emphasis will be placed on critical thinking, data integrity, and timely submission, ensuring students demonstrate both analytical skills and professional documentation practices. PDF report on the GMIU Portal.		10
	Total	20	10



	Examination Style: Data Accuracy, Integrity, and Record Maintenance Task (20 Marks) Student's ability to analyze datasets, identify errors, and maintain accurate laboratory records following GLP and ALCOA principles. Marks will be awarded for proper documentation, correct data interpretation, appropriate error correction methods, and systematic report preparation. Emphasis will be given to clarity, completeness, and adherence to standard laboratory practices. Data Analysis and GLP-Based Documentation Skills Task (10 Marks) Students will review experimental reports, correcting improper documentation, evaluating records based on ALCOA principles, and preparing structured result sheets. Assessment will focus on critical thinking, accuracy, data integrity, and timely submission. Students will be evaluated on their ability to apply theoretical knowledge to practical documentation and analytical tasks. Submit an individual report in PDF format on the GMIU Portal.		
5	A brief introduction to equipment <u>Topics</u> • Importance and role in scientific experiments • Classification (analytical, measuring, safety, general equipment) • pH meter, centrifuge, microscope, water bath, colorimeter • Applications in microbiology, biotechnology, and food labs • Working principles of basic instruments • Importance of accuracy and precision • Proper usage techniques • Do's and Don'ts in the laboratory <u>Practical:</u> 36. Study and identify common lab instruments and Write name, use, and basic function ➤ To familiarize students with commonly used laboratory instruments and their applications in routine laboratory operations. 37. Understand principles of pH meter, centrifuge, microscope, colorimeter ➤ To understand the working principles and analytical applications of essential laboratory instruments used in scientific research and testing. 38. Basic introduction of Molecular Biology equipment such as micropipette, Burette etc.	12	20 %



	➤ To gain basic knowledge of molecular biology equipment and their proper use in laboratory experiments and measurements.														
	39. Proper pipetting techniques and Calibration awareness and accuracy check ➤ To develop accurate liquid handling skills and understand the importance of calibration in obtaining reliable experimental results.														
	40. Temperature setting and monitoring and Understanding heating applications ➤ To understand temperature control techniques and their significance in various laboratory and analytical procedures.														
	41. Cleaning procedures for glassware and instruments and Storage techniques ➤ To learn proper cleaning, maintenance, and storage practices that ensure laboratory hygiene and instrument longevity.														
	42. Electrical safety, Handling sensitive instruments and Use of PPE during operation ➤ To promote safe laboratory practices by understanding electrical safety measures, instrument handling procedures, and personal protective equipment requirements.														
	43. Setting speed (RPM) and time and Safety precautions during operation ➤ To acquire practical knowledge of operating laboratory equipment safely by adjusting speed and time parameters accurately.														
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2	Instrument Handling, Analysis, and Skill Development: Students will work instrument identification exercises, SOP drafting, demonstration of equipment usage, and		10												



	interpretation of readings from instruments like colorimeter and pH meter. Emphasis will be on practical skills, critical understanding, safety awareness, and timely submission of assignments on the GMIU Portal.				
	Total	20	10		
Examination Style: Laboratory Equipment Operation and GLP Compliance(20 Marks) Assessment will be based on the student's understanding of laboratory instruments, their working principles, calibration procedures, and compliance with Good Laboratory Practices (GLP). Marks will be awarded for accurate identification of instruments, proper documentation, SOP preparation, safe laboratory practices, and systematic recording of observations and results in accordance with established laboratory standards. Instrument Handling, Analysis, and Skill Development(10 Marks) Students will perform hands-on activities involving the identification and operation of laboratory instruments, preparation of Standard Operating Procedures (SOPs), and analysis of data generated from instruments such as pH meters and colorimeters. Evaluation will be based on technical competency, understanding of instrument applications, adherence to laboratory safety practices, quality of documentation, and timely submission of reports through the GMIU Portal.					

Suggested Specification table with Marks(Theory):100

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage %	15%	15%	20%	15%	15%	20%

Course Outcome:

After learning the course, the students should be able to:	
CO1	To understand the principles and importance of GLP
CO2	To develop skills in laboratory safety and risk management
CO3	To learn proper documentation and record-keeping practices
CO4	To gain knowledge of quality assurance and quality control practices used in laboratories and industries.



CO5	To promote ethical and responsible laboratory practices
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Instructional Method:

The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

From the content 10% topics are suggested for flipped mode instruction. Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory.

The internal evaluation will be done based on Active Learning Assignment A practical/Viva examination will be conducted at the end of the semester for evaluation of the performance of students in the laboratory.

Reference Books:

- 1) Handbook Good Laboratory Practices-World Health Organization (WHO)
- 2) Life science protocol manual (2018)-DBT Star College scheme
- 3) Guidelines for good laboratory practices council of medical research, New Delhi (2008).
- 4) Handbook Good Laboratory Practice for Nonclinical Studies (2022)
- 5) Good Laboratory Practices(GLPs) and ISO 17025



Suggested Assessment Guidelines:**Module-1: Introduction to GLP**

Content and Understanding(20 Marks)		
Criteria	Description	Marks
Concept Understanding	Demonstrates clear understanding of GLP concepts including definition, importance, history, and role in research and industry.	5
principles and Guidelines	Understanding of GLP principles, regulatory bodies, and basic guidelines related to laboratory practices.	5
Analytical Ability	Ability to analyze laboratory scenarios, identify GLP violations, and interpret their impact on data reliability.	5
Application and Presentation	Preparation of flowchart/mind map, clarity in explanation, and ability to present concepts systematically.	5
Total		20

Module-2: Demonstration of Laboratory Safety

Fundamentals of GLP and Laboratory Safety Management (20 Marks)		
Criteria	Description	Marks
Concept Understanding	Demonstrates clear understanding of laboratory safety principles, GLP fundamentals, and safety management practices.	5
Knowledge of Safety Practices	Identifies and explains use of PPE, hazard symbols, chemical handling, and waste disposal methods.	5
Practical Demonstration Skills	Ability to demonstrate laboratory safety procedures, proper handling of equipment, and adherence to safety protocols.	5
Application and Awareness	Applies GLP and safety concepts in real laboratory scenarios with proper explanation and presentation.	5
Total		20

Module-3: Portfolio maintenance and Instrument maintenance

Performance Assessment in Laboratory Practices(20 Marks)		
Criteria	Description	Marks
Concept Understanding	Demonstrates clear understanding of portfolio maintenance, documentation structure, and importance of instrument maintenance in GLP.	5
Documentation and Record Keeping	Maintains complete and organized laboratory portfolio including records, SOPs, calibration logs, and observations.	5
Practical Skills in Instrument Maintenance	Shows ability to handle, clean, calibrate, and maintain laboratory instruments following standard procedures.	5
Application and	Applies GLP principles in maintaining records and instruments	5



Compliance	with accuracy, safety, and adherence to protocols.	
	Total	20

Module-4: Data maintenance and record

Data Accuracy, Integrity, and Record Maintenance Task (20 Marks)		
Criteria	Description	Marks
Concept Understanding	Demonstrates clear understanding of data accuracy, data integrity, GLP documentation practices, and ALCOA principles.	5
Data Recording and Documentation	Maintains proper laboratory records with correct format (date, aim, procedure, observation, result) and ensures completeness.	5
Analytical Ability	Ability to analyze datasets, identify errors/inconsistencies, and suggest corrections based on GLP principles.	5
Application and Reporting	Converts raw data into structured reports and result sheets with clarity, accuracy, and proper interpretation.	
	Total	20

Module-5: A brief introduction to equipment

Laboratory Equipment Operation and GLP Compliance(20 Marks)		
Criteria	Description	Marks
Concept Understanding	Demonstrates clear understanding of laboratory equipment, their functions, working principles, and importance in GLP.	5
Knowledge of Operation and Safety	Explains correct operation of instruments, safety precautions, and use of PPE while handling equipment.	5
Practical Skills and Calibration	Ability to handle instruments, perform basic calibration (e.g., pH meter), and follow SOPs accurately.	5
Application and Compliance	Applies GLP guidelines in equipment usage, maintenance, and documentation with proper recording of observations.	5
	Total	20

