B.Tech (Food Technology)

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E- Practical Manual (BUAT/EM/07/2025)

INTRODUCTION TO GOOD LABORATORY PRACTICES 2(0+2)

(SKILL ENHANCEMENT COURSE)

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About the subject

Introduction to Good Laboratory Practices (GLP) **is a** skill enhancement course introduced as part of the undergraduate curriculum under the recommendations of the **Sixth Deans Committee (2024–25)**. The course is designed to provide students with foundational knowledge and practical understanding of standard laboratory practices, procedures, and protocols essential for ensuring safety, reliability, and accuracy in scientific work.

This subject emphasizes the principles and implementation of GLP in food, chemical, and microbiological laboratories. It aims to develop skills related to proper handling of equipment, chemicals, and biological materials, documentation and data integrity, quality assurance, biosafety, and infrastructure requirements. Students will also learn about sampling, calibration, waste disposal, and contamination control through theoretical and hands-on exposure.

The course equips learners with the competence required for professional laboratory environments, fosters a responsible scientific attitude, and enhances their readiness for industrial, research, or quality control roles in the field of food science and technology.

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Practical 1

Introduction

Good Laboratory Practices (GLP) refer to a set of principles that govern the planning, performance, monitoring, recording, reporting, and archiving of laboratory studies. These principles are primarily designed to ensure the quality, integrity, and reliability of data generated during non-clinical laboratory studies, especially those used for regulatory and safety purposes. GLP is not focused on the scientific content or hypothesis of the study, but rather on how the study is conducted and documented. It promotes uniformity and standardization in laboratories, ensuring that all test data is traceable and reproducible. Originally developed in response to cases of fraudulent and poorly managed research practices, GLP today plays a critical role in ensuring the transparency and ethical conduct of scientific research, particularly in sectors like pharmaceuticals, chemicals, pesticides, cosmetics, and food safety.

Amendments and Historical Development

The concept of GLP emerged during the 1970s when the U.S. Food and Drug Administration (FDA) identified serious flaws and data manipulation in laboratory practices related to safety testing. This led to the formal introduction of GLP regulations in the United States in 1978, known as Title 21 Code of Federal Regulations (CFR) Part 58. Subsequently, the Organisation for Economic Co-operation and Development (OECD) developed internationally harmonized GLP principles in 1981 to promote the mutual acceptance of test data among member countries. These principles have since been periodically revised to include developments in quality systems and regulatory needs.

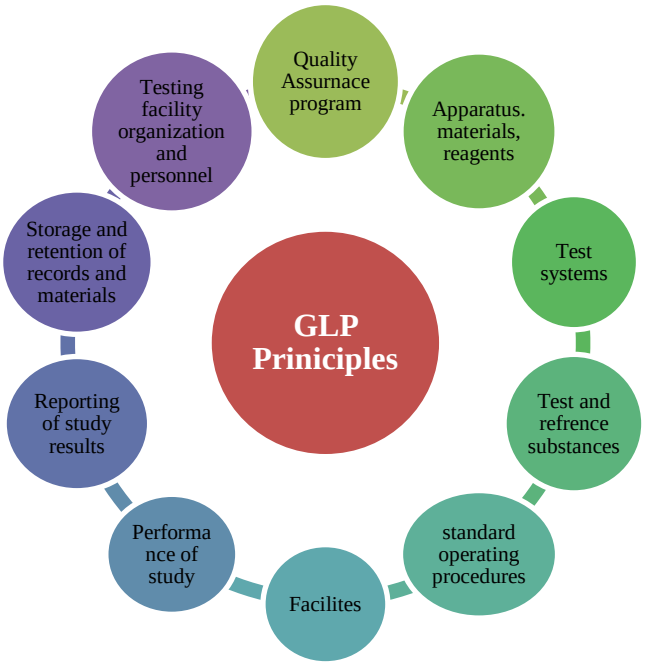
In India, the Department of Science and Technology (DST) established the National GLP Compliance Monitoring Authority (NGCMA) in 2002 to oversee GLP implementation and compliance. A significant milestone was achieved in 2011 when India became a full adherent to the OECD GLP system. This enabled Indian laboratories that are GLP-certified to generate data acceptable for regulatory purposes across all OECD member countries, thus boosting international trade and scientific collaboration.

Definition of GLP

According to the OECD, Good Laboratory Practice is defined as a "quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived, and reported." Similarly, the U.S. FDA defines GLP as a series of regulations designed to ensure the quality and integrity of data used in the development of products regulated by the FDA. These definitions emphasize the systematic and controlled approach required in laboratory settings to maintain data credibility and compliance with regulatory expectations.

Purpose of GLP

The primary purpose of GLP is to ensure that laboratory data is reliable, reproducible, and scientifically valid. It provides a structured framework that enhances the credibility of research data, particularly for studies evaluating the safety of products like pharmaceuticals, agrochemicals, and medical devices. GLP ensures transparency in research processes and facilitates traceability of each step involved in a study. Moreover, it enables laboratories to meet the standards required by national and international regulatory bodies, thus supporting the approval process for new products. Another important purpose of GLP is to promote ethical research practices by ensuring that laboratory personnel follow documented procedures and maintain accurate records. In essence, GLP builds a culture of quality and responsibility in the laboratory environment.



Importance of GLP

GLP is critically important for several reasons. First, it ensures data integrity, meaning that the results of a study are accurate, complete, and free from fabrication or bias. This is crucial for making informed decisions regarding the safety and efficacy of products intended for human, animal, or environmental exposure. Second, GLP supports regulatory compliance. Regulatory agencies around the world, such as the FDA (USA), EMA (Europe), and CDSCO (India), require GLP-compliant data for product approval. Third, GLP enhances international acceptance of test data. Through adherence to OECD GLP principles, data generated in one country can be accepted in others, avoiding the need to repeat studies and reducing costs and time-to-market.

In addition, GLP strengthens internal quality control within organizations by mandating the establishment of Quality Assurance Units (QAU) to audit and monitor study conduct. This helps identify and correct deviations early in the study process. GLP also contributes to environmental and public health protection by ensuring that safety studies are conducted rigorously and ethically, providing reliable data to prevent potential risks associated with chemical or drug exposure.

Exercise Questions

1. Define Good Laboratory Practices (GLP).
2. Why GLP was initially introduced in the United States?
3. What is the purpose of a Quality Assurance Unit in a GLP-compliant laboratory?

Practical 2

Good Manufacturing Practices (GMP)

Good Manufacturing Practices (GMP) is a set of guidelines that ensure that products are consistently produced and controlled according to quality standards. In the context of the food industry, GMP covers the manufacturing environment, equipment hygiene, employee practices, raw material handling, processing, packaging, and storage. The goal is to make sure that the food is safe, pure, and of the intended quality**.**

GMP focuses on the "how to make the product" part. It deals with avoiding contamination, ensuring batch consistency, maintaining hygienic conditions, and verifying that production processes are followed correctly. For example, in a biscuit manufacturing unit, GMP ensures that:

- The flour is sourced from approved suppliers.
- Mixing equipment is cleaned and sanitized between batches.
- Employees wear proper protective clothing.
- Finished biscuits are stored at the correct temperature and humidity levels.
- Each batch is traceable in case of complaints or recalls.

GMP vs. GLP in the Food Industry

To understand the difference between GMP and GLP, consider this example from a fruit juice manufacturing facility**.**

Scenario**:** A company produces packaged orange juice and is also researching how different packaging materials affect vitamin C stability during storage.

1. **GMP Activities (Manufacturing)**:
    - ✓ The production line must be clean and free from microbial contamination.
    - ✓ Juice must be heated (pasteurized) at a controlled temperature.
    - ✓ Bottles must be sealed properly to avoid oxidation or leakage.
    - ✓ Workers follow hygiene protocols, like wearing gloves and hairnets.
    - ✓ Every bottle should contain the right volume and correct labeling.

These activities ensure that the final product—the orange juice—is safe, uniform, and acceptable for sale**.** GMP ensures that if a consumer picks one bottle today and another next month, the quality and safety will be the same**.**

2. **GLP Activities (Research/Study in Lab)**:
    - ✓ A small lab study is conducted to compare glass bottles vs. PET plastic bottles for vitamin C retention.
    - ✓ Samples are stored at different temperatures and tested every 15 days.
    - ✓ The lab records all procedures, storage conditions, and results.
    - ✓ An independent quality assurance team checks if the study was done as per the written protocol.
    - ✓ The final study report is submitted to R&D or food regulatory bodies for review.

These activities are not about making the juice but about studying how packaging affects product quality over time. The study must follow GLP to ensure the data is reliable, accurate, and reproducible**.**

Key Differences

Aspect	GMP (Production)	GLP (Research/Study)
Focus	Ensuring product quality and safety during manufacturing	Ensuring study data is scientifically valid and trustworthy
Objective	Safe and consistent orange juice production	Valid data on vitamin C stability in different bottles
Area of Application	Factory floor, production line, packaging zone	Research laboratory, stability chamber
Personnel	Production workers, QC team	Scientists, study directors, QA auditors
Outcome	A bottle of juice ready for sale	A report explaining how packaging affects nutrient stability
Documentation	Batch production records, cleaning logs, temperature logs	Raw data sheets, study protocols, QA audit reports

Factors Influencing Implementation and Maintenance of GLP in a Quality Control Laboratory

Implementing and sustaining GLP in a food quality control laboratory is essential to ensure the **accuracy, reliability, and traceability** of test results, which directly impact food safety, consumer trust, and regulatory compliance. However, achieving and maintaining GLP standards is not just about following written rules—it involves multiple interconnected factors that determine how well the principles are practiced in real-life laboratory settings.

1. Management Commitment and Laboratory Culture

Strong leadership is the foundation for successful GLP implementation. When management prioritizes laboratory quality, allocates sufficient resources, and fosters a culture of accountability and integrity, GLP compliance becomes part of daily operations rather than a forced requirement. In a food lab, this could mean ensuring that every chemical analysis or microbiological test performed on food products is properly supervised and documented. *Example:* If a lab manager insists on routine training, invests in qualified staff, and supports regular internal audits, technicians are more likely to follow SOPs and handle deviations responsibly.

2. Infrastructure and Facility Design

The physical layout and design of the lab should support the separation of activities such as sample receipt, preparation, analysis, and waste disposal to avoid cross-contamination. Adequate lighting, ventilation, controlled temperature and humidity, and designated zones for handling allergens or hazardous chemicals all play a role. *Example:* In a lab testing milk samples for adulteration and microbial load, having separate rooms for chemical analysis and microbial culturing is essential to prevent contamination and ensure data integrity.

3. Competent and Well-Trained Personnel

GLP relies heavily on qualified personnel who understand both the technical procedures and the importance of maintaining data integrity. Training must be continuous, documented, and include SOPs, equipment handling, GLP principles, and safety practices. *Example:* A lab technician testing pesticide residues in vegetables must not only know how to operate GC-

MS equipment but also follow documentation practices such as entering sample details, calibration records, and results in the correct format.

4. Availability and Adherence to SOPs (Standard Operating Procedures)

SOPs are essential to maintain consistency in laboratory operations. They must be clear, regularly updated, and easily accessible to staff. Any changes in methods or procedures should be controlled and documented through a proper revision system. *Example:* If a food lab updates its method for aflatoxin detection in peanuts using a newer HPLC method, the revised SOP must be reviewed, approved, and all staff trained before its use.

5. Equipment Calibration, Qualification, and Maintenance

All instruments used for testing (e.g., spectrophotometers, pH meters, chromatographs) must be regularly calibrated and maintained. Equipment must undergo proper qualification before being used in analysis. *Example:* If a spectrophotometer used for food color analysis drifts in wavelength, results may be inaccurate. Routine calibration and maintenance ensure valid results.

6. Sample and Reagent Management

Proper handling, storage, labeling, and traceability of food samples, chemicals, and reagents are crucial. Expired or poorly stored reagents can lead to false results. A log system for sample entry, usage, and disposal must be in place. *Example:* In a lab testing fruit juices for preservatives, using expired standard solutions can lead to incorrect results, compromising food safety decisions.

7. Data Recording, Integrity, and Archiving

GLP emphasizes that data must be attributable, legible, contemporaneous, original, and accurate (ALCOA principles). Whether maintained in physical registers or electronic systems, data must be protected from tampering and loss. Any changes must be traceable. *Example:* If a microbial test result on a food batch is changed after review, the reason, date, and person responsible must be recorded clearly without overwriting the original data.

8. Role of the Quality Assurance (QA) Unit

A dedicated QA unit ensures that all laboratory activities comply with GLP through audits, protocol reviews, and report verifications. QA must be independent of those performing the actual testing to maintain objectivity. *Example:* Before releasing a final test report for cereal products tested for iron content, QA checks if the method followed was as per protocol, results were calculated correctly, and records are complete.

9. Documentation Control and Record Retention

All records—including test reports, raw data, calibration logs, training records, and SOPs—must be securely stored and easily retrievable. Laboratories must also ensure long-term preservation of data for audits or regulatory reviews. *Example:* A regulatory body may request five-year-old fat analysis data of processed cheese. If GLP is followed, the lab can confidently retrieve validated records from its archive.

10. Continuous Monitoring and Improvement

Implementation is not a one-time effort; maintaining GLP requires regular internal audits, staff feedback, root-cause analysis of deviations, and preventive action. It also involves staying updated with national and international food testing standards. *Example:* An internal audit finds expired reagent use; corrective actions are implemented and logged.

Exercise Questions

1. Differentiate between GMP and GLP in the context of the food industry, using a suitable example.
2. List any three factors that influence the implementation of GLP in a food quality control laboratory.
3. Explain with an example why equipment calibration is important under GLP.

Practical 3

Validation of Analytical Procedure, Calibration of Equipment and Instruments

1. Validation of Analytical Procedure

Method validation is a structured process used to confirm that an analytical procedure (i.e., a testing method) is suitable for its intended purpose. It proves that the method consistently gives accurate, precise, and reliable results. In a food testing lab, various methods are used to test quality parameters such as protein content in pulses, fat in dairy products, pesticide residues in vegetables, or preservatives in soft drinks. Before such methods can be trusted, they must be validated.

Without validation:

- The results cannot be trusted.
- Food products might pass or fail quality tests incorrectly.
- Regulatory agencies (like FSSAI) may reject lab data.

Key Parameters of Method Validation (with Food Examples):

1. **Accuracy** – Measures how close a test result is to the actual (true) value. *Example:* If a biscuit sample contains 5% fat and your method consistently shows 4.9–5.1%, it is accurate.
2. **Precision (Repeatability)** – The ability to get similar results when the same sample is tested multiple times. *Example:* Testing the sugar content of a juice sample five times and getting nearly identical values each time.
3. **Specificity** – Ability of the method to detect only the intended substance. *Example:* A test for benzoic acid should not give a false reading due to the presence of citric acid or other preservatives.
4. **Linearity** – Ability of the method to provide results directly proportional to the concentration. *Example:* A vitamin C test shows that doubling the concentration leads to double the absorbance.
5. **LOD (Limit of Detection)** – The smallest quantity of a substance that can be detected (but not precisely measured). *Example:* Your method can detect as low as 0.01 ppm of lead in flour.

6. **LOQ (Limit of Quantification)** – The lowest concentration that can be reliably measured with acceptable precision and accuracy. *Example:* A method can accurately quantify aflatoxin down to 0.05 ppm in groundnuts.
7. **Robustness** – The ability of a method to remain reliable despite small changes in conditions. *Example:* A protein test still works well even if the water bath temperature varies slightly.

2. Calibration of Equipment and Instruments

Calibration is the process of verifying and adjusting the performance of laboratory instruments to ensure that they provide accurate measurements. This is done by comparing the instrument's readings with a known standard.

Why Calibration is Essential?

Even a small error in measurement tools can lead to:

- Inaccurate food test results
- Wrong nutritional labeling
- Health hazards if contaminants go undetected
- Legal and regulatory issues

When Should Calibration Be Done?

- Before the first use of new equipment
- On a regular schedule (daily, weekly, monthly)
- After repair or suspected malfunction
- Before important testing or audits

Link Between Validation and Calibration

- **Validation** ensures that the **testing method** works correctly.
- **Calibration** ensures that the **equipment used** in testing is measuring correctly.

If either of these is faulty, the final results will be unreliable — no matter how experienced the lab technician is.

Example: You use a validated method to measure fat content in curd, but the weighing balance is uncalibrated. Your results will still be wrong.

◆ ***Examples of Equipment and Their Calibration in Food Labs:***

Instrument	What is Checked	Standard Used	Frequency
pH Meter	pH reading accuracy	pH buffer solutions (pH 4.0, 7.0, 10.0)	Daily or before use
Weighing Balance	Accuracy of weighing	Certified standard weights	Daily
UV-Vis Spectrophotometer	Wavelength and absorbance accuracy	Potassium dichromate or certified solutions	Monthly
Moisture Analyzer	Temperature and weight calibration	Moisture reference samples	Monthly
Oven/Incubator	Temperature accuracy	Certified thermometer	Periodic
Autoclave	Pressure and temperature accuracy	Biological indicators, pressure gauges	Periodic

Exercise questions

1. Define method validation**.** Why is it important in food quality testing?
2. List any four key parameters used in method validation and explain anyone with an example from the food industry.
3. What is the difference between Limit of Detection (LOD) and Limit of Quantification (LOQ)? Give one practical example of each.
4. Explain why calibration of laboratory instruments is necessary. What could be the consequence of using uncalibrated equipment in food testing?

Practical 4

GLP of handling various equipment, chemicals and glass wares in laboratory

General Requirements

Good laboratory practices concern all people who work in areas where it applies, whether they are managers, group leaders or other personal. Although persons working in GLP environment is carrying out different tasks using different skills, there are some basic rules which can be generally applied are follows:

i. Make sure to have the correct written instructions before starting a task.
ii. Do not carry out a task for which user have not been trained or in which user do not feel competent.
iii. Always follow instructions precisely.
iv. Define in advance what we are going to do.
v. Check that what have done and what shall have to be done.
vi. Keep records of information, results and actions taken. Maintain clear accurate records of the activity what was done and the checks carried out.
vii. Check that the instruments / equipment's used are clean, calibrated and correct ones as per procedure before use.
viii. Always be on guard for labeling errors.
ix. Labels shall always be held securely and not left lying around.
x. Always notify if labels are seen either detached or appear to be incorrect or are in wrong place.
xi. Report any labels that are damaged or dirty.
xii. Never remove a label which has been incorrectly applied and never stick a new label over an old one of the same type. Incorrectly affixed should be strike it off with sign and date and paste new correct label adjacent to it.
xiii. Ensure that printed labels which are used are legible; if not then replace the same. The labels with poor legibility shall be "X" marked with marker pen and discarded by tearing wherever possible.
xiv. Keep everything clean and tidy.
xv. Investigate problems. Always be on the lookout for mistakes, defects and unusual events. Report them immediately.

xvi. Quality Control Laboratory shall be clean and the workbenches kept tidy in accordance with written cleaning schedules and whenever it is required.

xvii. The cleaning and disinfection of microbiological testing areas shall be regular and according to written schedules and procedures.

xviii. The cleaning of Raw Material, Packaging Material, Finished Product and Stability samples storage compartment is to be done by using vacuum cleaner (if required) followed by cleaning with soft lint free duster. During cleaning avoid any possible cross contamination of the samples.

xix. Clean the instruments / equipment's like Glassware drying oven, Refrigerator, Deep freezer, Water bath, Sonicators, etc., used in the Quality Control Laboratory fortnightly or earlier as and when required.

xx. Clean the workbenches after completion of work or at the end of the day whichever is earlier and keep the respective specification, GTP's, SOP's etc. used, back at the designated place.

xxi. General and specific written down instructions for safety shall be circulated to each staff member and the instructions shall be revised periodically as appropriate (e.g. audio-visual material, poster displays and by seminars/conferences).

xxii. While closing the Quality Control laboratory, ensure that all water taps, instruments (which are not running), equipments, computers are switched 'OFF'. Put off the lights, AC's and inform the Engineering department to put off the AHU's (wherever required) and close the department.

xxiii. The laboratory main door keys shall be submitted to Security department.

Personnel

Good Laboratory Practices (GLP) not only govern the use of equipment and procedures but also focus on the personal behaviour and responsibilities of individuals working in laboratories. A well-disciplined personal approach is key to maintaining a safe, organized, and efficient lab environment. Each individual has a duty to understand and follow established protocols for personal hygiene, behavior, and protective measures

i. There shall be adequate number of personnel qualified with appropriate education, training and / or experience to perform and supervise the tasks assigned. A laboratory shall have a Head (Quality Manager or Technical Manager) for carrying out all technical activities and for implementation of documented quality system.

ii. Head of the laboratory must be of high professional standing with experience in drug analysis and laboratory management who is responsible for:

iii. Ensuring the control and maintenance of documents including the quality system as per the requirements of regulatory authorities which involve all raw data, SOP's, documentation exhibits, protocols, training charts, etc.

iv. Planning and organizing the audit of the quality system and initiation as well as follow up action of the corrective actions, if any.

v. Investigation of technical complaints.

vi. Taking final responsibilities for recommending any regulatory action in the event of noncompliance of tested samples.

vii. All personnel prior to employment shall be medically examined and then periodically re-examined for medical fitness. The Head Quality Control shall ensure that the personnel are medically fit to carry out the job.

viii. Personnel who are suffering from an infectious disease or having open lesions on the exposed surface of the body are prohibited from participating in any activities that could result in compromising the quality of analysis.

ix. All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.

x. Pyramid according to the job responsibilities and functions shall be clearly defined.

xi. The job responsibility shall be assigned according to competency of the person and it shall be timely revised for addition or deletion of responsibilities assigned previously.

xii. The job responsibilities of the personnel engaged shall be specified in writing and followed strictly.

xiii. Personnel shall practice good sanitation and health habits.

xiv. In laboratory areas, smoking, eating, drinking, chewing, keeping plants, food, drinks, and personal medicines, as well as installing or removing contact lenses, are strictly prohibited. Do not drink anything available in laboratory.

xv. Personnel shall wear clean clothing (company uniform) suitable for activity with which they are involved and this clothing shall be changed on daily basis or when appropriate. Personnel shall strictly follow entry / exit and gowning procedures.

xvi. While sampling and handling cytotoxic materials, poisonous, carcinogenic materials etc., while handling hazardous chemicals and while performing microbiological analysis etc., procedure of change of clothing and use of personal protective

equipments and safety appliances shall be strictly followed. Personnel shall avoid direct contact with material / product.

xvii. Never handle any chemicals, raw materials, intermediate or finished, unpacked products with bare hands. Always use appropriate hand gloves while handling the same.

xviii. Maintain discipline inside the laboratory premises.

Laboratory Equipment and Instruments

Laboratory equipment includes a wide range of instruments such as analytical balances, hot air ovens, incubators, centrifuges, spectrophotometers, and more. These instruments are critical to laboratory operations and must be handled with care and precision.

i. The laboratory should be furnished with all types of instruments / equipment's as may be necessary for carrying out the different activities within the laboratory.

ii. The analytical instrument should be housed in dust-free environment whenever required. Conditions of temperature and humidity should be maintained and periodic checks on temperature and humidity should be made and recorded.

iii. The instruments / equipment's, instrument / equipment bench and surrounding areas should be kept clean, tidy and free from vibration at all times.

iv. Instruments / equipment's requiring calibration should be calibrated at regular intervals and records of such calibration or maintenance should be maintained. There should be written instructions in the form of Standard Operating Procedures for the operation and calibration wherever applicable. A log Book (day to day entry including status of the equipment) shall be maintained for all major instrument or wherever applicable.

v. Other equipment's / accessories such as burettes, pipettes, volumetric flasks, weight boxes, thermometers etc. should be thoroughly checked for accuracy of calibration before acceptance for use.

vi. During weighing excess working standard should not be placed back into the original container and should be discarded except Reference or costly material.

vii. Standard Operating procedure should be displayed or kept near instruments/ equipment's and should be followed whenever used.

viii. While performing analysis on instruments / equipment's display the analysis status indicating details of ongoing analysis.

ix. Fume Cupboards/Fume Hood: Work involving the evolution of harmful and obnoxious vapors shall be carried out in a fume cupboard.
x. Each balance weight print should be clearly identified and wherever possible/applicable the balance weight prints should be stamped with Rubber stamp with minimum but not limited to the details like weight, Test, AR No./B. No.

Chemicals and Reagents

Chemicals in the laboratory may be hazardous and must be treated with caution. GLP related to chemicals starts with proper labeling. Every chemical bottle or container must carry a clear label mentioning the name of the substance, concentration, date of preparation (if applicable), expiry date, and appropriate hazard symbols. This ensures traceability and minimizes confusion, especially when dealing with similar-looking substances.

i. All reagents and solutions in the laboratory shall be properly identified with a label.
ii. Containers of stock solutions and of standard solutions shall bear the following details:
iii. Name of analytical chemist who prepared the solution.
iv. Date of preparation.
v. Each volumetric solution shall have ―use before date/valid up-to date depending upon the stability of the solution.
vi. The transfer of hazardous chemicals and regents from one container to another container shall be carried out with suitable equipment by taking the care of safety.
vii. Ensure that the instruments are qualified before use.
viii. Ensure that instruments are calibrated and maintained as per the respective calibration procedure and schedule. Calibration shall be performed as per the schedule.
ix. The calibration status of the instrument shall be displayed on the instrument.

Glassware

Glassware is widely used in laboratories for measuring, transferring, storing, and reacting chemicals. It includes test tubes, flasks, pipettes, burettes, and beakers. Being fragile, glassware must be handled with extra caution to prevent breakage and contamination.

i. Before using any glassware, it should be visually inspected for cracks, chips, or any residue from previous experiments.

ii. Damaged glassware should never be used as it may break under pressure or heat. After use, it should be cleaned thoroughly. Generally, cleaning involves soaking in detergent or acid solution, scrubbing if necessary, and rinsing thoroughly with tap water followed by distilled water. Final drying can be done using a drying oven or by air drying, depending on the type of glassware.

iii. Glassware should never be subjected to sudden changes in temperature as it may shatter due to thermal shock.

iv. Volumetric glassware, such as measuring flasks and pipettes, should not be heated directly as this may alter their calibration.

v. Storage of clean glassware should be in dry, dust-free cabinets. Inverted placement helps avoid contamination. Any broken or contaminated glassware should be disposed of in designated containers labeled “Broken Glass.” These containers should never be used for general waste to avoid injury.

Exercise Questions

1. Why is personal hygiene important in laboratory practices?
2. List any three types of PPE commonly used in laboratories and state their purpose.
3. What behaviors should be avoided to maintain a safe working environment?
4. How should you respond if you spill a chemical on your lab coat?

Practical 5

Scope of testing applicable for a food laboratory

The scope of testing in a food laboratory defines the types of tests, methods, and sample types the laboratory is competent to perform. It includes chemical analysis, microbiological testing**,** systematic sampling, and evaluation of packaging materials to ascertain the safety and quality of food.

1. General Requirements (As per Guidelines)

- These guidelines specify general requirements to ensure:
    i. Systematic sampling of food and packaging materials.
    ii. Execution of chemical and microbiological tests.
    iii. Use of standard**,** non-standard, and laboratory-developed methods for analysis.
- Applicability:
    i. These guidelines are applicable to all types of testing laboratories, including:
        - First-party labs (in-house testing)
        - Second-party labs (vendor/supplier testing)
        - Third-party labs (independent testing bodies)
    ii. Applicable to laboratories performing inspection**,** product certification, or any other testing services.
    iii. These apply regardless of the lab size, number of personnel, or the range of testing services.
    iv. If certain activities like sampling or method development are not undertaken by the lab, then those requirements are not mandatory.
- Clarifying Notes:
    i. Notes provided in the guidelines offer clarifications and examples.
    ii. They are not binding requirements and do not form a mandatory part of the compliance framework.

2. Functional Use of the Guidelines

Laboratories can use these guidelines to:

i. Develop a management system that integrates quality, technical, and administrative functions.
ii. Maintain a robust operational system that meets industry expectations.
iii. Help regulatory authorities, customers, and accreditation bodies to assess the laboratory's competence**.**
iv. Note: This document is not intended for laboratory certification**.**

3. Exclusions and Additional References

- These guidelines do not cover**:**
  i. Regulatory compliance or safety requirements.
  ii. Calibration of laboratory equipment or glassware**.**
  iii. Specific safety practices for operation of the lab.
- These guidelines are designed to complement ISO/IEC 17025:2005, especially for:
  i. Food testing laboratories involved in chemical and microbiological testing.
  ii. Labs conducting sampling and packaging material testing for quality assessment.
- Laboratories aiming for accreditation must fully comply with ISO/IEC 17025:2005 standards.

4. **Reference materials**:

i. The laboratory shall prepare working standard by comparing with the reference standards.
ii. A register pertaining to reference and working materials must be maintained by the laboratory. The register should contains the following details:
iii. Source of supply.
iv. Date of receipt.
v. Batch number or identification number of the supplying agency.
vi. Details like assay value, water content or any other information provided.
vii. Storage condition of the material.
viii. Date of expiry, if any and date of manufacturing if possible.

D. Microbiological Cultures:

i. Standard Operating Procedure for maintenance of microbial culture and sub-culture must be prepared by the laboratories.
ii. If the cultures have become non-viable or mutant, proper procedure shall be followed to destroy these cultures by autoclaving under an authorized personnel for biological testing.
iii. All activities be carried out in a aseptic area by authorized person.
iv. The laboratories shall perform standard biochemical tests on the sub-culture as given in literature to ensure their viability.

5. Quality system:

i. The measurements and calibrations shall fully conform to the compendial requirements and the methods demonstrably based on validation protocols are followed.
ii. Remedial action on the observations by internal and external audits are taken appropriately.
iii. There must be comprehensive and effectively implemented Quality Control systems which shall be fully documented and their effectiveness shall be monitored.
iv. Quality Control Personnel shall have access to Production and Warehouse areas for sampling and investigation as appropriate.
v. Quality Control shall ensure that every product it manufactures and distributes, consistently meets with standards of Quality, Purity, Efficacy and Safety.
vi. Quality Control is responsible for fulfilling the regulatory requirements for product registration.
vii. Organogram is to be prepared for the Quality Control department.

6. Standard Operating Procedures:

i. Standard Operating Procedures are written procedures for different activities and are integral part of Good laboratory Practices.
ii. Testing laboratories shall have Standard Operating Procedure manuals and have its periodic review.
iii. It shall be user friendly documents and shall include designation of the person responsible for intended activity.

7. **Raw data:**

i. Raw data refers to the laboratory work sheet, analysis sheet, records, and other activities and such raw data shall include hand written notes, photographs, software, drawings, computer printouts, spectral charts etc.

ii. A single line shall strike through the data being changed; the correct information shall be recorded along with the old data and the reason of change. The analyst making the change shall be identified by his signature with date. In case of automated data collection system, the person responsible shall be identified at the time of data output. The original entry must be saved and the system have audit trial for all the data.

iii. Raw data refers to the laboratory work sheet, analysis sheet, records, and other activities

iv. Data integrity and security shall be maintained and the data shall not be accessible to any unauthorized person.

8. Training:

i. Training shall be regularly conducted by qualified individuals and shall cover, at a minimum, the particular operations that the employee performs and GMP as it relates to the employee's functions. GLP / GMP ultimately depend on people. Training shall be given on both the theory and practice of the work being undertaken in a particular area, as well as relevant 'on-job' (i.e. task-based) training.

ii. Records of training must be maintained. Training shall be periodically accessed. All staff, including new and existing shall be given basic training on 'Good Laboratory Practices' during induction and at regular intervals subsequently. These training programs shall be periodically updated. In addition during training, emphasis shall be laid on regulatory requirements, health, safety and hygiene.

9. Documentation:

i. Clearly written documentation prevents errors may occur in verbal communication.

ii. Specifications, instructions, procedures and records must be free from errors and available in writing. Standard operating procedures should be available for sampling, inspection and testing of raw materials, API's, intermediates, bulk finished products, finished products, stability samples, packaging materials and whenever necessary.

iii. Documents should be approved, signed and dated by appropriate and authorized persons.

iv. On receipt of certificates from outside location / organization (such as. Working standard certificate, approval External party calibration certificate, certificate of analysis of raw material received from supplier etc.) the same should be reviewed and verified by the quality control personal with sign.

10. Desiccant Use and Replacement:

i. Sufficient quantity of self-indicative silica gel or molecular sieve shall be used, Wherever the control on absorption of moisture is required during operation or measurement, e.g. analytical balances where exposure of hygroscopic material during weighing will result absorption of moisture and in-appropriate weighing amount.

ii. In Quality Control department the instruments / areas like Analytical Balance, Autotitrator, Karl Fischer Titrator, FTIR, UV Spectrophotometer, Desiccators, Karl Fischer Coulometer, Gas manifold needs use of desiccant and routine monitoring of replacement of the same.

iii. Before using any instrument / equipment, check the color of silica gel / rubin gel used as desiccant for the instrument and equipment.

iv. Also the desiccant used in the different desiccators is to be replaced if desiccant gets deactivated (Blue color faded to pink / colorless). Maintain the record of the desiccant replacement.

v. Replace the used desiccant with the new or regenerated desiccant.

Exercise Questions

1. Define the scope of food testing laboratories with suitable examples.
2. Describe any three major areas of testing in food laboratories.
3. Why is the scope of accreditation important in a food testing laboratory?

Practical 6

GLP during estimation of nutritional composition in food

This highlights key practices to ensure accuracy, reliability, and safety while estimating nutritional components in food such as carbohydrates, proteins, fats, fiber, vitamins, and minerals. Estimation of nutritional composition is a critical aspect of food analysis that determines the health, safety, and labeling accuracy of food products. Applying Good Laboratory Practices (GLP) ensures the reliability of test results**,** compliance with standards**,** and protection of personnel and the environment.

1. Sample Handling and Preparation

i. Collect samples using clean, contamination-free equipment.
ii. Label all samples clearly with sample ID, date, and test parameters.
iii. Homogenize the sample to ensure uniform distribution of nutrients**.**
iv. Avoid exposure to air, moisture, and light (especially for vitamin estimation) to prevent degradation.
v. Always record the source, condition, and time of sampling in a laboratory notebook.

2. Use of Calibrated Equipment

i. Ensure all glassware and instruments (balances, spectrophotometers, Kjeldahl units, etc.) are properly calibrated**.**
ii. Use standardized reagents and reference standards to ensure comparability.
iii. Maintain calibration records and perform verification as per the standard operating procedures (SOPs)**.**
iv. Do not proceed with estimation if calibration is overdue or if instruments show irregularities.

3. Personal Conduct and Safety

i. Wear appropriate personal protective equipment (PPE): lab coat, gloves, goggles, and face mask when required.
ii. Follow hygienic practices – wash hands before and after analysis, do not eat or drink in the lab.
iii. Handle chemicals (e.g., acids, solvents) used in digestion and extraction steps with care.

iv. Dispose of chemical and biological waste according to institutional biosafety and waste protocols.

4. Documentation and Record Keeping

i. Record all observations, raw data, calculations, and deviations in lab notebooks or digital systems immediately.
ii. Use pre-approved formats for data entry; avoid overwriting or erasing original entries.
iii. Ensure traceability of results from raw data to final report.
iv. Every document should be signed, dated, and reviewed.

5. Quality Control and Validation

i. Use blanks, replicates, and control samples during the analysis to monitor consistency.
ii. Run certified reference materials (CRM) where available to verify accuracy.
iii. Validate the method for linearity, accuracy, precision, and limit of detection before routine use.
iv. Re-analyze a portion of the samples if results show major discrepancies.

6. Reporting of Results

i. Express results in appropriate units (e.g., g/100g, mg/kg) with standard deviations where applicable.
ii. Include method references, instrument models, and testing conditions in the report.
iii. Clearly mention uncertainty of measurement, if applicable.
iv. Final reports should be reviewed and signed by qualified personnel before release.

7. Review and Audits

i. Conduct internal audits to review GLP compliance in nutritional analysis procedures.
ii. Maintain audit trails, training records, and corrective action reports**.**
iii. Participate in proficiency testing or inter-laboratory comparison to assess lab performance.

Exercise Questions

1. What are some examples of reference materials used in nutrient estimation?
2. Describe GLP practices that help ensure traceability in laboratory testing.

Practical 7

Structure of food lab, Infrastructure and accommodation and related requirements

A food laboratory must operate with well-organized staffing, appropriate infrastructure, and a clear hierarchy. These elements ensure that testing of food and packaging materials is accurate, efficient, and compliant with regulations.

1. Personnel Structure

Food lab personnel include managerial, technical, and support teams. Each group has defined responsibilities, and together they ensure smooth operation and accurate analysis. All analysts and technicians should be adequately trained in Good Laboratory Practices (GLP), laboratory safety, and handling of sensitive equipment and chemicals. Regular capacity building through refresher training and hands-on workshops helps ensure continued compliance with analytical standards.

Head of Laboratory

- Oversees both technical and administrative activities.
- Coordinates with food safety officers (FSOs) and regulatory bodies.
- Prepares sampling work plans and may provide expert witness testimony.
- Ensures legal and quality compliance in all lab functions.

Supervisors

- Manage specific sections or units (e.g., chemistry, microbiology).
- Allocate samples, monitor workload, and solve analytical problems.
- Supervise 10–12 analysts for optimal efficiency.
- Maintain equipment, safety, and housekeeping standards.

Team Leaders

- Senior analysts responsible for coordinating a small group (up to 4).
- Focus on specific tasks or time-bound surveys.
- Act as a link between analysts and supervisors.
- Gain experience for possible future supervisory roles.

Analytical Staff

- Conduct chemical, microbiological, and instrumental analysis.
- Prepare reports and may advise industry on compliance.
- Should maintain impartiality and avoid conflicts of interest.
- May need to testify in court on testing outcomes.

Support Staff

- Handle tasks such as:
  - Glassware cleaning
  - Sample disposal
  - Pest control and lab cleaning
- Typically 15–20% of the number of analytical staff.
- Must be trained in basic safety and hygiene practices.

Administrative Staff

- Perform clerical and documentation tasks.
- Include secretaries, data entry clerks, filing assistants, etc.
- Crucial for report preparation, record maintenance, and audit support.

2. Management and Organizational Chart

The laboratory should maintain an up-to-date organizational chart that defines reporting lines and responsibilities. This chart is typically included in the Quality Assurance Manual. It is particularly important in food regulatory labs like those under FSSAI, where coordination with Food Safety Officers (FSOs) and regulatory bodies is essential. The structure generally includes a Head of Laboratory, supported by officers-in-charge of different sections such as chemistry, microbiology, biotechnology, and administration.

A well-defined organizational chart must:

- Display the hierarchy and flow of responsibility.
- Be part of the Quality Assurance Manual.
- Include sections such as:

- Chemistry
- Microbiology
- Biotechnology

3. Infrastructure and Accommodation Requirements

The infrastructure of a food testing laboratory must be planned for efficiency, safety, and compliance with quality standards.

Laboratory Layout

- Separate areas for:
    - Sample receiving
    - Chemical & microbiological testing
    - Media preparation and sterilization
    - Instrumental analysis
- Logical workflow to reduce cross-contamination.

Safety and Environmental Controls

- Ventilation, lighting, and temperature control.
- Fume hoods, biosafety cabinets, fire extinguishers, and first-aid kits.
- Proper chemical and sample waste disposal systems.

Storage and Utilities

- Separate storage for:
    - Chemicals and reagents
    - Clean and used glassware
- Non-absorbent, washable surfaces.
- Power backup for instruments and refrigeration.

Personnel Facilities

- Lockers, changing rooms, restrooms.
- Clean drinking water and hygiene facilities.
- Restricted access to critical lab zones.

Pest Control and Housekeeping

- Regular cleaning and pest prevention schedules.
- Documented protocols for sanitation and maintenance.

Exercise Questions

1. Discuss the general structure of a standard food testing laboratory.
2. Explain the role of various work areas such as sample receiving, wet lab, and microbiology lab in a food lab.
3. What are the important features of a well-designed food microbiology section?

Practical 8

Infrastructure and Accommodation and Related Requirements

General Principles

The infrastructure of a food laboratory should support effective, safe, and accurate analysis. Facilities must be designed to serve long-term objectives (10–20 years), considering future expansion, new analytical techniques, and emerging food safety concerns. Rather than focusing on short-term or current work programs, the design must be forward-thinking and adaptable.

Design of the Laboratory

Although architects and engineers finalize the design, laboratory personnel—especially analytical staff—should be consulted. Their insights into workflow, instrumentation needs, and safety considerations are crucial.

Food laboratories typically handle:

- Chemical analyses (e.g., nutrients, additives, toxins, GM testing)
- Microbiological tests
- Sensory or organoleptic evaluations

The laboratory should accommodate all such diverse functions under one efficient layout.

General Considerations

Efficient lab layout minimizes unnecessary movement of personnel and promotes smooth analytical flow. Still, procedures that pose risks of cross-contamination must be spatially separated.

Key considerations include:

- **Timeframe for construction**: Usually 5 years from planning to operation
- **Adaptability**: Avoid overly specific design tailored to current tasks; allow flexibility for future workload shifts and analytical advancements
- **Activity zones**:
    - *Generic*: Wet chemistry areas with fixed benches, fume cupboards, sinks, etc.
    - *Instrumental*: Flexible spaces with piped gases, power stabilization, movable benches
    - *Specialized*: Clean air rooms, radioactive or toxic sample handling zones, rooms for standards and dusty processes like grinding or blending

Other essential spaces:

- Offices for management and clerical work
- Toilets and washing areas
- A separate staff room to ensure safety and sample integrity
- Multiple exits for emergency escape

The Chemical Laboratory

Design directly impacts the quality of results. Poor design may lead to contamination, cross-sample interference, or erroneous results.

To prevent such issues:

- Keep trace analyses separate from concentrated solutions and standards
- Allocate separate cleaning and glassware storage areas
- Use protective clothing specific to areas to avoid transfer contamination
- Maintain dust-free zones using:
    - Glass-fronted reagent shelves
    - Clutter-free worktops
    - Vacuum cleaning systems
    - Avoid dusters and brushes

Proper placement of ventilation and fume hood exhausts is also critical to prevent air recirculation, contamination, or health hazards.

Equipment and Instruments

Setting up a fully functional laboratory demands a large variety of equipment. An individual analysis often depends on multiple tools—missing even one may halt the test.
However, over time:

- Equipment needs stabilize
- Running costs reduce
- Overall productivity improves as shared instruments serve multiple analyses

Essential Instruments (measuring devices):

- Analytical balance
- pH meter

- UV-visible spectrophotometer (double-beam)
- Atomic absorption spectrophotometer
- HPLC with UV and RI detectors
- Gas chromatograph with FID and ECD

Essential Equipment (processing devices):

- Blender, grinder, hammer mill
- Forced-draft and vacuum ovens
- Muffle furnace
- Centrifuge
- Refrigerator and freezer
- Hot plates, heaters, steam and water baths
- Water distillation or deionization unit

Most of these are movable, except large or sensitive units. Fume hoods are typically fixed and essential due to solvent and acid use. Material selection for hoods must consider their specific use (e.g., solvent extraction vs. acid digestion). Locally built hoods coated with epoxy may work for certain purposes.

Utilities

Reliable utility services are fundamental. Unstable utilities can interrupt analysis and damage equipment.

Key utility provisions:

- **Electricity**: Stable supply or voltage stabilizers (centralized or per instrument)
- **Water**:
    - Cold water at all benches
    - Hot water at select sinks
    - Distilled/deionized water distribution in large labs
- **Compressed air**:
    - Required for AAS; should be constant and dedicated to avoid risk of flashback or flame disruption
- **Fume hood fittings**: Water taps, compressed air, electrical sockets, etc.

Design of utility systems:

- Concealed main supply lines (above false ceilings or floor ducts)
- Easy-access points for maintenance
- Drainage: Use chemically resistant piping (e.g., HDPE or copolymer polypropylene)
- Waste management: All effluents should pass through dilution pots/tanks before sewer discharge to prevent contamination

This infrastructure not only ensures smooth daily operation but also aligns with Good Food Laboratory Practices (GFLPs), ensuring accuracy, safety, and sustainability of food analysis operations.

Exercise Questions

1. Explain the role of laboratory personnel, especially analysts, in the design of laboratory infrastructure. How does their involvement benefit the final layout?
2. What are the different zones typically included in a food laboratory, and why should activities like trace analysis and microbiological testing be spatially separated?
3. Describe how improper laboratory layout and infrastructure design can affect test results. What measures can be taken to prevent contamination and ensure accurate results?
4. List and explain the essential utilities required in a food testing laboratory. How do utility failures impact laboratory performance?

Practical 9

Environmental Control, Housekeeping and Safety Features

1. Environmental Control

- Maintain temperature, humidity, and dust control for staff comfort and equipment performance.
- Optical instruments need stable temperature; electronic equipment must operate within specified temperature/humidity ranges.
- Computers should be shielded from magnetic fields (especially important for pacemaker users).
- Some instruments require cooling water from mains or local refrigeration units.
- Store test materials, reagents, and standards under controlled conditions.
- Protect light-sensitive substances from sunlight or fluorescent light.
- Use vibration-free surfaces for balances and optical instruments.
- Document environmental requirements and procedures for monitoring and corrective action**.**
- Keep records of:
    - Sample handling under controlled environments
    - Environmental monitoring results (temperature, humidity, light, airflows)

2. Housekeeping Control

- Clearly define responsibilities of cleaning vs. laboratory staff.
- Maintain cleanliness of:
    - Floors, walls, doors, cupboards
    - Workbenches, shelves, equipment
    - Refrigerators, freezers, fume hoods
- Regular checks for:
    - Condition of stored contents
    - Performance of AC and dust/fume extraction units
    - Pest control
- Include work schedules and logs in the QA program.

3. Safety Features

The building and laboratory design should include a number of safety features including:

1. The fire areas of corridors should be formed of concrete blocks.
2. Services should include a shower sprinkler system near each doorway so that a worker can take an immediate shower, clothes and all, in the case of accidental general contact with corrosive or poisonous liquids or fire.
3. There should be built-in eye wash fountains or at least portable eyewash stations (obtainable from most chemical supply firms).
4. The traffic flow, the egress pattern and the proportions of the laboratory are all safety considerations. It must always be possible to leave the laboratory safely irrespective of the initial site of a fire. Serious thought must be given to the number and location of fire extinguishers and stand pipe systems, and to the availability of sprinkler systems.
5. Laboratories should be well-lit so that the operator does not have to peer too closely over potentially hazardous material in order to see what he is doing. There should be ample working space and bench tops and other surfaces should be kept clear of all material except that in current use.
6. Benches are best without shelves, only services, these being operated from the front so that the operator does not have to stretch across the bench. It is still common to see reagents on shelving at the back of benches (or above the centre of double-width benches) but it is probably safer if such reagents can be kept on side - shelve or in trays which are brought to the bench as required.
7. Flooring needs to be of a non – slip material, resistant to acids and solvents, but not so hard as to be tiring to stand on for a few hours at a time. No material is entirely satisfactory. Well-laid linoleum and a filled epoxy resin on top of concrete are among the best available. It is advisable not to polish laboratory floors.
8. Pollutants generated within the laboratory must be removed safely, quickly and efficiently. In particular, toxic or noxious gases must be removed expeditiously through a duct system that does not exhaust near the building air conditioning intake.
9. The building must be planned for security. Restriction of access is of considerable importance because of the extremely valuable and sensitive equipment used in the laboratory work as well as to protect the integrity of official samples.

10. It is very advisable to have an efficient fire and smoke detection system with appropriate alarms. Common fire detection equipment is usually either rate-of temperature-rise or fixed-temperature detector using a substance of known melting point. There are advantages (and disadvantages) to each type of detector and the laboratory Head should select the one he feels best fits his laboratory.

A safe solvent storage area is ideally separate from the laboratory building in a standalone structure. It can be a small building of one room and some possible design features are: (reasons are given in parenthesis)

1. Construction of cement blocks or bricks. (Only non-flammable materials surround the solvents.)
2. For a stand-alone building, double walls with insulation between. The exterior wall can be material other than block or brick. (Provides insulation from the sun and makes air conditioning more effective.)
3. An epoxy film to cover the entire floor plus 10 cm up the base of the walls. (Any solvent spillage will pool and evaporate, rather than soak through the floors or walls.)
4. A copper pipe (about 25 mm) inside the room, which goes through the floor and is embedded about 2 m in earth. (A ground pipe to bleed off any static electricity charges - which often build up when solvents are poured).All metal objects in the room are to be attached to the pipe using heavy guage single strand copper wire. Also, attach a short wire with an alligator clip. (This grounds all metal. The clip is used to ground any metal cans used for solvent transfer)
5. Storage shelves of metal and connected by wire to each other and the grounding pipe.
6. Air conditioning is external, with the entrance duct at the top of one corner of the room and the exit duct at the base of the opposite corner.(The room must be cooled as many solvents will boil at hot outside temperatures. The air entrance on top and exit on the bottom diagonally across the room will cool the room and will also serve to sweep and remove any solvent fumes on the floor - solvent fumes are generally heavier than air and will pool on the floor.)
7. The door is of metal and fire-rated for at least one hour, with a positive closure. It must seal well when closed. The door sill is at least 10cm high. (Fire doors are metal sheathed around cement. The closure, the sea land the high sill all act to prevent escape of solvent, either floor spillage or fumes.)

8. Air conditioner exits duct with a fire baffle (to prevent flashback) and ducted to exit in the outside air at building roof height. (Fumes have a better chance of being carried away by breezes and someone smoking nearby will not present a fire risk.)

9. An extinguisher system, which should be carbon dioxide or Freon type and not water sprinklers.

Exercise Questions

1. List any four safety features that must be incorporated into laboratory design and explain their significance.
2. What precautions should be taken while storing solvents in a laboratory setting?
3. Mention the role of housekeeping in maintaining Good Laboratory Practices. Who should be responsible for what?

Practical 10

Test methods, Equipment, CRM's and reference cultures

Test Methods:

1. The laboratory shall use only official methods depending on the requirement of the test, its sensitivity and nature of the commodity which is being tested and quality/safety factors to be determined.
2. In case of non-official method, validation of the methods as per set norms is a must and their range of detection/quantification, L.O.D./L.O.Q. limitations etc. must be established.
3. Selection of method is very important depending upon the requirement of the test and customer requirement.
4. Estimation of uncertainty of measurement should be available for each method in context of the food commodity and test to be done.
5. External calibration of the equipment is a must annually or depending upon its use. However in case of any equipment being used very frequently, internal calibration facility should be available and done regularly with a record thereof.
6. Glass apparatus should be calibrated.
7. In case of standard chemicals required in testing, whose purity can alter the result should be certified reference material with proper traceability.
8. In case of recovery and PPM level extraction from a food commodity, percentage recovery must be established for each food and the contaminant/constituent which have to be determined and the calculation should take care of such recovery.
9. Sometimes official methods do not prescribe the interfering material in the test method, limitations ,its sensitivity, range of detection and qualification, capability of the equipments being used, due to change of the sophisticated equipment as prescribed in the method for a particular model/ technology. Hence it is necessary to establish the suitability of such methods for their particular test and equipment, etc before giving the results. Obviously the method needs to be validated internally for its particular use using particular equipment.
10. Standard solution/CRM Solution should be stored at required temperature and condition and its strength should be checked regularly and record thereof should be maintained.
11. Calculation should be done and rounded off while reporting the results to the required level of standard.
12. SOP as far as possible should be available for test method along with the protocol.

13. Method should be available while performing any test to follow exactly the test method prescribed. No short cuts should be followed and tests should not be done on a memory basis alone.
14. Purity of the solvents, water being used and other chemicals should be checked regularly and a record thereof should be maintained.
15. In case of any controversy or marginal results, only reference methods should be used.
16. In case of micro biological analysis standard culture must be available to establish the confirmation of the microbes. SWAB testing must be done for inoculation room and media preparation room regularly to ensure that it is not contaminated.
17. The results should be recorded with the calibration of the glass apparatus etc e.g. in case of a burette, the result should be reported only to the displayed capabilities of the burette.
18. Special precaution should be taken for pipetting and ejecting the solution from the pipette. The solution should not be blown by air through mouth.
19. All the apparatuses specially glass should be contamination free and should be cleaned and rinsed thoroughly before use. No chemicals should be used after its expiry or otherwise if it looks like deteriorated or decomposed.

Equipments

1. All the equipments being used should be under permanent control of the laboratory and should be capable of in context of the test method.
2. The equipment must be calibrated depending upon the requirements by an outside accredited lab and/or internally as the case may be.
3. In case the sophisticated instruments are shifted from one place to another the same should be re-calibrated.
4. Depending upon the uses, the equipments should be internally calibrated either daily or at a periodically interval as the case may be.
5. Instruction manual, operation manual and other details of the equipments like calibration, due date of calibration, safety precaution, etc must be available at the side of the equipment.
6. Each equipment should be uniquely identifiable.
7. The equipment should be placed and test must be performed under a proper environmental condition as prescribed. Normally the room should be dust-free, air conditioned with controlled humidity. Special condition needs to be followed in case of equipment being used in case of micro biological analysis like Air handling unit, etc.

8. Each sophisticated equipment should have IQ, OQ and PQ Certificate from the manufacturer.

9. LOD/LOQ/ Range of detection/ range of quantification must be established for each equipment in context of the test method, nature of the food commodity, constituent to be determined. The reason being that normally in official methods, the model of the equipment being used along with its accessories becomes old whereas due to technological advancement a model of the equipments are upgraded along with accessories and software, hence the LOD, LOQ, etc must be established and should be checked as claimed by the manufacturer which may not commensurate with the limits given in the official methods. SOP must be available for operation.

10. Equipments not working should be placed under a tag "out of order"

11. Software being used in the equipment must be validated and a record thereof should be available.

12. Maintenance plan of the equipment should be available and should be done under annual maintenance contract.

13. Equipments should not be subjected to overloading or mishandling which could give erroneous results.

14. In case the equipment send outside the laboratory for repair, etc. proper procedure of packing and transportation as prescribed by the manufacturer should be followed.

15. Intermediate checks of the equipments must be done through known and certified standards regularly. The equipment should be handled by technically competent and trained personnel only. Such personnel should be trained on routine maintenance and minor repair of the equipments.

16. Proper procedure as prescribed by the manufacturer should be followed for cleaning of the equipments and its accessories before and after use.

17. The SOP for safe handling, transportation, storage, use and plant maintenance of the equipments must be available to ensure proper functioning and to prevent deterioration /contamination.

18. Do and don'ts regarding important instruction should be available along with side of the equipments and should be visible all the time.

19. Due care should be taken to ensure constant voltage supply of electricity as required for the equipment to avoid fluctuation and thus variation in results.

20. After return of the equipment from repair, the same procedure should be followed as that for new equipment to ensure that the results rendered by the equipments are as per capability of the equipment. In such cases the instruments needs to be recalibrated before put to use.
21. Equipments where gases are being used, the purity of the gas should be as per requirement of the equipment/test method.
22. Gas cylinders should be put outside the laboratory room at a well secured and approachable place.
23. Temperature and humidity of the room where the equipments are placed must be recorded daily. In case of micro biological laboratory, special precaution should be taken as per requirement of the test method for environmental conditions especially in case of isolation and determination of pathogens.
24. In case of a mobile food testing laboratory a separate SOP should be available and the equipments used in such laboratory should be technologically sturdy to avoid variation in results. Calibration of such equipment needs to be done very frequently preferable daily before being put to use.
25. Software being used in the equipment should be capable of achieving the accuracy required and should be complied with the specification related to the test method.
26. Software should be upgraded and validated from time to time.
27. Obsolete equipments giving erroneous results in context of the requirement of the test method should not be put to use.
28. The equipment should be placed on a vibration free platform.
29. Daily cleaning of the equipment should be done by trained personnel as per SOP.
30. Proper safety precautions should be taken for equipment running round the clock in the absence of the personnel.

Certified Reference Materials (CRMs), Standards and Reference Culture

Certified Reference Materials (CRMs), standards, and reference cultures play a critical role in ensuring the accuracy, reliability, and traceability of test results in any food testing laboratory. These materials are essential for method validation, calibration of instruments, and ensuring the long-term quality of analytical work. Without them, it is impossible to achieve dependable measurements or maintain standardization across tests.

Reference materials are used to develop and validate methods, calibrate equipment, and monitor lab performance. They are often supplied by recognized international bodies such as NIST, Sigma, Merck, or Supelco, and come with certificates that include important information like the material's purity, expiry date, storage conditions, and chemical composition. These materials should always be stored properly—sealed in vials, away from heat, moisture, and light—to maintain their stability and integrity. Their use and storage conditions should be carefully documented and monitored through quality control procedures.

In laboratories, standard solutions are typically prepared from these reference materials. These include stock, intermediate, and working solutions depending on the need. Solutions should be properly labelled and stored—either at room temperature, in refrigerators, or in freezers depending on the requirements. If the expiry date is not mentioned by the supplier, general shelf-life guidelines are followed (e.g., 5 years for room temperature, 2 years for refrigerated, and 1 year for frozen items). Regular checks and records are essential to ensure the standards are still fit for use.

Similarly, reference cultures are pure microbial strains used to assess the quality of media and kits, or to validate methods in microbiological testing. These strains are obtained from recognized collections like ATCC or MTCC and are traceable to their origin. They are usually received in a lyophilized (freeze-dried) or slant form and are revived in the laboratory under sterile conditions. Once revived, they are checked for purity, typical growth characteristics, and their expected biochemical reactions.

These microbial cultures are sub-cultured periodically to produce working cultures for routine use. They should be clearly labeled and stored properly to avoid contamination or health hazards. Just like CRMs, all reference cultures must be maintained under the supervision of a trained person, and all related records must be kept up to date.

Exercise Questions

1. What is the importance of using certified reference materials (CRMs) in a food testing laboratory?
2. What is the purpose of using reference microbial cultures in food microbiology testing?
3. Why should electronic instruments be operated within specific environmental conditions?

Practical 11

Calibration and performance assessment related requirements, Purchase of consumables/equipment related

To ensure accuracy, reliability, and consistency in analytical results, food laboratories must establish robust calibration and verification protocols for all equipment and instruments. These practices are essential for meeting Good Food Laboratory Practices (GFLPs), maintaining data integrity, and complying with national and international standards.

1. Laboratories must ensure all equipment used is fit for the intended analytical purpose and capable of delivering accurate and valid results.
2. A well-defined schedule should be established for the calibration and performance verification of instruments and equipment that influence test outcomes.
3. Calibration can be conducted internally by trained lab personnel or externally by competent and accredited agencies, depending on equipment type and criticality.
4. Management must classify instruments based on their calibration needs and decide the frequency based on usage, past performance, and criticality.
5. Before hiring external agencies, labs must verify their accreditation status, capability, calibration range, and service reliability to ensure traceability.
6. Instruments like balances should preferably be calibrated onsite, while others may be sent to authorized workshops or service centers.
7. Upon receiving any calibrated instrument, the lab must verify its certificate for conformity with required parameters such as traceability, uncertainty, and due date of next calibration.
8. High-end instruments such as GC, HPLC, LC-MS/MS, UV-VIS, AAS, and ICP-MS should undergo annual performance verification and operational qualification through the OEM or authorized service providers.
9. Environmental monitoring devices like thermometers, humidity meters, and pressure gauges must be regularly calibrated as they directly influence analytical conditions.
10. Equipment such as ovens, incubators, and water baths must be validated for thermal stability, uniformity, and time to equilibrium, with documented monitoring of operating temperatures.
11. Instruments like pH meters, refractometers, and conductivity meters must be verified against standard reference solutions before and during use.

12. Autoclaves must be checked for time, temperature, and pressure parameters, with each cycle monitored and validated using chemical or biological indicators.
13. All balances should be calibrated regularly and checked before each use to ensure precise weighing.
14. Volumetric equipment like pipettes, dispensers, and volumetric flasks must be verified for volume accuracy and precision using certified materials, and where possible, supported by internal checks.
15. Laboratories must maintain comprehensive records for each piece of equipment, including the calibration method (internal/external), frequency, last calibration date, next due date, and performance history.

In order to maintain the reliability of testing outcomes, laboratories must implement a structured system for the procurement and management of consumables, chemicals, reagents, glassware, and equipment to avoid supply-related inconsistencies that may affect the quality of test results.

1. A proper system should be in place for the purchase, service, and supply of laboratory consumables and appliances to ensure reliable and confirmed supply chains that do not compromise analytical performance.
2. All procurement-related details including the name of the item, chemical or appliance, brand name, quantity required, available stock, rate contract or quotations, and responsible personnel must be well-documented.
3. Purchases should follow a structured protocol that accounts for periodic needs (quarterly, half-yearly, annually), consumption patterns, budget estimates, and laboratory protocols.
4. Equipment procurement must be based on actual laboratory requirements considering parameters such as accuracy, sensitivity, sophistication, compatibility with future workload, and latest technological standards.
5. Upon arrival, all purchased items should be verified against the order specifications, including quantity, brand, product code, certificates of analysis, expiry dates, warranty, and the physical condition of the items.
6. Proper documentation and inventory entries must be maintained for all incoming supplies, and all instructions related to storage, handling, and accountability must be followed meticulously.

7. Laboratories must assess whether the quality of consumables and equipment impacts the test results and evaluate accordingly before use.
8. All calibration, service, or maintenance reports from external agencies must be verified and documented to ensure traceability and quality assurance.
9. Supplier and service provider performance must be periodically evaluated, and an approved list with their complete details should be maintained and updated regularly.
10. It is the laboratory's responsibility to establish and follow written procedures and maintain all necessary records related to procurement, quality checks, inventory control, and supplier evaluations.

Exercise Questions

1. List three key considerations while determining the calibration frequency of laboratory instruments.
2. What is the significance of traceability in calibration, and how is it ensured?
3. What details should be included in the approved supplier and service provider list?
4. Mention two factors to consider when selecting laboratory equipment for procurement.

Practical 12

Sampling and sample handling, Biosafety Levels, Quality assurance measures Guidance on Internal Quality Control (QC) measures as well as external QC measures for types of Parameters required to be tested by the food lab

Sampling is the foundational step in any testing or analysis process. It involves selecting a representative portion of a product or material for physical, chemical, or microbiological evaluation. The results of testing heavily depend on the accuracy and appropriateness of the sampling process.

Not all laboratories are required to perform sampling. However, if a laboratory does engage in sampling, it must have a clear policy and trained personnel responsible for the activity. Sampling procedures should be well-documented, statistically sound, and aligned with relevant regulatory or scientific guidelines.

Sampling plans must describe how, where, and when the samples are taken and prepared. Appropriate tools and equipment must be available for this task, and every sampling event must be recorded—documenting the location, time, sampler's identity, sample condition, and transportation details.

When samples arrive at the laboratory, the receiving personnel verify their condition, labeling, transportation mode, and quantity. For microbiological analysis, the sample should arrive in sterile containers. If any issues are observed, clarification is obtained from the client before the sample is accepted for analysis. Once accepted, the sample is assigned a unique identification number and entered into the laboratory register, ensuring traceability throughout its lifecycle.

Samples are stored under controlled conditions based on their physical and chemical nature—dry storage, refrigeration, or freezing. The lab should have documented procedures for sample retention, disposal, and internal use for quality assurance. The integrity and identity of each sample must be maintained from receipt to disposal.

Sample containers must be durable and appropriate for the product. For instance, fatty foods shouldn't be stored in metal containers, and perishable foods must be analyzed within 36

hours or stored under frozen conditions. For microbiological testing, sub-sampling before freezing is advisable to maintain sample integrity.

Every test portion (the analytical sample) must be drawn carefully to ensure it reflects the overall composition. Analysts must confirm the containers are sealed and all records complete before starting analysis.

If a sample is referred to another lab due to the absence of required facilities or workload constraints, this must be clearly stated in the final report, especially if the receiving lab isn't under the same quality system.

After testing, samples must be disposed of properly, particularly hazardous materials like aflatoxin-contaminated samples. Valuable residual materials might be returned to the sender.

To support quality assurance, proper documentation is essential. This includes:

- A sample receipt register
- Sample movement flowcharts
- Records of sample storage and handling
- Test results linked to the unique sample ID

Biosafety Levels (BSLs)

Biosafety Levels are a series of protection measures required in laboratories to handle infectious agents safely. These levels range from BSL-1 to BSL-4**,** with increasing containment requirements. The classification is based on the infectivity, severity of disease, transmissibility**, and** nature of the work being conducted.

BSL-1: Basic Level

- **Agents**: Not known to consistently cause disease in healthy adults (e.g., *E. coli* K-12).
- **Practices**: Standard microbiological practices.
- **Personal Protective Equipment (PPE)**: Lab coats, gloves, eye protection as needed.
- **Facilities**: Open bench work; no special containment equipment.

BSL-2: Moderate Risk

- **Agents**: Associated with human diseases of moderate hazard (e.g., *Salmonella*, *Hepatitis A*, *Influenza*).
- **Practices**: Limited lab access, biohazard signage, proper waste decontamination.
- **PPE**: Gloves, lab coat, face and eye protection.
- **Facilities**: Biosafety cabinets (Class I or II) used for aerosol-generating procedures.

BSL-3: High Risk

- **Agents**: Can cause serious or potentially lethal disease via inhalation (e.g., *Mycobacterium tuberculosis*, SARS-CoV).
- **Practices**: Controlled access, decontamination of all waste and lab clothing.
- **PPE**: Full PPE including respirators if needed.
- **Facilities**: Work conducted in biosafety cabinets; lab under negative air pressure and with sealed windows/doors.

BSL-4: Maximum Containment

- **Agents**: Dangerous/exotic agents with high risk of aerosol-transmitted infections and no known treatment (e.g., Ebola, Marburg viruses).
- **Practices**: Strictest containment, highly trained personnel.
- **PPE**: Full-body, air-supplied, positive pressure suits.
- **Facilities**: Isolated zones, dedicated air supply, effluent decontamination systems.

Quality Assurance Measures

Quality assurance (QA) in laboratories includes all policies and activities that affect the quality and reliability of laboratory outputs.

1. A QA programme ensures that test data are accurate, timely, cost-effective, and suitable for the intended use by following a formal and structured approach.
2. The scope of QA covers the identity and integrity of samples, the competency of staff, suitability and calibration of equipment, and the lab's consistent ability to produce valid results.

3. Essential components of QA in any lab include validated test methods, adherence to standard operating procedures (SOPs), traceable calibrations using certified reference materials, and participation in external proficiency assessments.
4. QA activities must ensure that every staff member knows their role, performs it correctly, and maintains proper documentation to support traceability and accountability.
5. The QA programme consists of three main pillars:
    i. **Prevention** – advanced planning, routine calibration, maintenance, training, and use of certified standards.
    ii. **Assessment** – periodic performance checks, internal audits, and method validation.
    iii. **Correction** – identifying and resolving any issues through troubleshooting, method review, or staff re-training.
6. External proficiency testing allows laboratories to compare their results with others, providing an impartial evaluation of accuracy and performance using inter-laboratory test materials.
7. Internal quality control methods include blank analysis (to detect contamination), duplicate testing (to assess repeatability), and spike analysis (to test recovery and accuracy).
8. External performance evaluations by accredited agencies assess lab operations, infrastructure, personnel competence, equipment quality, and compliance with QA systems.
9. A QA manual is required and should document the organizational structure, QA objectives, operational procedures, documentation practices, internal audits, corrective actions, and performance review strategies.
10. Implementation of QA involves coordinated efforts between lab management, QA units, section leaders, and analysts, where management allocates resources, QA units monitor compliance, and analysts follow protocols.
11. The QA manual should be regularly updated to reflect changes in laboratory workload, technology, or staffing, ensuring continued relevance and effectiveness.
12. Complete documentation is critical and must include registers, audit records, calibration certificates, SOPs, and quality reports to ensure traceability and compliance with quality norms.

Record keeping

1. All relevant information related to the sample materials and the analyses performed must be systematically documented throughout their passage in the laboratory.
2. Documentation should ensure traceability of test materials back to their arrival, including any information they came with.
3. Records must allow for reanalysis under the same conditions and method as originally performed.
4. All records must be retained and protected from misuse, loss, or deterioration for a specified duration, as agreed upon by the laboratory management.

Analyst's Worksheets

1. Worksheets provide a written account of analytical results and must contain all essential information before analysis begins.
2. Worksheets should be initialed by the analyst upon receipt and filled out in permanent ink with legible handwriting.
3. No entries should be erased or overwritten. Corrections must be made by striking through the incorrect entry, adding the correct one above, and including the date and analyst's initials.
4. No data should be discarded without a proper explanation.
5. The exact analytical method used must be referenced. If unpublished, it should be written in full or attached.
6. For duplicate or triplicate tests, all individual and summarized results must be recorded.
7. If multiple analysts are involved, the worksheet must show which analyst performed each part of the analysis and who broke the seal.
8. Any continuation sheets should be numbered clearly (e.g., 1 of 5, 2 of 5).
9. Supervisors or designated persons should check worksheets for completeness, accuracy, and consistency.
10. The worksheet must state the date of submission and reference any modifications made to the method with reasons.
11. All calculations must be clearly shown using proper significant figures.
12. Use of controls and their results should be specified on the worksheet.

Instrument-Generated Records

1. Instrument outputs like chromatograms must be clearly labeled with the test material number, analyst's name, date, and necessary identifiers.
2. All chromatograms (standards, recoveries, samples) must be cross-referenced and stored in order.
3. Full chromatographic conditions should be either stated on the chromatogram or recorded in the analyst's notebook.

Laboratory reports

General

The laboratory report is a summary of worksheet data and must include all details necessary for customer understanding and use of the results.

Typical Format of Laboratory Report

1. Name and address of the laboratory
2. Name and address of the customer
3. Certificate or report number
4. Page identification (e.g., Page 1 of 3)
5. Details of sample receipt (dates, names of deliverer and receiver)
6. Clear identification of sample or test material (description, lab number)
7. Description of analysis performed, methods used, and any deviations
8. Preparation steps and portion taken for testing
9. Test results and measurement uncertainty
10. Relevant comments on findings if needed
11. Date of report
12. Authorizing signature

Retention of Laboratory Records

1. All documentation must be maintained in a continuous, traceable sequence to ensure a clear history of the test material.

2. Records such as sample registers, worksheets, reports, and related documents must be retained for a defined period, agreed upon with the customer.
3. Records must be protected from fraud, tampering, fire, flood, and loss, with electronic backups renewed regularly.
4. Withdrawal and return of stored records must be logged with dates and signatures.

Documentation for QA Programme

1. Analyst worksheets
2. Laboratory reports
3. Procedures for result verification
4. Authorization protocols for reports
5. Document retention timelines
6. Procedures for archiving and disposal

Sources for Biological Reference Material in India

1. IMTECH, Chandigarh – www.imtech.res.in
2. National Chemical Laboratory, Pune – www.ncl-india.org
3. Christian Medical College, Vellore – www.cmch-vellore.edu
4. Central Research Institute, Kasauli – http://mohfw.nic.in
5. National Institute of Communicable Diseases, Delhi – www.nicd.ac.za

Exercise Questions

1. What are the key principles to be followed during sampling and sample handling to ensure the integrity and traceability of test materials in a laboratory?
2. Define a Quality Assurance (QA) Programme in a food laboratory and explain its major components that ensure reliable and accurate test results.
3. Differentiate between Biosafety Level-1 and Biosafety Level-3 laboratories in terms of containment practices, risk group of organisms handled, and protective measures required.
4. Why is it essential to maintain a continuous and traceable record of test materials throughout their passage in the laboratory? Explain with an example

Practical 13

Standard operating procedures and documentation, Handling of spillage.

Standard Operating Procedures (SOP):

1. Standard Operating Procedures are written procedures for different activities and are integral part of Good laboratory Practices.
2. Testing laboratories shall have Standard Operating Procedure manuals and have its periodic review.
3. It shall be user friendly documents and shall include designation of the person responsible for intended activity.

Raw data:

1. Raw data refers to the laboratory work sheet, analysis sheet, records, and other activities and such raw data shall include hand written notes, photographs, software, drawings, computer printouts, spectral charts etc.
2. A single line shall strike through the data being changed; the correct information shall be recorded along with the old data and the reason of change. The analyst making the change shall be identified by his signature with date. In case of automated data collection system, the person responsible shall be identified at the time of data output. The original entry must be saved and the system have audit trial for all the data.
3. Raw data refers to the laboratory work sheet, analysis sheet, records, and other activities
4. Data integrity and security shall be maintained and the data shall not be accessible to any unauthorized person.

Training:

1. Training shall be regularly conducted by qualified individuals and shall cover, at a minimum, the particular operations that the employee performs and GMP as it relates to the employee's functions. GLP / GMP ultimately depend on people. Training shall be given on both the theory and practice of the work being undertaken in a particular area, as well as relevant 'on-job' (i.e. task-based) training.

2. Records of training must be maintained. Training shall be periodically accessed. All staff, including new and existing shall be given basic training on 'Good Laboratory Practices' during induction and at regular intervals subsequently. These training programs shall be periodically updated. In addition during training, emphasis shall be laid on regulatory requirements, health, safety and hygiene.

Documentation:

1. Clearly written documentation prevents errors may occur in verbal communication.
2. Specifications, instructions, procedures and records must be free from errors and available in writing. Standard operating procedures should be available for sampling, inspection and testing of raw materials, API's, intermediates, bulk finished products, finished products, stability samples, packaging materials and whenever necessary.
3. Documents should be approved, signed and dated by appropriate and authorized persons.
4. On receipt of certificates from outside location / organization (such as. Working standard certificate, approval External party calibration certificate, certificate of analysis of raw material received from supplier etc.) the same should be reviewed and verified by the quality control personal with sign.

Sample, solid chemical and broken glassware Spillages

1. Clean the Spillages of analytical samples (such as Tablets, Capsules, Raw material) solid chemicals and broken glassware by using suitable broom or wet mop cloth. (Broken glassware and their particles shall be collected carefully, do not collect the particles directly with bare hands).
2. Collect the particles/samples in specified container.
3. Clean the place by wet moping followed by dry moping.

Solvent and hazardous chemicals Spillages:

1. In case of any spillages of solvent or hazardous chemicals below method shall be used.
2. For Hazardous chemical first neutralized it by using 0.1 N sodium hydroxide/ diluted hydrochloric acid.

3. If the chemical having strong odour such as ammonia or acetic acid then used flavored solved such as detol or sevlon to mask the odour.
4. Clean the spillages of solvent by dry moping.
5. In case of solvent spillages is near about hot zone area, switch off the instrument nearby to avoid any accident.
6. While handling these spillages always use personal _PPE (Gloves, Mask, apron and safety shoes).
7. Wash the area with plenty of water.
8. Clean the water with dry moping.

Water Spillages: Always use dry mop to clean water spillages.

'Do's inside the QC laboratory:

1. The use of correct and current specifications and STP. 18.2 Timely recording of raw data in the issued work sheets as well in log books.
2. Checking of the instrument calibration validity before used.
3. Data is written with proper cross reference, wherever required.
4. Immediate reporting of the Out of specification results, out of trend results, or any abnormalities observed to the superior.
5. Use of clean and dry glassware for analysis.
6. Label the glassware with minimum details like Product name, batch number, test name, dilutions (if any) and analyst sign and date for identification and tractability. For small glassware labeled as much as possible details.
7. Use of fume hood for odour/fume releasing materials.
8. Handling of hazardous materials as per Standard operating procedure (SOP).
9. Rectification of writing errors – cross out with signature and date.
10. Use _personal protective equipment wherever possible.
11. Adjust the level up to the mark means "Make up the level with liquid up to lower meniscus for colorless solutions and upper meniscus for colored solution.
12. Fill the HPLC vial up-to 80 % of its capacity.
13. Use amber color glassware including HPLC vials for analysis as per requirement.
14. Keep vials into respective system as soon as possible after filling vials with solutions. Precaution to be taken during related substance/degradation product analysis: Use

designated or separate place (as possible) to avoid contamination. Also ensure the cleanness of glassware, analyst hand/gloves etc. before analysis.

15. Rinse the vials with sample solution to be filled for 5 times before vial filling and glassware with diluent before analysis.
16. Store all the remaining preparations as recommended in standard test procedure till completion of analysis.

'Dont's inside the QC laboratory:

1. Use of loose paper sheets for writing the observations.
2. Blowing of pipettes by mouth.
3. Use of broken glassware for analysis.
4. Use of eraser or white ink.

Exercise Questions

1. What do you learn from this subject "Good Laboratory Practices (GLP)"?
2. Explain the importance of Standard Operating Procedures (SOPs) in maintaining Good Laboratory Practices.
3. Describe the proper steps to be followed in case of a chemical spillage in the laboratory.
4. What is the significance of maintaining proper documentation in a laboratory? What are the key elements that should be recorded?

References

1. OECD. (2021). *OECD Principles on Good Laboratory Practice (GLP)*. Organisation for Economic Co-operation and Development. Retrieved from https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm
2. WHO. (2009). *WHO Good Laboratory Practice (GLP) Guidelines for Quality Control Laboratories*. World Health Organization, Technical Report Series, No. 957, Annex 1. Retrieved from https://www.who.int/publications
3. Chatwal, G. R., & Anand, S. K. (2010). *Instrumental Methods of Chemical Analysis* (5th ed.). Himalaya Publishing House. (Chapter: Laboratory Safety and Good Laboratory Practices)
4. Indian Pharmacopoeia Commission. (2018). *Good Laboratory Practices (GLP) Manual for Quality Control Laboratories*. Ministry of Health & Family Welfare, Government of India.
5. U.S. Food and Drug Administration (FDA). (2022). *Good Laboratory Practice Regulations*. Retrieved from https://www.fda.gov
6. Singh, S., & Rajput, D. S. (2021). Good Laboratory Practices in Food Testing: A Regulatory Overview. *Journal of Food Quality and Hazards Control*, **8**(3), 115–120. https://doi.org/10.18502/jfqhc.8.3.7146
7. Sharma, B. K. (2016). *Industrial Chemistry* (Goel Publishing House). (Chapter: Laboratory Practices and Safety Measures)
8. Kapoor, A., & Sharma, R. (2020). Implementation of Good Laboratory Practices in Academic Institutions. *International Journal of Research and Analytical Reviews (IJRAR)*, **7**(2), 410–417.
9. International Organization for Standardization. (2017). *ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories*. Retrieved from https://www.iso.org/standard/66912.html
10. National Accreditation Board for Testing and Calibration Laboratories (NABL). (2020). *NABL 112: Guidelines for Good Laboratory Practices*. Retrieved from https://nabl-india.org
11. Kumar, P., & Goyal, S. (2019). Importance of GLP in Scientific Research. In: Awasthi, V. (Ed.), *Recent Advances in Scientific Research* (pp. 189–202). Scientific Publishers.