

GUIDANCE DOCUMENT FOR SETTING UP OF A REGULATORY FOOD ANALYSIS LABORATORY

Abstract

This is a resource document intended to help in the setting up a Food Analysis laboratory for regulatory purposes. Discussed is a step-by-step process to guide the laboratory management team through the early planning and design phases when establishing a Food Control Laboratory. It is important to note that these guidelines must be considered during the design process, as they can directly influence how the laboratory will be designed. The guidelines are formatted to address issues pertinent to laboratories that test for regulatory compliance viz planning the laboratory building and layout, security, choosing and hiring suitable staff, equipment requirement and appropriate environmental conditions, laboratory safety design and waste disposal measures. The document is not “all inclusive. It does not cover all design situations and building design.

Food Safety and Standard Authority of India

www.fssai.gov.in

Table of Contents

1 Introduction	2
2 Scope and Objectives	3
3 Setting up a Regulatory Food Analysis Laboratory	4
3.1 The analytical process for regulatory compliance	4
3.2 Laboratory Organisation	5
3.2.1 The Head/Director of the Laboratory	5
3.2.2 Analytical staff	6
3.2.3 Administrative Staff	7
3.2.4 Support Staff	7
3.3 Manpower requirements for a regulatory Food Analysis Laboratory	8
3.4 Quality Control Section (optional)	9
4 Laboratory Building Requirements and Design	
4.1 General requirements	9
4.2.1 Laboratory Layout	10
4.2.2 Microbiology Laboratory	20
4.2.3 Administration or office area	22
4.2.4 Chemical and Supplies	22
4.2.5 Overall Space Utilization Guidelines	23
4.2.6 Security	23
4.2.7 Laboratory Signages	24
4.2.8 Corridors and aisles	24
4.2.9 Exits/Doors and Windows	25
4.2.10 Flooring	25
4.2.11 Walls and ceiling	25
4.2.12 Sinks	26
4.3 Storage	
4.3.1 Chemical Storage in the Laboratory/Bulk storage	26
4.3.2 Gas Cylinder Storage and Gas Lines	28
4.4 Laboratory and Personnel Safety	
4.4.1 Safety Equipment	28
4.4.2 Safety design in labs	28
4.4.3 Electrical Services and Safety	29
4.5 Lab Furniture	
4.5.1. Work Tables	30
4.6 Waste Disposal	31
4.6.1 Chemical Waste	31
4.6.2 Biological Waste (Microbiology Lab)	32
Annexure 1 List of General Laboratory Equipment	34
Annexure 2 List of Sophisticated Equipment	35
Annexure 3 Equipment list for Microbiology Lab	37
Annexure 4 List of glassware and general apparatus for start-up	38
Annexure 5 List of Chemicals for start-up	40
Annexure 6 List of Media for Microbiology	42

1.0 Introduction

Food safety issues and the enhancement of health security are of growing national and international concern. Key global food safety concerns include spread of microbiological hazards, chemical food contaminants, assessment of rapidly changing technologies in food production, processing and marketing. Increasing scientific understanding of the adverse consequences of unsafe food, amplified by the rapid global transmission of information has heightened consumer awareness about food safety risks to new levels. Microbiological hazards, contaminants in the form of pesticides and heavy metals and economically motivated adulterants (substitution of cheaper raw materials or look alike) are a major food safety concern all over the world.

The Indian food consumption basket has diversified from cereals towards higher value and more perishable products, such as fruits and vegetables, dairy, meat and fish. Higher disposable incomes to spend on non-home cooked foods and increased women in the workforce are the key drivers for the demand of ready to eat, ready to cook and semi-prepared foods, and as a result the growth of the processed food industries. These trends bring increased attention to safety concerns in the handling, processing and packaging of foods. Increasing international trade has expanded food safety into a global business. Such movements will continue to drive the market for high-quality lab testing National standards for both domestic and export trade lay down parameters for pesticide residues, antibiotic and veterinary residues, heavy metals, mycotoxins, pathogens, and other contaminants. Therefore, a food analytical laboratory is a critical and integral part of the supply of safe and quality food. It is the silent 'expert system' ensuring that the customer gets the safe and quality food he or she is expecting.

1.1 Food Testing Laboratories

Food testing laboratories, deploying a comprehensive range of state-of-the-art analytical techniques are a necessary and vital arm of a responsible, responsive food regulatory system, important for robust implementation and enforcement. These laboratories with adequate infrastructure, facilities, equipment, supplies, reference materials, access to calibration and maintenance, and operating under an international quality assurance programme, are benchmarks that support the increasingly stringent quality and safety standards. An adequate number of food analysts with suitable qualifications, training, experience and integrity; management and support staff form the heart of a testing laboratory. Formal accreditation, operation of effective internal quality control procedures together with participation in laboratory proficiency testing (PT) schemes are key elements in ensuring the quality of results generated by analytical laboratories. Food testing laboratories that meet recognized best practices of analytical competency will allow FSSA(I) the regulatory agency to more expeditiously utilize laboratory data to identify, prevent and remove unsafe food products from the market shelf.

The types of analyses can be divided or categorized as shown in Figure 1

<p>General Parameters</p> <p>Moisture Total Ash, Acid Insoluble Ash Water Soluble /Insoluble Ash Alkalinity of Ash Acidity, Total soluble solids, Total volatile extracts</p>	<p>Nutritional Evaluation</p> <p>Fat, Protein, Crude fibre, Dietary Fibre Carbohydrates) Calories, Fatty acid (MUFA, PUFA) Cholesterol, Amino acid composition Vitamins Minerals</p>
<p>Food additives & Contaminants</p> <p>Colors Antioxidants Preservatives Artificial sweeteners Pesticide residues analysis Heavy metals Drug and antibiotic residues Mycotoxin analysis Food adulterant</p>	<p>Microbiology</p> <p>Total Plate Count, Coliform count, Aerobic spore count Anaerobic spore count Yeasts and mold count. <i>E. coli</i>, <i>Salmonella spp.</i>, <i>Shigella Spp</i>, <i>Vibrio cholera</i>, <i>Vibrio parahaemolyticus</i>, <i>S. aureus</i>, <i>Listeria monocytogenes</i>, <i>Clostridium botulinum</i>,</p>

Figure 1 Types of analysis in a Laboratory for Food Analysis

The types of analyses will determine the investment and space needed. Proximate analyses are used for characterization for general nutritional parameters, and the capacity to perform these analyses should be seen as the minimum requirement for every laboratory. Other types of analysis (contaminants, drug residues authenticity etc) are more specialized and need specific high-end equipment and facilities. Consequently, these analyses require highly skilled personnel with deep knowledge and sensitive and expensive equipment, but also demand superior working environment to avoid contamination.

The high-quality demands in reference /state food testing laboratories therefore, require large investment in personnel, equipment and infrastructural facilities and guarantee the independence of the laboratory and avoid conflict with commercial interests.

2.0 Scope and Objectives

Currently in India, there exist neither a comprehensive set of legislation nor standards related to laboratory design, organisation, number of personnel for a regulatory. Unlike the US, UK and

Australia where laboratory designs are based on their relevant local standards. The guidelines describe below take into cognisance relevant international standards that are applicable to the scenario in India as direct adoption of the common international standards may not be possible. Shortage of space and manpower, are among the crucial factors that may call for variation from common international standards. The objective is to provide a consistent and harmonized reference across food testing laboratories to progressively raise the quality of testing and safety standards of laboratories in India.

3.0 Setting up a Regulatory Food Analysis Laboratory

The setting up and physical realization of a new laboratory involves: •

- a. Selection, identifying building facilities and construction if required for various analyses
- b. Developing an organizational structure and assigning responsibilities
- c. Selection of analyses to be performed
- d. Selection and purchase of equipment/chemicals
- e. Appointment and maintaining qualified analysts/technicians/skilled and unskilled staff
- f. Establishing standard operational and working procedures.
- g. Establishing a Quality Assurance programme such as ISO 17025:2005

All of these issues are related to the analytical work, and more specifically to the methods, that the laboratory intends to conduct. The choice of methods is therefore a critical step. Therefore, an overview of the analytical process and available methods, followed by their implications for construction or selection of buildings and facilities, purchase of equipment and putting in place an organizational structure with defined responsibilities for the personnel are presented.

3.1 The analytical process for regulatory compliance

The foundation of a regulatory laboratory is the analytical process which ensures that procedures and protocols are followed to consistently meet the rigor and high standards of regulatory compliance and international Quality Assurance requirements.

The various stages of the analytical process are shown in Figure 2. This process starts with the receipt of samples from the Food safety officer (FSO)/Designated Officer (DO) with a request for the analyses. On receipt of the samples security and appropriate storage is initiated followed by, sample preparation and analyses. The results of these tests are collated, verified and following approval from an authorized person, a final report, is dispatched to the FSO/DO. It is important to ensure that the accountability, security, integrity and chain of custody of the sample is met. The laboratory must ensure the legal defensibility of analytical data produced by the laboratory. Responsibility for all these details should be clearly defined. Sample materials are stored in the laboratory for a fixed time, e.g. one month, from completion of analyses and either discarded or destroyed

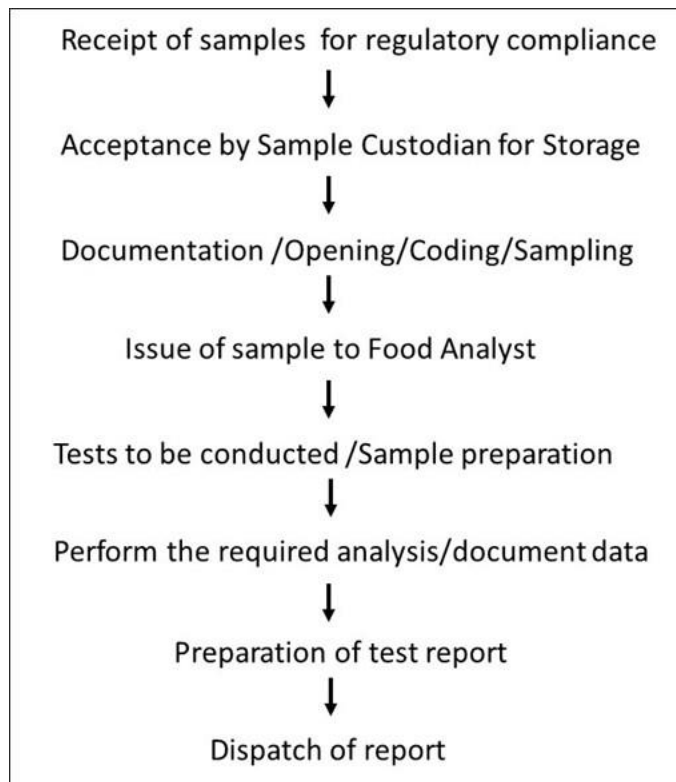
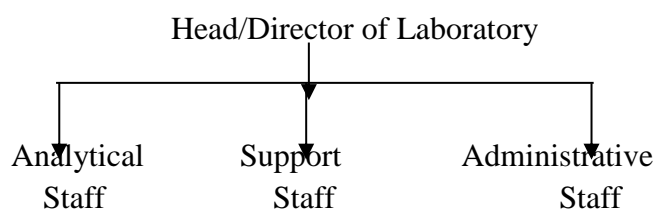


Figure 2 The various stages of an analytical process

3.2 Laboratory Organisation

A skeleton structure for the Organisation of a typical regulatory food analysis laboratory is as follows:



3.2.1 The Head/Director of the Laboratory should preferably be a Ph. D in Science (Chemistry/Biochemistry/Food Science or related subjects) with hands on experience of 5-10 years in food analysis. He should dynamic with strong communication and interpersonal skills, be able to solve analytical problems and should be well versed in the with analytical procedures, instrumentation and quality assurance. He should ensure proper laboratory safety and house-keeping practices are adhered to; should review the reports of completed work. He/she should ensure that the lab has supply of necessary chemicals and instrumentation. A key role of this position is to ensure data produced is reliable and data is thoroughly checked prior to releasing

reports and undertake the full responsibility for results reported. The Head is the spokesman for the laboratory and should have minimum 10 years of experience in Food Testing and Quality Management Systems with thorough and deep knowledge and understanding of FSSA(I), FSS Rules and Regulations (2011) and other national and international rules and regulations. It is expected that he/she will be a FSSA(I) certified Food Analyst.

Technical Lead/Supervisor: Each analytical section should be headed by Technical Lead/supervisor, who is the in-section manager. Having a technical lead / supervisor assigned to specific units or areas of work permits the Laboratory Head to effectively execute the total workload of the laboratory. He/she is responsible for the daily organization of the analytical process, ensuring that daily and weekly deadlines for test results are met; quality control for each batch of testing meets requirements and is recorded; staff training is up-to-date; and that there are sufficient staff to meet the workload requirements. Ensuring that proper laboratory safety and housekeeping practices are followed by the group. Recommending to the Head new instruments or equipment needed. He or she must be capable of answering questions and assisting in solving analytical problems posed by individual analysts. Maintaining stocks of the necessary chemicals and consumables are also the responsibility of the senior technician, who should inform the Laboratory Manager in sufficient time to enable ordering and delivery prior to stocks running low. Qualifications could be commensurate with a Senior Analyst with a minimum of 5 years' experience in the respective testing area. It is expected that he/she will be a FSSA(I) certified Food Analyst.

3.2.2 Analytical staff: Analytical personnel are the heart of every laboratory. They have to be reliable, precise, competent and motivated. The personnel required to perform the analyses in a food analysis laboratory can be divided into:

Technical assistant with basic analytical skills. The education required is high school graduation (10+2) having studied chemistry /biology to carry out certain routine laboratory tasks. They can be trained in tasks such sample grinding, sieving mixing, subsampling/media preparation/autoclaving etc. Familiarity with the use of weighing balances, pH meter, making reagents with an attention to detail such as chemical names, expiry date, purity of the chemical etc.

Junior Analyst with medium analytical skills. The education required is a post graduate (Master Degree in Chemistry/Biochemistry/Analytical Chemistry/Food Science/Food Technology and related subjects. Post graduates who are FSSA(I) certified Food analysts are preferred. The analyst should have deep knowledge of basic chemical reactions and the principle of the method used; be aware of laboratory safety when working with solvents and strong acids and bases; computer competency; use and handling of gas cylinders; spectrophotometer; use of manual and use of specific equipment for proximate analysis vis ash, fiber, Soxhlet fat extraction; Kjeldhal protein estimation, gravimetric analysis, thin layer chromatography, paper chromatography, titration, qualitative tests for food adulterants and bomb calorimeter. Laboratory experience is essential. Alternately a graduate in chemistry or microbiology with three to five years of experience in food analysis may also be taken as analysts and can be trained in sample preparation and other analyses as described above.

Junior analysts(s) are responsible for performing analytical work following Standard Operating Procedures (SOPs), under the direction of the Technical Lead or Senior Analyst

Senior analysts with high analytical skills. The education required is a post graduate (Master Degree in Chemistry/Biochemistry/Analytical Chemistry/Food Science/Food Technology and related subjects. A Ph. D is preferable with laboratory experience and Specialized training in analytical methods using, i.e. High-Performance Liquid Chromatography (HPLC/UPHPLC) Gas Chromatography (GC, GC-MS); Gas Chromatography-Mass Spectrometry (GC-MS/MS); Liquid Chromatography-Mass Spectrometry (LC-MS/MS); and Inductively coupled plasma atomic emission spectroscopy (ICP-AES, ICP-MS); associated software programs; able to maintain and troubleshoot required instrumentation. Microbiological testing should be performed and supervised by an experienced person, qualified in microbiology or equivalent. The Senior analyst should possess the ability to optimize methods, develop Standard operational procedures (SOPs), make independent decisions regarding peak identification and its area. Awareness of all laboratory safety requirements, use of safety equipment when working with toxic and carcinogenic compounds. Laboratory experience is essential, along with relevant University or recognized technical qualifications. Analysts should have preferably cleared FSSA(I) Food Analysts exam.

3.2.3 Administrative Staff:

The administrative staff includes all administrative assistance such as a General administration, Finance & Accounts, Stores and Purchase, secretary, typing and filing clerks etc. These staff are generally involved in "office" or "paperwork" functions such looking after the office, finance and purchase/ stores procedures and maintaining the records of samples, preparation of test reports, maintenance of accounts, etc. and general welfare of the employees and very important to the smooth operation of a laboratory. Lack of sufficient staff in the administrative group often results in being done by the analytical staff. The secretary for the laboratory generally works directly for the Head. Qualification: Any recognized Bachelor's degree with computer knowledge and use of software relevant software, tender preparation, LIMS, TALLY etc and experience commensurate to the field

3.2.4 Support Staff

Operational Head Instrumentation: is responsible for the upkeep and optimal functioning specific equipment and operating methods, especially trouble-shooting, maintenance and solving problems, as well as continuing training of junior staff when required. Training records for staff should be regularly maintained.

Technician for instrument and general maintenance shall have diploma in electronics or electrical or instrumentation with two years of experience in the operation and maintenance of state-of -the-art equipment. Alternatively, a graduate in instrumentation engineering may also be taken.

Laboratory attendants: are all of those persons working in and for the laboratory who are not conducting analyses or are not involved in administrative duties. Usually with no educational qualifications but must be able to read and write with ability to help the food analyst/chemist in the glassware washing, cleaning & housekeeping, disposal of sample reserves (when no longer

required), pest control and other laboratory activities. It is most important that sufficient persons are hired as support. 15-20% of the total number of analytical staff or one per lab is often sufficient.

3.3 Manpower requirements for a regulatory Food Analysis Laboratory (indicative list).

The number of personnel and their educational and experience levels depends on the analyses to be offered, the methods chosen and the expected sample throughput. The analysis of enforcement and surveillance food samples can be carried out analytical parameter wise (Figure 1) or product wise to meet compliance. In either case microbiological, heavy metals and pesticide/antibiotic residue analysis need specialised independent facilities and personnel with high analytical skills.

A detailed typical organisational structure is shown in Figure 3

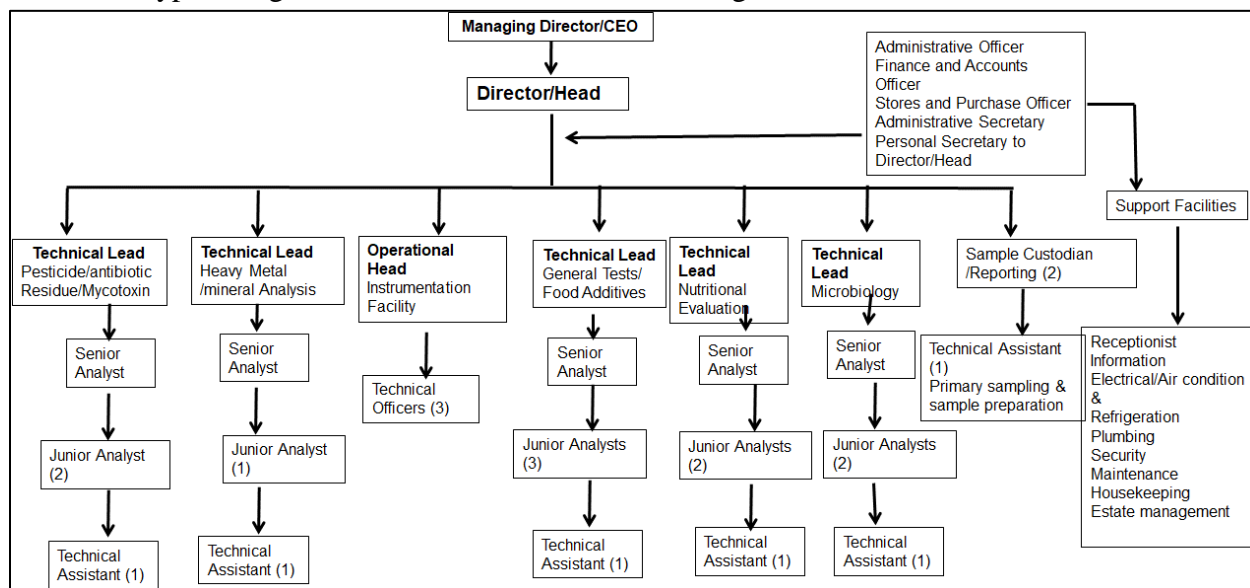


Figure 3 A typical organisation chart for a food analysis laboratory. The required numbers are shown within parenthesis.

The indicative list to carry out all the analysis of all the food categories under FSS Rules and Regulations 2011 is:

Head	1
Technical Lead	5
Operational head (Instrumentation)	1
Senior Analysts	5
Junior Analysts	10
Technical Assistants	6
Sample custodian	1
Report preparation, dispatch and maintenance of records	1
Administrative staff –	
a. Administrative Officer	1
b. Finance and Accounts Officer	1

c.	Stores and Purchase Officer	1
d.	Administrative Assistants	3
e.	Personal Secretary to Director/Head	1
Support staff- 10		
i)	Office Attendant	2
ii)	Lab Attendants –	8

3.4 Quality Control Section (optional)

The goal of the food analysis laboratory is to guarantee the generation of accurate and reliable analytical results. Having a quality control section, which is optional minimizes reporting of erroneous results, prevents excessive repetition of analytical runs. These procedures are designed Quality control is designed to detect deficiencies in a laboratory's internal analytical process and to make certain that samples are representative and data are reliable and defensible prior to the release of results. Quality control samples are samples taken at random and the testing process carried by analysts in the QC division using the same method and operating conditions. The purpose of including analysis of samples by the QC division is to evaluate the reliability of lab results. The analysts of the QC division play an important part in assuring the quality of laboratory tests. The manpower required is one senior analyst, two junior analysts and one technical assistant

4 Laboratory Building Requirements and Design

4.1 General requirements

The laboratory should be located in an area with some basic requirements, including good infrastructure good access (road system) with assured water and uninterrupted power supply. The use of chemicals and other potentially hazardous compounds separates a laboratory from other types of building spaces. Primarily the laboratory must provide a safe and healthy working environment which complies with current thinking on comfort, energy efficiency, energy conservation and impact on the environment. It should be adequately equipped with essential services and utilities, good ventilation with fume extraction where needed, adequate lighting, safety systems such as fire control measures, secure and protected storage for records, including computer back-ups and water and gas supplies. The regulatory laboratory should be secure to provide for confidentiality and be accessed only by authorised personnel. Adequate arrangements for different types of testing must be addressed by a combination of management practices and physical segregation. All health and safety hazards must be identified and carefully evaluated so that protective measures can be incorporated into the design.

The laboratory is most commonly created either by refurbishment of an existing building or by construction of a new laboratory building, the preferred option. The design should also be left as flexible as possible so that changes of emphasis in the work can be accommodated. For either building option, advice from an architectural expert specializing in laboratory design will be invaluable, especially with respect to compliance to all the relevant local building legislation and codes and safety requirements.

4.2 Laboratory building and facilities

4.2.1 Laboratory Layout

The laboratory is generally designed on the basis of the analysis to be carried out and the methods to be used, keeping in mind future analytical requirements and expansions. Laboratories must have separate zones/rooms, depending on types of analysis and functionality. The separation of laboratory space to perform the various activities is primarily required to avoid cross-contamination with undesirable substances and to maximize the use of space.

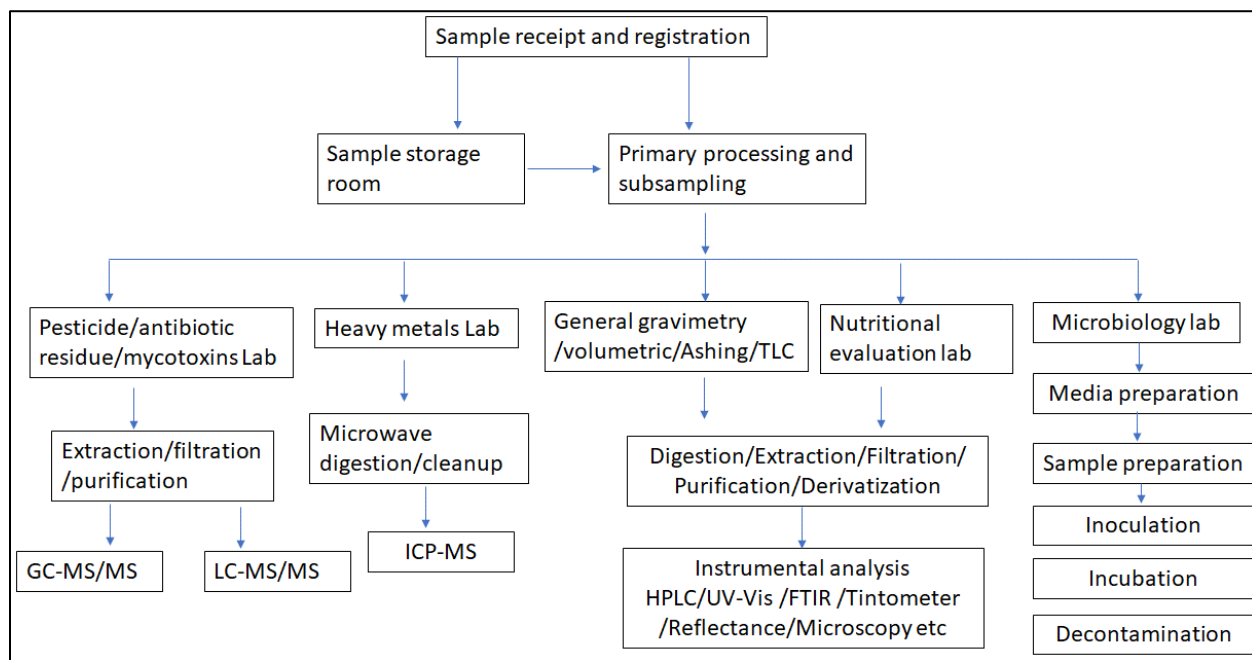


Figure 4: Schematic of laboratory sections of a food analysis laboratory

Such demarcation would include but not limited to: sample receipt and storage are conducted in designated areas, wet chemistry laboratories are separated from microbiology laboratories, separate storage for standards and reference materials and cultures, and media preparation and sterilization in microbiology labs are separated from work areas. Primary sample preparation involves grinding, sieving, which produces dust and noise, and should be physically separated from other activities. Gravimetric analysis involves weighing, drying and incineration are mostly linked to each other and do not involve working with chemicals. Traditional wet chemistry labs and sample preparation for contaminants/mycotoxins using high end equipment are physically separated to avoid cross contamination. Mixing of flammable solvents and corrosive chemicals is a chemical hazard and are carried out in separate sections e.g. microwave digestion with acids prior to ICP-MS and extraction of pesticides with organic solvent and clean-up prior to LC-MS/MS. Sensitive instruments such as the LC-MS/MS, GC-MS/MS, ICP-MS, HPLC, amino acid analyser etc are placed in a clean environment in separated from each other, away from other activities. If mycotoxins are to be analysed there will be a requirement for a biological safety cabinet to be available in the laboratory. The layout for a microbiology laboratory involves a

unidirectional flow of evens with suitable air handling units. The restrooms and rooms where food and beverage are consumed should not be in close proximity to the Microbiology lab. Figure 4 shows a schematic presentation of different sections of a food analysis laboratory. For maximum efficiency, after the samples have been registered and the analyses assigned to technical staff, laboratory activities should be separated into different sections, each with different requirements as elaborated below

Sample receipt and registration. An area convenient for couriers/postman to deliver samples. Most often room is at the entrance of the laboratory. Sample should be received through a large window and all communications carried out through this route. Here the samples are logged into a booking system which is either manually in a register or using LIMS or related software. The sample is given a unique identification number by the laboratory. The requested analyses by the FSO is logged in the sample register. The sample parcel is opened under CCTV surveillance. All information about the sample package including number of seals, packing material etc is recorded and then passed on to the primary sample processing and subsampling section. If the analysis cannot be the sample is held in storage under appropriate conditions.

Area:	ca 50 m ² with Large window with Access control for authorised personnel
Equipment and related items:	Computer Printer CCTV surveillance
Furniture	Office tables and including chairs Storage facilities
Safety	Fire extinguisher Hand washing facility First aid kit Waste disposal containers

Sample storage room: Storage of the sample must not alter it in any significant way – whether through contamination, loss, deterioration or other means. Physical security of sample prevents intentional adulteration and alteration of the sample. Hence entry to the storage area should be restricted to authorised personnel. Maintenance of proper storage temperatures is required to maintain the integrity of the sample/analyte to analysed. The room is under CCTV surveillance.

Area	ca 50 sq m with Access control for authorised personnel Air-conditioned Temperature 20± 2 °C RH 50-70%
Equipment and related items	Frost free refrigerator Upright freezer (-20 to – 25 °C) CCTV surveillance
Furniture and related items	Storage possibilities such as shelves and cupboards for sample material
Safety	Fire extinguisher

Waste disposal containers

Primary sample processing and subsampling preparation: Subsampling and analytical sample are prepared by grinding the laboratory sample. Homogeneity of samples are achieved with grinding mills, homogenizers, coffee grinders, or a suitable equivalent device, depending on the size and the structure of the laboratory sample. In the case where the laboratory sample is flour or liquid, homogenization is not needed but mixing or shaking is still necessary. An independent room connected to Sample receipt room where sub-sampling, blending, grinding and, if necessary, pre-drying can be performed. and if necessary an air extraction unit can be utilized to remove odour as well as excess heat. Grinding will produce noise and dust therefore masks required

Area	ca 50 sq m
Equipment and related items	Grinding mill/Waring Blender with jars and sieves Brushes for cleaning sieves and grinder Cubicles connected to a ventilation system for grinding Refrigerator Upright freezer Sample splitter Drying oven Network connection or Computer and accessories
Furniture and related items	Work table/bench, chairs
Safety items	Dust masks Safety glasses and ear protection Eyewash Hand washing facilities First aid kit Waste disposal containers

Wet Chemistry Laboratories: Digestion, filtration, distillation, titration, extraction, derivatization and dilution are all unit operations in a typical food analysis laboratory. Independent laboratory rooms can be provided for independent activities as shown in Figure 4. In each laboratory keep a separate area for acid use and storage. These areas require access to water and should be close to glassware supplies, balances, fume hoods and chemical supplies. Keep a separate area for solvent use and storage. This area requires access to water and should be close to glassware supplies, balances, fume hood and chemical supplies. Laboratory space must be arranged for maximum utilization as well as proper work flow. It is usual to allow about 10 square meters of laboratory space and 3 meters of bench surface per analyst.

Room 1 Proximate and General analysis

Area	ca 60 sq m
*Equipment and related items	Weighing balance (0.1 and 0.001 g) Soxhlet Extraction

	Kjeldhal digestion and titration
	Auto titrators
	Muffle Furnace
	Hot air ovens (110-130 C)
	Refrigerator
	Water bath
	Hotplates
	Freezer
	Fume hoods connected to an exhaust system
	Water and gas supply
	Vacuum facilities
	Network connection or Computer and accessories
Furniture and related items	Work table/bench, chairs
	Safety cabinets for storage of chemical solutions (acids & bases, solvents to be stored separately) and chemicals
	Glassware, including beakers, crucibles, dispensers, pipettes and measuring cylinders
Safety items	Lab coats
	Gloves
	Safety glasses
	Eyewash
	Hand washing facilities
	First aid kit
	Fire extinguisher
	Solvent cabinets
	Chemical spill kits
	Waste disposal containers for broken glass, chemical waste, plasticware, paper
Room 2 Nutritional evaluation	
Area	ca 60 sq m
•Equipment and related items	Weighing balance (0.1 and 0.001 g)
	Filtration unit
	pH meter
	Reflux system Acid concentrator
	Rotary evaporator
	Fibre and fat extraction systems
	Centrifuges
	Incubator shakers

	Hot air ovens (110-130 °C)
	Refrigerator
	Water purification system
	Vortex
	Ultrasonic bath
	Water bath
	Hotplates
	Freezer
	Fume hoods connected to an exhaust system
	Water and gas supply
	Vacuum facilities
	Network connection or Computer and accessories
Furniture and related items	Work table/bench, chairs
	Safety cabinets for storage of chemical solutions (acids & bases, solvents to be stored separately) and chemicals
	Glassware, including beakers, crucibles, dispensers, pipettes and measuring cylinders
Safety items	Lab coats
	Gloves
	Safety glasses
	Eyewash
	Shower
	Hand washing facilities
	First aid kit
	Fire extinguisher
	Solvent cabinets
	Chemical spill kits
	Waste disposal containers for broken glass, chemical waste, plasticware, paper

- Indicative list can vary with the test being performed. Equipment from the list (Annexure 1&2) as required for the test can be procured

Instrumentation room

Area	ca 120 sq m
•Equipment and related items	Gas Chromatograph with FID detector
	High Performance Liquid Chromatograph (HPLC) with RI, Fluorescence and Photodiode array detector
	UPLC with binary solvent system
	Amino acid analyser
	Karl Fischer Titration

	Real Time PCR
	UV-Visible Spectrophotometer
	Elemental-analyser
	Microscope
	Fluorescence spectrometer
	Uninterrupted power supply
	Water and gas supply
	Air conditioning
	Purified water system for chromatography work
	Network connections to allow direct laboratory access to data generated from the equipment
Furniture and related items	Work tables (Vibration proof) and benches, including chairs
	Equipment manuals
Safety items	Laboratory coat
	Gloves
	Safety glasses
	Eye wash station
	Fire extinguisher
	First aid kit
	Waste disposal containers for broken glass, chemical waste, plasticware, paper
	<ul style="list-style-type: none"> • Annexure 1 and 2 provide a list of equipment used on Food analysis labs and as per the test requirement equipment can be installed
	Instrument rooms a suite of two rooms each for LC-MS/MS and GC-MS/MS/
Area	ca 30 sq m for each instrument room ca 15 sq m for sample preparation, extraction and clean-up
Room and environment requirements	Dust Free Controlled Temperature 16-25 °C Short-term (1.5 h) variations must be no more than 2 °C. Advisable to have two air conditioners so that each can be run for alternatively. Relative Humidity not more than 70% Active exhaust vent must provide a minimum vacuum of 2 millibar below atmospheric pressure (negative pressure). It must be capable of supporting a maximum instrument exhaust gas load of 2000 L/hour Uninterrupted power supply

Equipment/Furniture and related items	<p>Water and gas supply</p> <p>Vibration free table (7(l)× 4 (w) ft ×4 (h) ft)</p> <p>Solvent cabinets</p> <p>Refrigerator& freezers for storing standards and reference material.</p> <p>Automated Solid phase extraction system for GC and LC-MS/MS sample preparation room</p> <p>Automated Nitrogen evaporator for GC and LC-MS/MS sample preparation room</p> <p>Analytical balance (0.0001 mg)</p> <p>Provide space for air circulation, gas lines, & electrical connections (24” behind the system).</p> <p>Dissipate room heat and allow for routine maintenance (at least 3 feet above the system)</p> <p>The area under the bench must be large enough for the fore line pump(s).</p> <p>The rotary pump or optional scroll pump must be positioned on the floor, either behind or underneath the instrument.</p> <p>Make sure there is adequate ventilation around the rotary/scroll pump so that the ambient temperature around the pump does not exceed 40 °C</p> <p>Provide an adequate fume exhaust system for the outlet of each fore line vacuum pump</p>
Power requirements	<p>Mains voltage fluctuations must not exceed ±10%.</p> <p>A measured ground to neutral potential of greater than 3 volts ac or dc indicates grounding problems that will need correction.</p> <p>The power supply boards with sockets must be located within 2 m (6.5 ft.) of the instrument</p> <p>It is recommended that time delay fuses and circuit-breakers are used to prevent nuisance tripping</p> <p>Additional protection to be provided for the instrument by means of Ground Fault Circuit Interrupters</p>
Gas requirements	<p>Nitrogen: A nitrogen gas supply that can provide up to a maximum of 12 L/min of gas regulated at 80 psi is sufficient for ESI or APCI operation for one LC/MS. Nitrogen purity must be >99.999%. All nitrogen generators require regular maintenance.</p>

A compressed air gas supply, capable of providing up to 2 L/min of gas regulated to 80 psi with a two-stage regulator, is required as a nebulizing gas for negative ESI. The air must be clean and dry, with less than 0.1 ppm total hydrocarbons, including methane, and have a -40 °C dew point

Argon is required as collision gas for MS/MS work with triple quadrupole instruments. The argon must be dry, high purity (99.997%), and regulated), using a two-stage high purity gas regulator with stainless steel diaphragm

Helium: For GC carrier gas, use 99.995% helium with less than 1.0 ppm each of water, oxygen, and total hydrocarbons. One full-size tank has an outlet pressure of 400 to 700 kPa (60 to 100 psi). Oxygen and hydrocarbon traps to be used. Use Single- or dual-stage high purity regulators that contain stainless steel diaphragms. The regulator output pressures must be consistent with the pressures

Safety items

Lab coat

Safety glasses

Nitrile gloves

Fire extinguisher

First aid kit

Waste disposal containers for broken glass, chemical waste, plasticware

Instrument rooms for ICP-MS (a suite of two rooms)

Area

ca 30 sq m for instrument room

ca 15 sq m for sample preparation

Room and environment requirements

Dust Free

Controlled Temperature 16-25 °C

Short-term (1.5 h) variations must be no more than 2 °C. Advisable to have two air conditioners so that each can be run for alternatively.

Relative Humidity not more than 70%

Temperature and RH meter

Microwave digester and Clean bench for ICP-MS sample preparation room

Fume Hood in ICP-MS sample preparation room

Furniture and related items

Sinks, hand wash facilities in sample preparation rooms

Active exhaust vent must provide a minimum vacuum of 2 millibar below atmospheric pressure (negative pressure). It must be capable of supporting a maximum instrument exhaust gas load of 2000 L/hour

Uninterrupted power supply

Water and gas supply

Vibration free table (7(l)× 4 (w) ft ×4 (h) ft)

Solvent cabinets

Refrigerator for storing standards and reference material

Analytical balance (0.0001 mg)

Provide space for air circulation, gas lines, & electrical connections (24” behind the system). Dissipate room heat and allow for routine maintenance (at least 3 feet above the system

The area under the bench must be large enough for the fore line pump(s).

The rotary pump or optional scroll pump must be positioned on the floor, either behind or underneath the instrument.

Make sure there is adequate ventilation around the rotary/scroll pump so that the ambient temperature around the pump does not exceed 40 °C

Provide an adequate fume exhaust system for the outlet of each fore line vacuum pump

Power requirements

Mains voltage fluctuations must not exceed ±10%.

A measured ground to neutral potential of greater than 3 volts ac or dc indicates grounding problems that will need correction.

The power supply boards with sockets must be located within 2 m (6.5 ft.) of the instrument

It is recommended that time delay fuses and circuit-breakers are used to prevent nuisance tripping

Additional protection to be provided for the instrument by means of Ground Fault Circuit Interrupters

Gas requirements

Nitrogen: A nitrogen gas supply that can provide up to a maximum of 12 L/min of gas regulated at 80 psi is sufficient for ESI or APCI operation for one LC/MS. Nitrogen purity must be >99.999%. All nitrogen generators require regular maintenance.

A compressed air gas supply, capable of providing up to 2 L/min of gas regulated to 80 psi with a two-stage regulator, is required as a nebulizing gas for negative ESI. The air must be clean and dry, with less than 0.1 ppm total hydrocarbons, including methane, and have a -40 °C dew point

Argon is required as collision gas for MS/MS work with triple quadrupole instruments. The argon must be dry, high purity (99.997%), and regulated), using a two-stage high purity gas regulator with stainless steel diaphragm

Helium: For GC carrier gas, use 99.995% helium with less than 1.0 ppm each of water, oxygen, and total hydrocarbons. One full-size tank has an outlet pressure of 400 to 700 kPa (60 to 100 psi). Oxygen and hydrocarbon traps to be used. Use Single- or dual-stage high purity regulators that contain stainless steel diaphragms. The regulator output pressures must be consistent with the pressures

Safety items

Lab coat

Safety glasses

Eyewash

Nitrile gloves

Fire extinguisher

First aid kit

Waste disposal containers for broken glass, chemical waste, plasticware

Glassware washing & drying facility area

Area

ca 30 sq m

Equipment and related items

Hot-air oven (110 °C)

Drying cabinets (50-60 °C)

Dishwasher

Furniture and related items

Water supply and drain Tiled floor and walls

Work table and bench Storage facilities

Safety items

- Separate waste disposal containers for broken glass, plastic ware, paper etc
- Lab coat
- Gloves
- Safety glasses
- First aid kit

An example of a laboratory area for eight analysts a complete floor layout with above described areas is shown in is Figure 5.

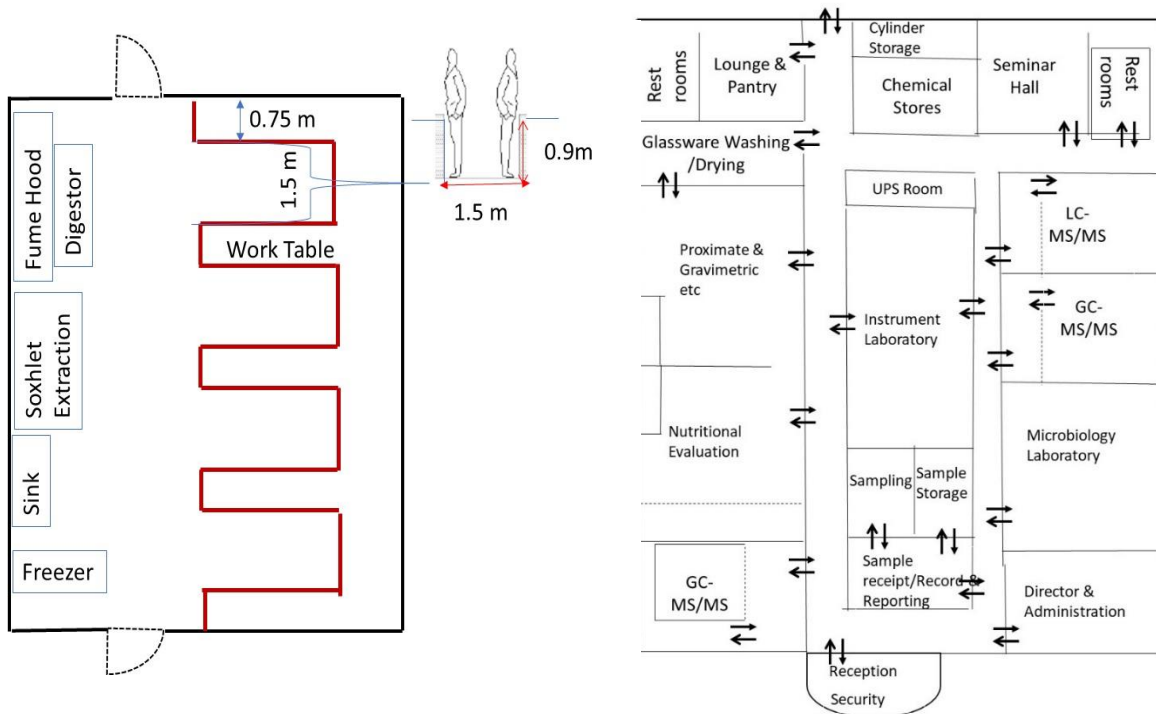


Figure 5 Schematic of a) laboratory room for eight analysts and b) a complete layout for a Food analysis laboratory

4.2.2 Microbiology Laboratory:

The Microbiology laboratory and support equipment (e.g. autoclaves, Laminar floor, Biosafety cabinet etc) glassware) should be dedicated and physically separated from other areas. There should be adequate suitable space with separate storage locations for e.g. biological indicators, reference organisms and media etc. The Lab should be away from restrooms etc to prevent cross contamination. The air supply to the microbiology laboratory should be through separate air-handling units and other provisions. Temperature and humidity must be maintained. The quality of the air supplied to the laboratory should be appropriate and not be a source of contamination. Laboratory equipment used in the microbiology laboratory should not be used outside the microbiology area.

Access to the microbiological laboratory should be restricted to authorized personnel (Biometric or use of card reader. Personnel should follow

- I. the appropriate entry and exit procedures including gowning;

- II. the intended use of a clean rooms and corridors
- III. the restrictions imposed when working in such areas
- IV. Use the appropriate containment level biosafety (e.g BSL-2 for *Clostridium botulinum*)
- V. Use back-fastening laboratory gowns or coats should be worn

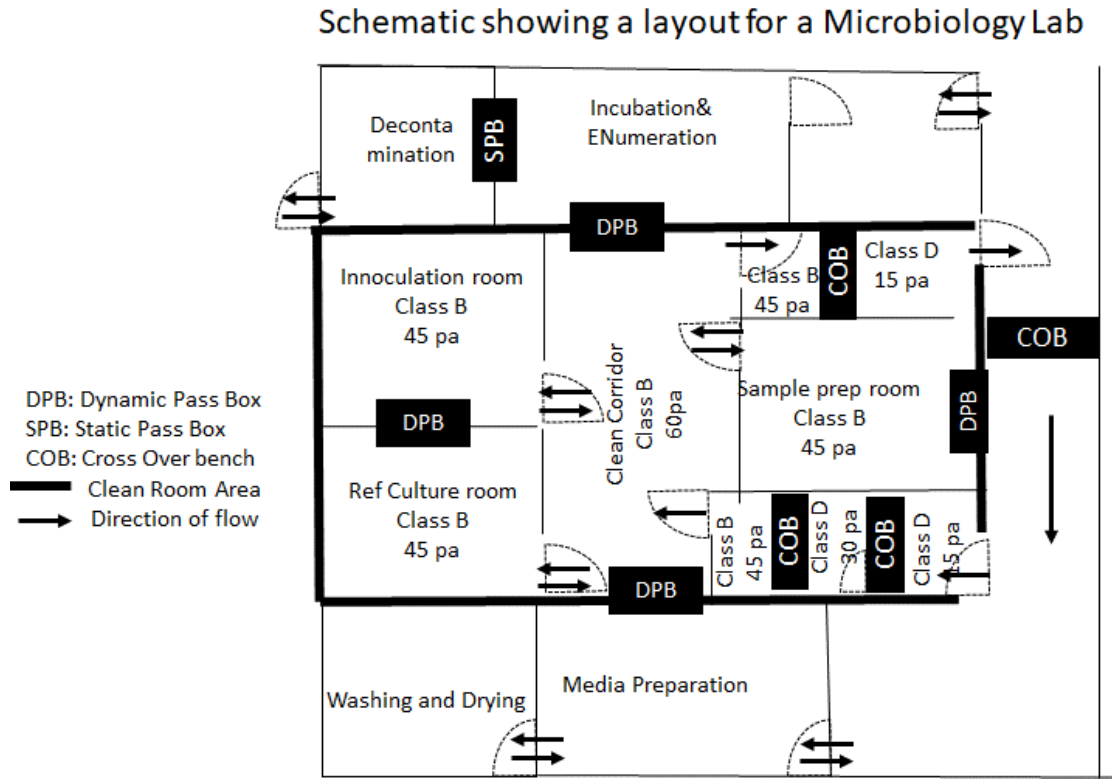


Figure 6 A schematic layout for the microbiology section of a food laboratory

4.2.1 Microbiology Lab Layout

- a) If entry to the laboratory is via a lobby, there should be some means of safeguarding the pressure differential between the laboratory and the lobby
- b) Operations should be carried out preferably in the following zones

Working zone	Installation grade	Maximum number of cfu in the environment
Sample Receipt	Unclassified	Not Applicable
Media Preparation room	Grade D	<200 cfu/m ²
Sample preparation room	Grade B	<50 cfu/m ²
Inoculation room	Grade B	<50 cfu/m ²
Reference culture room	Grade B	<50 cfu/m ²

Incubation and Enumeration Room	Grade D	<200 cfu/m ²
Decontamination room	Grade D	<200 cfu/m ²

- c) A change room should provide lockers to store street clothing, storage shelves for laboratory clothing,
- d) Floors should be smooth, slip resistant and seamless
- e) Coving on the interface between the walls and the floor
- f) There should be a documented cleaning and disinfection programme.
- g) There should be a procedure for dealing with spillages.
- h) Entry to the clean room should be via a system of airlocks and change room where operators are required to don suitable clean-room garments.
- i) The final change room should be the same grade as the room it serves.
- j) Change rooms should be of adequate size for ease of changing.
- k) There should be clear demarcation of the different zones.
- l) Adequate hand-washing and hand sanitization facilities should be available
- m)** A wash-hand basin(s) should be located near to the exit of the laboratory.
- n) Appropriate waste disposal containers in each section

4.2.2 Equipment for microbiology laboratory

Dedicated equipment should be available in each of the clean areas. They should not be moved around. Pass boxes must be used to move the sample from one clean area to another. A list is shown in Annexure 3

4.2.3 Administration or office area

Area	ca 20 sq. m each for General administration, Finance and Stores and Purchase
Facilities	Computers and Printers Air conditioning unit Scanner Photocopier Paper shredders Fax Phone
Furniture and related items	Work tables, including chairs Filing cabinets Storage facilities for results Waste disposal container

4.2.4 Chemical and Supplies: Storage of the chemical and supplies must be easily accessible to the laboratory area. The store is a secure area. Hence entry to the stores should be restricted to authorised personnel. Maintenance of proper storage temperatures is required to maintain the integrity of the chemicals. The room is under CCTV surveillance.

Area	ca 50 sq m with Access control for authorised personnel Air-conditioned Temperature 20± 2 °C RH 50-70% 100% Vented to remove toxic fumes
Equipment and related items	Frost free refrigerator Upright freezer (-20 to – 25 °C) CCTV surveillance
Furniture and related items	Storage possibilities such as shelves and cupboards for sample material Specialised storage cabinets for acids, bases, solvents, oxidisers etc
Safety	Fire extinguisher Gloves Lab Coat Safety Glasses Sink with eyewash Spill kit First aid Emergency phone Waste disposal containers

A waste disposal area must be identified depending on the available area.

4.2.5 Overall Space Utilization Guidelines

- a) The laboratory area should include, or have access to, all support spaces required, such as; instrument and preparation labs, laboratory stores, sample stores, chemical stores, wash up, media prep rooms, sterilization facilities, waste storage and waste treatment facilities.
- b) Administration and office accommodation should not be within the laboratory working area but should ideally be in close physically proximity to the laboratories they serve.
- c) Access to offices or other non-laboratory areas (lounge seminar hall, restrooms) should not require going through laboratory spaces
- d) Write up areas are permitted within the working area of laboratory however, these should be separated from areas where hazardous materials are stored or processes undertaken.
- e) Write-up areas should not be located right opposite a fume cupboard or biological safety cabinet, but should be located near the exit.
- f) A laboratory area should contain the microbiological, chemical, radiological or physical hazards as far as possible.
- g) Sufficient floor space should be provided for refrigerators, freezers, incubators autoclaves and large centrifuges.
- h) Furniture or equipment should not protrude into passage ways and exit routes of a laboratory.

- i) Provision for adequate space and facilities for the safe handling and storage of chemicals, compressed gas cylinders and other hazardous materials, etc. if they are to be used.
- j) Consideration should be given to the provision of a pantry or separate room for food & drink consumption to avoid eating & drinking in laboratories
- k) Meeting or seminar areas should be separated from the laboratories.
- l) Facilities for storage of street clothing and personal items of analysts should be provided outside the laboratory working areas. Suitable storage space for Personal Protective Equipment should be provided.

The design of a laboratory should conform to the following principles:

4.2.6 Security

- a) The building must be planned for security. Restriction of access is of considerable importance to protect the integrity of the official regulatory samples, prevent unauthorized personnel from gaining access and because of the extremely valuable and sensitive equipment used in the laboratory
- b) Fire proof construction for the building, completely separated from outside areas.
- c) Adequate office space, isolated from the laboratory, but still near. It is prohibited to store and consume food, apply make-up or chew gum in areas where hazardous materials are used/stored.
- d) The laboratory shall have means of securing specifically regulated materials such as legal samples, received controlled substances (cyanide, alcohol, radioactive materials etc)
- e) A security system for a typical lab should include some means of access control, often arranged in layers within a building
 - A computerized security management system (SMS) like
 - Keypad access control systems
 - Biometric
 - Card reader
 - Special door hardware locksets
- f) A means of visually monitoring sensitive or secure areas
 - Security Guards
 - Visitor control
 - Video surveillance/Security camera

4.2.7 Laboratory Signages

All labs must be provided with the following globally harmonized signs:

- a) A Laboratory Information Card at the entrance door of each laboratory shall be identified. Emergency exits shall be marked accordingly.
- b) A Health and Safety information should be posted on the door of each laboratory indicating accurately the hazards that are present in the laboratory, personal protection required and the emergency contacts.
- c) Identifier signs for all safety emergency equipment/devices
- d) “Danger” identifier for toxic chemicals

- e) “Flammable liquid” identifiers on all cabinets intended for flammable liquids.
- f) “Acids” identifier on all cabinets intended for acids.
- g) “Bases” or “alkalis” identifiers on all cabinets intended for alkaline liquids.
- h) “Oxidizers” identifiers on all cabinets intended for strong oxidizers.

4.2.8 Corridors and aisles

- a) Corridor widths and escape routes must be in accordance with the Building Codes of India.
- b) Corridors and passages to the exits should be clear of all obstructions, no furniture, instruments etc.
- c) The minimum separation between a working bench and floor-positioned equipment (eg autoclave, refrigerator, centrifuge) should be according to the following:
 1. No worker on either side 90 cms.
 2. Workers on one side of the aisle, no through traffic 100 cms
 3. Workers on both sides of the aisle, no through traffic 140 cms
 4. Workers on both sides of the aisle, plus through traffic 145cm
- d) Heat generating equipment, such as ovens and incubators, should be located away from corridors, aisles, passage ways and frequently occupied spaces.

4.2.9 Exits/Doors and Windows

The number of emergency exits must be in accordance to the building laws and codes.

The laboratory should have an Emergency Evacuation Plan’ and route for all buildings floors and areas and posted in every laboratory section and corridor

- a) Two or more well- marked & unobstructed evacuation exits are recommended in a lab
- b) Laboratories shall have access doors which swing in the direction of egress (exit travel). Automatic self-closing doors are advisable and should open with minimum effort without the use of a key from inside at all times
- c) Exit paths shall not be obstructed by lab furniture or equipment. To prevent blocking egress lab benches, and other furniture should be placed at least 5 feet (1.5m) from the exit door.
- d) The main emergency egress from the laboratory shall have a minimum clearance 3 ft (0.90 m).
- e) All exit and emergency doors serving hazardous occupancies shall swing in the direction of egress (exit travel).
- f) Each door into a laboratory room must have a view panel. or alternative means of viewing the laboratory activities from outside. Panels should be made of tempered/toughened glass.
- g) On the wall/panel next to each door entry into a laboratory must have a standardized clear frame (Board) with the room number/lab name and any hazard warning signage insert.
- h) Inside the laboratory, adjacent to the door latch, provision for light switches, telephone, thermostat/Relative humidity meter and fire extinguisher.
- i) Laboratory doors which open to egress/access corridors must not be vented
- j) If the laboratory has windows that open they must be fitted with insect screens
- k) Special facilities should be provided for the safe access and egress of disabled persons where applicable.

4.2.10 Flooring

- a) The floor must be a one piece (seamless construction) impervious to water, resistant to acids, alkalis, solvents and disinfectants, easy to clean, slip- and wear-resistant and be chemical resistant and shall have covings to the wall.
- b) Tiles and wooden planks are not appropriate because liquids can seep through the small gaps between them.
- c) The floor surface shall be coved where it meets the walls and fixed benches/cabinets to ensure spills cannot penetrate underneath floors/cabinets.
- d) Floors in storage areas for corrosive liquids shall be of liquid tight construction.
- e) All edges at the walls should be sealed or welded to prevent seepage of spilled materials.
- f) Supported coving should be used to facilitate easier cleaning and prevent contaminants from seeping into floor level service voids behind false walls.

4.2.11 Walls and ceiling

- a) Wall surfaces should be free from cracks and unsealed penetration.
- b) Walls should be non-porous and painted with a durable, impervious finish to facilitate decontamination and cleaning.
- c) Ceiling heights should be sufficient to accommodate the safe installation of fume cupboards and Biological Safety Cabinets where applicable.
- d) Gypsum board ceilings should be finished with durable and impervious paint.
- e) Ceiling-mounted lighting in laboratories where potentially infectious materials are handled should be recessed with a cover/diffuser flush at the ceiling level.

4.2.12 Sinks

- a) Each laboratory must contain a sink with proper plumbing for hand washing alone. Hand free operation faucet controls (e.g. elbow-, foot-or sensor-operated) to prevent direct hand contact are recommended especially in Biosafety level 2, and other microbiology laboratories
- b) Hand wash facilities should be provided close to the exit of the laboratory for hand washing immediately before leaving the laboratory.
- c) Each laboratory where hazardous materials are used should have a sink for hand washing.
- d) A separate hand-washing sinks should be provided for a Biosafety level 2 and microbiology laboratories.
- e) Sink faucets and hose bibs that are intended for use with attached hoses must be equipped with back siphon prevention devices.
- f) Laboratory sinks shall have lips that protect sink drains from spills.
- g) Stainless steel sinks are preferred.
- h) In the glassware washing room a sink with a draining board will be more useful. It is preferable to fix two-way or three-way laboratory type taps for the sinks.

4.3 Storage

4.3.1 Chemical Storage in the Laboratory/Bulk storage

- a) Always read the chemical's label and mark it with the date of receipt before storing.

- b) Never store highly reactive chemicals for longer than 6 months.
- c) Never store a chemical with an obscured or missing label.
- d) Open shelves used for storage of chemicals or any other hazardous materials should have edge guards having dimensions height (12.7 mm to 19 mm) to prevent containers/reagent bottles from falling off the back/front of the shelf
- e) The shelves should be no higher than eye level. The shelving should be made of a chemically resistant material.
- f) Never store liquid hazardous chemicals above eye level.
- g) Designate separate storage areas for highly toxic chemicals.
- h) 'Flammable liquid storage cabinets' are required for flammable and combustible liquid storage.
- i) Acids and bases should be stored separately in 'Corrosion resistant'-storage cabinets
- j) Exhausts vents are usually not recommended for these cabinets, because the volatile vapours can escape into the building.
- k) Chemicals should never be stored in a fume hood or on directly on the floor.
- l) Chemical storage rooms should be ventilated by at least 15 air changes per hour and should have dedicated exhaust systems.
- m) Chemicals should be stored in plastic or metal containers whenever possible, not in breakable glass.
- n) All chemicals should be properly labelled, and should be arranged on the shelf in *chemically compatible families, not alphabetically*. Store alphabetically within the groups.

A schematic for a Chemical storage room is shown in Figure 7

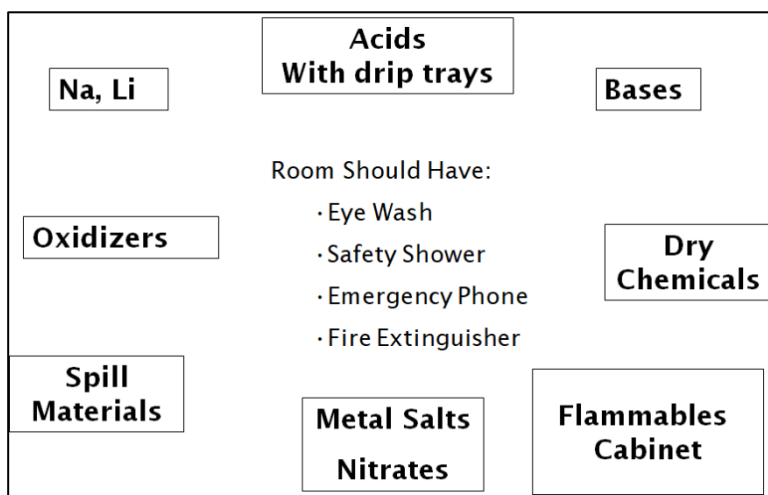


Figure 7 Chemical storage area layout

4.3.2 Gas cylinder storage and gas lines

- a) Empty and full cylinders should be stored in separate cages outside the laboratory in the ground floor
- b) It is preferred and recommended to supply piped gas through clearly identifiable metal piping to instrument rooms and other equipment.
- c) Compressed gas cylinders if used in the lab must be firmly attached to a secure structure by a non-combustible material such as metal chain. Nylon straps are not recommended.
- d) Gas cylinders must be transported on purpose-built trolleys within the laboratory
- e) Oxygen cylinders, full or empty, should not be stored in close proximity to flammable gases.

4.4 Laboratory and Personnel Safety

4.4.1 Safety Equipment

The availability and use of a number of types of safety equipment is essential and must be present in well-marked, highly visible, and easily accessible locations in or near all laboratories in the facility and must be maintained in working conditions. **All laboratories should be provided with the following Safety and Emergency Equipment**

- a) Fume hoods (60–100 ft/minute capture velocity, vented outside) and Safety shields with heavy base
- b) Hand wash facility
- c) Hand-free eye-wash stations (not eye-wash bottles) that conform to ANSI Z358.1–2004
- d) Safety showers that conform to ANSI Z358.1–2004
- e) Fire extinguishers (dry chemical and carbon dioxide extinguishers) and Sand bucket
- f) Fire blankets
- g) Fire detection or alarm system with pull stations
- h) Chemical storage cabinets (preferably with an explosion proof ventilation system)
- i) Emergency lights
- j) Emergency signs and placards
- k) First-aid kits
- l) Spill control kit (absorbent and neutralizing agents)
- m) Large plastic buckets for carrying chemical bottles
- n) Ground-fault interrupter electrical outlets
- o) Separate Containers for broken glass and sharps
- p) Material Safety Data Sheets (MSDSs) of all hazardous chemicals
- q) Emergency Action Plan for the laboratory

4.4.2 Safety design in labs

- a) In most cases, labs should be organized with the highest hazards (e.g., fume hoods) farthest from the entry door and the least hazardous elements (e.g., write-up stations) closest to the door.

- b) Write-up desks and benches should be accessible without having to cross in front of fume hoods.
- c) All safety equipment such as emergency showers, eyewashes, first-aid kits and spill kits should be readily accessible.
- d) An emergency centre in a central location on each floor, provides easy access for everyone. This centre should have reagent neutralizers, spill kits, first aid etc
- e) There should be at least one ABC fire extinguisher either inside the lab, or in close proximity.
- f) Extinguishers should not be blocked access or covered up.
- g) In each lab, there should be an eyewash unit
- h) Provided at least 10 seconds away from any analyst.
- i) It should supply a multi-stream cross flow of water at 20-25 °C (65°- 75°F).
- j) Contaminated eyes should be flushed for 15 minutes.
- k) Water flow at a rate of 10-20 L (3 to 7 gallons) of water per minute
- l) Safety showers should never be more than 100 ft. away from the analyst, along a clear and unobstructed path.
- m) Safety showers have historically been placed in the corridor, highly visible from the lab exits. a door is now considered an obstruction therefore preferable inside the lab. All safety showers should include an eyewash.
- n) Putting a floor drain under the shower is not recommended. To prevent contamination, it is preferable r to allow the chemicals at the shower to be mopped up
- o) Electrical apparatus, telephones, thermostats, electrical control panels, or power sockets should not be located within 0.5 m of the emergency shower or eyewash or within any area that may be considered as a splash or flood zone.
- p) Safety showers should provide low-velocity water at 25-30 °C (70° to 90° F).
- q) Manual close valves are recommended for all safety showers. A safety shower should be designed with an automatic cutoff.

4.4.3 Electrical Services and Safety

In the laboratory, a wide variety of electrically-powered equipment including stirrers, shakers, pumps, hot plates, heaters, power supplies, ovens, and others are used. The following are some basic guidelines for electrical services in the laboratories:

- a) Electrical outlets should have a grounding connection and accept three-prong plugs. Multiple plug outlet adapters should not be used.
- b) General power outlets should be above the bench height. Ceiling-mounted, or floor-mounted receptacles should be provided as needed for laboratories where equipment will be located away from walls to avoid trailing cables on the floors.
- c) Electrical socket outlets, outlets for telecommunication appliances and outlets for computer networks should positioned away from sinks/showers etc.
- d) Electrical outlets should also be positioned as far as possible from valves for flammable gas and flammable solvent storage

- e) Location of electrical panels and shut-off switches must be easily identifiable to quickly disconnect power in the event of an emergency.
- f) Leave at least a 3-foot clearance around electrical panels, circuit boxes, for easy and ready access. Maintain an unobstructed access to all electrical panels.
- g) Uninterrupted power supply required for equipment must be considered while designing the laboratory power supply system.
- h) Emergency lighting and illuminated exit signs are mandatory to facilitate emergency evacuation in the event of power failure.
- i) All the circuit breakers and the fuses should be labelled to indicate whether they are in the "on" or "off" position
- j) Fuses must be properly rated.
- k) Avoid using extension cords
- l) Electric cables should not be routed over metal objects such as emergency showers, overhead pipes or frames, metal racks, etc.
- m) Avoid multi-outlet plugs unless they have a built-in circuit breaker.

4.5 Lab Furniture

4.5.1. Work Tables

- a) The working surfaces should be hard and non-adsorbent
- b) The surfaces must be compatible with any chemicals likely to be used in the laboratory and must be impervious to water, resistant to acids, alkalis, solvents and disinfectants and easy to clean and a drip strip must be cut on the undersurface
- c) Materials used should be of low emission of formaldehyde.
- d) Bench tops should be of seamless design. If the bench top is against a wall, it shall be coved or have a backsplash against the wall.
- e) Work surface front corners may be rounded for ergonomic reasons but rounded work bench front edges should be avoided to prevent spills following the contours onto the under surfaces.
- f) Bench height should depend on the working position of the laboratory users. Typical bench is about 90 cm high for standing work.
- g) Typical bench depth is in the range of 60-90 cm (optimum 75 cm) for ease of access to the rear of the bench.
- h) Work surface area for each worker must be more than 1.2 m across (recommended to be at least 1.5 m) and 0.6 m deep, excluding bench space for laboratory equipment (Figure 5a)
- i) Deeper worktop may be required for specific and large equipment where access to back of the worktop from the front is not normally required.
- j) Sufficient leg/knee clearance should be left under the bench top for persons who use the bench top as a working/write-up area.
- k) Personnel working within laboratory areas must be able to work and move unimpeded by each other and by fixed equipment.

- l) As a minimum there must be a 1.5 m passageway between benches, or 1.7 m passageway between back-to-back working benches (Figure 5a).

4.6 Waste Disposal

It is the clear responsibility of the Head and all analysts of the laboratory to ensure the safe and correct disposal of all wastes produced during the analysis. Waste must be categorized as to its identity, constituents, and hazards so that it may be safely handled and managed. Improper and irresponsible disposal of chemical wastes down drains or into the atmosphere is forbidden. **The Aldrich Handbook** provides a useful summary of the correct disposal procedure for most chemicals. 'Generated knowledge' can be used for waste characterization, such as the knowledge of waste characteristics and constituents by laboratory personnel who conducted the process, procedure, or experiment. It is essential that all the laboratory personnel accurately and completely identify and clearly label all chemical and waste containers in their respective sections/laboratories.

4.6.1 Chemical Waste can take the form of solvents, aqueous solutions, dry powders, and unwanted old chemicals. The following procedure should be implemented

- I. Chemicals that can be wash down drains with excess water
 - a) Concentrated acid after dilution and dilute acids and alkalis
 - b) Harmless soluble inorganic salts (including all drying agents such as CaCl_2 , MgSO_4 , Na_2SO_4 , P_2O_5)
 - c) Alcohols containing salts (e.g. from destroying sodium)
 - d) Hypochlorite solutions from destroying cyanides, phosphines, etc.
 - e) Fine (TLC grade) silica and alumina
- II. No material on the "Red List" should ever be washed down a drain. This list is as follows:
 - a) Substances that do not mix or dissolve readily in water (e.g. fats)
 - b) Compounds of the following elements: - antimony, arsenic, barium, beryllium, boron, cadmium, chromium, cobalt, copper, lead, mercury, molybdenum, nickel, selenium, silver, tellurium, thallium, tin, titanium, uranium, vanadium and zinc.
 - c) Halogenated organic solvents/ organochlorine compounds (e.g. chloroform, dichloromethane, epichlorohydrin, carbon tetrachloride).
 - d) Toxic organic solvents (e.g. methanol, acetonitrile, xylene)
 - e) Organohalogen, organophosphorus or organonitrogen pesticides, triazine herbicides, any other biocides.
 - f) Cyanides and azides; Cyanide wastes must be placed in an appropriate waste bottle and the solution kept alkaline at all times.
 - g) Antibiotics
 - h) Formaldehyde or paraformaldehyde solutions
 - i) Phenol, benzene or derivatives of these
 - j) Mineral oils and hydrocarbons
 - k) Poisonous organosilicon compounds, metal phosphides and phosphorus element
 - l) Fluorides and nitrites
- III. Solvent Waste collection in individual labelled containers for:

1. Halogenated solvents (methylene chloride, tetrachloroethylene, and chlorinated fluorocarbons)
2. Nonhalogenated solvents (acetonitrile, xylene, acetone, ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, methanol, and *n*-butyl alcohol).
3. Soluble organic waste including most organic solids
4. Paraffin and mineral oil (from oil baths and pumps)

IV Each laboratory section should have the following waste bins preferably color coded and labelled. Ensure every bin has a lid. When the laboratory bin is $\frac{3}{4}$ full, the lid should be placed on the bin and the contents transferred to the larger solid waste bins:

- a) **Controlled waste:** Items in this category includes dirty paper, plastic, rubber and wood, which will be collected by the cleaners daily.
- b) **Glass:** All broken laboratory glassware including disposable test tubes, bottles etc
- c) **Bottles:** Empty reagent bottles to be collected separately. The tops/caps must be removed from all bottles put out for disposal and there should be no detectable smell of chemicals from any bottle put for disposal.
- d) **Metal sharps:** Any sharp objects like can tops, pins, syringe needles, scalpel blades, razor-blades, scalpel blades. Under no circumstances must any item of glass, sharp metal or fine powder ever be put in a normal laboratory waste bin
- e) **Plastic ware:** All disposable plasticware including, Eppendorf vials, syringes, pipette , tips , plastic bottles etc.
- f) **Batteries:** All used batteries
- g) **Waste for special disposal** collected in labelled individual bottles
 - Mercury
 - Cyanide solutions
 - the quantity of special waste must be kept to an absolute minimum and stored under suitable conditions.
 - Should be disposed as per the regulations of the State Pollution Control Board

4.6.2 Biological Waste (Microbiology Lab)

Each individual laboratory may negotiate a contract with a commercial firm which is licensed by their respective State Pollution Control Board, to remove and transport biological waste to a designated disposal site for incineration.

For safety reasons, all the disposable petri-plates used for the inoculation and enumeration of the microorganisms, should be autoclaved (steam sterilised) to inactivate the biological agents. Once autoclaved, waste can be disposed of.

Do not pour melted agar into sink or floor drains. Allow it to cool and solidify for disposal as a bio waste and can be placed with non-hazardous waste.

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WHO Good Practices for Pharmaceutical Microbiology Laboratories. WHO Technical Report Series, No. 961, 2011 Annex 2

Annexure 1

S. No	List of General Laboratory Equipment
1.	Analytical Balances (0.01, 0.001 and 0.0001g accuracy)
2.	Auto pipettes - (1 - 5ml Range)
3.	Auto Titrators – 1 (25 – 100 ml Range)
4.	Autoclaves
5.	Bottle dispensers
6.	Centrifuges
7.	Conductivity meters
8.	Desiccators
9.	Electric Heaters -
10.	Frost free Double Door Refrigerators
11.	Fume Hoods
12.	Hand Held Refractometer
13.	Heating Mantles
14.	Hot plate cum stirrers
15.	Hot Plates
16.	Incubators 37 °C and 55 °C – 1Nos each
17.	Laboratory Blender
18.	Magnetic Stirrer
19.	Microwave digestor
20.	Muffle Furnace – 450°C
21.	Muffle Furnace -550 °C
22.	Oven – for glassware drying
23.	Oven – Moisture -100°C
24.	Oven – Moisture -130 °C
25.	pH Meters
26.	Sample Shakers
27.	Solvent Dispensers - Organic & Acids –
28.	Soxhlet Apparatus
29.	Sulphur-di-oxide Apparatus
30.	TDS meter
31.	Temperature controlled Water baths
32.	Toluene Distillation Set
33.	Upright Freezers (Normal, -20°C and -80 °C)
34.	Vacuum Oven
35.	Vortex Mixers
36.	Waring Blender/grinding mill
37.	Water Distillation Set

38.	Weighing Balance (500gm – 10kg) -2Nos
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Annexure 2

List of Sophisticated Equipment		
S. No.	Description	Application
1.	Automated liquid handling system	For accurate dispensing and aspiration of routine lab reagents etc.
2.	Automated Nitrogen evaporators	Concentration of samples for LC and GC-MS/MS
3.	Automated Solid phase extractor	Enrichment of pesticide/antibiotic residues and removing of interfering matrices for LC-MS/MS and GC-MS/MS
4.	Automatic Flash Point Tester	
5.	Atomic Absorption Spectrometer with Graphite Furnace	Metal analysis
6.	Automated amino acid analyser	Nutritional evaluation of proteins
7.	Binary/quaternary gradient HPLC with photodiode array, fluorescence and Evaporative light scattering detectors	For estimation of preservatives, artificial sweeteners and leachates from food packaging material
8.	Butyro Refractometer Reading System with temperature control	BRR of oils
9.	Clean bench systems Biosafety cabinets	Sample preparation under sterile conditions for ICP-MS
10.	Fully automated Fiber analyser	Required for analysis of dietary fiber, soluble and insoluble.
11.	Fully automated Kjeldhal analyzer	Nitrogen, protein estimation
12.	GC-MS-MS	General purpose instrument for screening chemical contaminants and leaches of food packaging s
13.	High speed floor model centrifuge	For separation of solid particles.
14.	HPLC-ICP-MS	This machine has been used effectively in the simultaneous separation and determination of nine species of the three elements arsenic, selenium and antimony. Using this technique, calibration by isotope dilution mass spectrometry (IDMS) can be carried out. Organic speciation analysis has also been carried out using LC ICP-MS.

15.	HR GC MS/MS	For detection and confirmation of food additives chemical contaminants melamine, acrylamide bisphenol
16.	ICP-MS	Heavy metal and trace metal analysis
17.	LC-MS-MS with Ion trap	Pesticide residues, antibiotic residues, mycotoxins etc
18.	Multimode ELISA reader and plate washer	For automated ELISA of various contaminants
19.	Microwave Digestor	For metal analysis sample preparation
20.	Tintometer	For reading color
21.	Rotary Evaporator	Required for concentration
22.	Sonic water-bath	General purpose
23.	Spectrofluorometer	For bioassays and detection of aflatoxin and vitamins
24.	Table top microfuge refrigerated and non-refrigerated	General Purpose to clarify samples
25.	Temperature controlled orbital Water Bath shakers	Required for extraction and analysis Do
26.	Tintometer	Colour /Reflectance Measuring System)
27.	UV-Vis double beam spectrophotometer	Required for colorimetric estimation of various analytes
28.	Viscometer	To measure viscosity
29.	Video Microscope	To determine foreign starch
30.	Water purification system (Element analysis grade)	For use in ICP-MS, GC-MS-MS sample preparation instrumental use
31.	Wireless Real Time Lab Monitoring System	A monitoring system of temperatures and others parameters: relative humidity, differential pressure, CO ₂ , O ₂ , dry contacts are critical parameters for quality assurance under ISO 17025.

Annexure 3

Equipment list for Microbiology Lab	
1.	Anaerobic Jar
2.	Analytical Balance
3.	Autoclave Vertical
4.	Automated Culture Media Preparator with pourer stacker
5.	Automated glassware washer
6.	Binocular Microscope
7.	Bio Safety Cabinet Class II Type B2 (Total Exhaust)
8.	BOD Incubator
9.	Carbon di oxide incubator
10.	Circulating water bath
11.	Digital Colony Counter
12.	Digital pH Meter
13.	Frost Free Double door (side by side) Refrigerator
14.	Fumigator
15.	Hot Air Oven
16.	Howard Mold Counter
17.	Incubators: 1) Ambient to 70 °C and 2) 5 °C to 50°C
18.	Lab Blender (Paddle type)
19.	Laminar Air Flow
20.	Micro Filtration Assembly
21.	Micropipette (6 No)
22.	Orbital shaker/water bath
23.	Sonic water bath
24.	Refrigerated Centrifuge
25.	Trinocular microscope
26.	Upright Frost Free Vertical Deep Freezer (-25 °C)
27.	UV Viewing Chamber
28.	UV-Vis Spectrophotometer
29.	Water Bath – Serological

Annexure 4

List of glassware and general apparatus for start-up	
Sl No.	Description
1.	Beaker all sizes
2.	Bell Jar
3.	Blue litmus paper
4.	Burette
5.	Conical flask with stoppers
6.	Desiccators/vacuum desiccators
7.	Digestion Flask (300 ml)
8.	Erlenmeyer Flasks
9.	Filter paper Circles (No 1, 41, 42)
10.	Funnels
11.	Glass Pipettes
12.	Kjeldhal Distillation flasks
13.	Litmus Paper
14.	Measuring cylinders
15.	Pipete bulbs
16.	Red litmus paper
17.	Separating Funnels
18.	Sieves
19.	Silica dishes
20.	SO ₂ Distillation set
21.	Soxhlet Extraction Unit
22.	Test tubes all sizes (stoppered and un stoppered)
23.	Thimbles 20/80
24.	TLC Chamber rectangular (250 x 250 x 120 mm)
25.	Tripod Stand
26.	Volumetric flasks
27.	Wash bottles (glass) (plastic)
28.	Wire gauze

29.	Microbiology Laboratory: Test tubes Petri Dishes Durham 's tubes Dilution and media storage bottles Spreaders. Slides and cover slips. Disinfectant jars Inoculation loops Non – adsorbent cotton wool.
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Annexure 5

List of Chemicals for startup

The list of fine chemical and chemical required for testing will vary depending on the analysis. The general chemical listed below are those required for a start-up. Fine chemicals, standards and certified reference materials should be procured depending on the parameter being analysed. A basic indicative list is provided below

Sl. No.	Name of chemicals
1	Acetic acid
2	Ascorbic acid
3	Ammonia
4	Ammonium Oxalate
5	Ammonium Molybdate
6	Ammonium Thiocyanate
7	Acetone
8	Benzoic acid
9	Butanol – n
10	Boric acid
11	Bromo cresol green
12	Bromo cresol
13	Buffer tablets (4 & 7)
14	Chloroform
15	Copper sulphate
16	Calcium chloride Fused
17	Dextrose
18	Diethyl ether
19	Dichlorophenol indophenol dye
20	Ethyl alcohol
21	Hydrochloric acid
22	Hydrogen peroxide
23	Iodine
24	Lead acetate
25	Methyl orange
26	Methylene blue
27	Metaphosphoric acid
28	Nestler's reagent
29	Nitric acid
30	Oxalic acid

31	Potassium Hydroxide
32	Potassium Metabisulphite
33	Potassium dihydrogen phthalate
34	Phenolphthalein
35	Potassium Persulphate
36	Potassium iodide
37	Potassium iodate
38	Potassium dichromate
39	Potassium chromate
40	Potassium permanganate
41	Petroleum ether (40-60°)
42	Petroleum Ether (60-80°)
43	Sodium carbonate
44	Sulphuric acid
45	Sodium hydroxide
46	Selenium dioxide
47	Sodium Potassium Tartrate
48	Sucrose
49	Silver nitrate
50	Sodium benzoate
51	Sodium Saccharin
52	Sodium sulphate anhydrous
53	Sodium chloride
54	Sodium bicarbonate
55	Marble chips
56	Zinc granules

Annexure 6

Sl. No	List of Media for Microbiology
1.	Acetate Agar
2.	Andrade peptone water
3.	Asparagine-Proline Broth
4.	Baird Parker Agar
5.	Bile Esculin Azide Agar
6.	Bile salts agar
7.	Bismuth Sulphite Agar
8.	Blood agar
9.	Brain Heart Infusion Broth
10	Brilliant green agar
11	Brilliant Green Lactose Bile Broth
12	Bromocresol Purple Carbohydrate Broth
13	Buffered Peptone Water
14	Butterfield's Buffered Phosphate Diluent
15	Carbohydrate Utilization Broth
16	Cetrimide agar
17	Chloramphenicol Yeast Glucose Agar
18	Cooked Meat Salt Medium
19	Czapek Yeast (Autolysate) CYA agar
20	Decarboxylase Test Medium (Lysine, Ornithine, Arginine provide separately)
21	Deoxycholate Citrate Agar Medium
22	Dextrose Tryptone Agar
23	EC Broth
24	Egg Yolk Tellurite Supplement
25	Frazer Broth
26	Gelatin agar
27	Gelatin Phosphate Salt Broth
28	Glucose Salt Teepol Broth
29	Gram Negative Broth (GN)
30	Half Frazer Broth
31	Hektoen Enteric Agar
32	Hugh Leifson Medium
33	Kauffman Mueller's Tetrathionate Broth Base
34	Kligler Iron Agar
35	Koser's Citrate Broth

36	Lactobacillus MRS Agar
37	Lactose Broth
38	Lactose Gelatine Medium
39	Lauryl Tryptose Broth
40	Levine Eosin-Methylene Blue Agar (L- EMB Agar)
41	Liver Broth
42	Lysine decarboxylase broth
43	Lysine Iron Agar
44	Malonate Broth
45	Malt Agar
46	Mannitol Yolk Polymyxin (MYP) Agar
47	McConkey broth/agar
48	Methyl Red Voges Proskauer (MR-VP) (Glucose Phosphate Broth Broth
49	Milk agar with cetrimide
50	Modified Oxford Agar
51	Motility Test Medium
52	MY-40 Agar
53	Nitrate Broth
54	Nutrient Agar
55	Nutrient Broth
56	Palcam Agar
57	Peptone Water Diluent
58	Phenol Red Carbohydrate Broth
59	Phosphate Buffered peptone water
60	Plate Count Agar
61	Potato Dextrose Agar
62	<i>Pseudomonas</i> Presumptive Test Broth
63	<i>Pseudomonas</i> confirmation medium (Skim Milk Agar)
64	Rappaport Vassiliadis Soya Broth
65	Selenite Cystine Broth
66	Selenite F broth
67	Sheep Blood Agar
68	Simmons Citrate agar
69	Slanetz and Bartley Medium
70	Sulphite Agar
71	T1 N1 Agar
72	Tergitol-7 Agar Base
73	Tetrathionate Broth

74	Thioglycollate Agar
75	Thiosulfate-Citrate-Bile Salts-Sucrose Agar (TCBS)
76	Triple Sugar Iron Agar
77	Trypticase Soy Broth
78	Tryptone Broth
79	Tryptone Glucose Extract Agar
80	Tryptone soya agar
81	Tryptose-Sulfite Cycloserine (TSC) Agar
82	Urea Broth
83	Violet Red Bile Agar
84	Xylose Lysine Deoxycholate Agar (XLD)