

	QUALITY MANUAL Food Safety and Analytical Quality Control Laboratory Christy Friedgram Industry Pvt Ltd	Issue Date: 23/02/2023 Issue No: 02	Rev. Date: 19/09/2025 Rev.No:02
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Quality Manual

FOOD SAFETY AND ANALYTICAL QUALITY

CONTROL LABORATORY

CHRISTY FRIEDGRAM INDUSTRY PRIVATE LIMITED

A2 & A3 SIDCO INDUSTRIAL ESTATE, ANDIPALAYAM,

TIRUCHENGODE,

NAMAKKAL DISTRICT, TAMILNADU – 637 214.

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Laboratory, Chirsty Friedgram Industry Private Limited.

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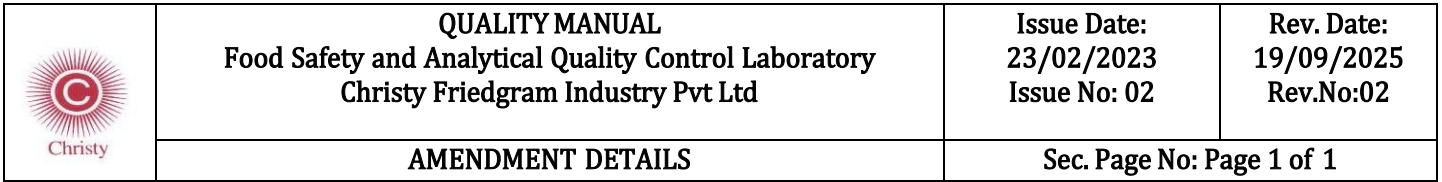
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This Quality manual is prepared to meet the requirements of ISO/IEC 17025: 2017 and the requirement of management system. The laboratory functions in accordance with the Quality manual issued.

The manual contains the following;

The Header of the manual contains

- Christy Friedgram Industry Pvt Ltd Logo in the left side,
- Laboratory name, Section No. & Name in the center,
- Issue date & No., Revision Date & No., Manual and section page No. in the right side.

The footer of the Section Contains

- Name and designation of person preparing the Manual in the left side,
- Name & designation of person reviewing and approving in the right side of the footer.

If there is any amendment / changes in the Manual/ Quality Procedures, Documents and Standard Operating procedures, the respective amendment or changes is made in the relevant clause and the revision number is changed and revision date is changed. Until no revision is done, the revision number will be "0" and revision date will also be marked as "0". When first revision is done it is numbered as "1" and until "4" revisions, the revision number will continue. The issue No. will be changed for after the 4th revision. The Issue date is changed when issue number is changed. Until the issue number changed, it is numbered as "0".

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1.0 Scope

This Quality Manual facilitates:

- 1.1 Recognition of technical competence for standard methods and Laboratory developed methods, impartiality and consistent operation. We perform in the field of chemical and Biological testing.
- 1.2 Following the International standard, ISO/IEC 17025: 2017 for the testing which forms a part of inspection and product certification.
- 1.3 The notes or examples if any given in the manual does not form an integral part of the standard or manual.
- 1.4 Developing the management system for quality, administrative and technical operations by using ISO/IEC 17025: 2017.
- 1.5 The manual facilitates audit by customer, regulatory authorities, accreditation bodies and customer satisfaction.
- 1.6 Following the Good Laboratory Practices (GLP) in regulatory and safety aspects.
- 1.7 Audits by customer, regulatory authorities and accreditation bodies.
- 1.8 Customer satisfaction
- 1.9 Meeting the requirements of ISO/IEC 17025:2017 & NABL Documents as follows:

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Documents as follows:

Document No	Document Title	Issue Date	Last Amend No	Last Amend Date
NABL 100 A	General Information Brochure	23/11/2022	02	22/11/2024
NABL 120	Guidance for Classification of Product Groups in Testing & Calibration Field	12/02/2019	05	31/12/2021
NABL 131	Terms & Conditions for Obtaining and Maintaining NABL Accreditation	16/07/2020	02	11/09/2023
NABL 132	Procedure for Dealing with Complaints	02/03/2020	01	03/06/2020
NABL 133	Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark	13/12/2019	03	03/09/2024
NABL 134	Procedure for Dealing with Appeals against Adverse Decisions Taken by NABL	03/03/2023	00	
NABL 141	Guidelines for Estimation and Expression of Uncertainty in Measurement	10/02/2020	00	
NABL 142	Policy on Metrological Traceability of Measurement Results	1/01/2021	00	
NABL 151	Application Form for Testing Laboratories	25/06/2018	06	13/07/2023
NABL 160	Guide for Preparing Management System Document / Quality Manual	11/09/2018	03	22/02/2024
NABL 161	Guide for Internal Audit and	05/02/2020	01	22/02/2024

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	Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)			
NABL 163	Policy for Participation in Proficiency Testing Activities	29/10/2020	01	03/09/2024
NABL 190	Application Form for Reference Material Producers (RMP) Accreditation	16/05/2020	01	24/01/2024
NABL 209	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)	19/04/2016	04	09/12/2021
NABL 216	Procedures for Dealing with Adverse Decisions	13/12/2019	02	01/06/2021
NABL 218	Desktop Surveillance	19/04/2016	06	21/02/2024
NABL 218A	Checklist for Annual Surveillance	06/08/2025	00	
NABL 219	Assessment Forms and Checklist (Based on ISO/IEC 17025:2017)	16/02/2021	01	02/07/2021
NABL 220	Document Review Checklist (as per ISO/IEC 17025: 2017)	20/07/2020	01	08/07/2021

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2. Normative References

Reference List

- ISO/IEC Guide 2 - General terms and their definitions concerning standardization and related activities.
- VIM: 1993 - International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.
- ISO/IEC 17025: 2017 – General Requirements for the Competence of Testing and Calibration Laboratories.
- ISO/IEC: 17000 Conformity Assessment -Vocabulary and general principle.
- ISO :9001 Quality Management system and relevant NABL documents asmentioned in section :1

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3. Terms and Definitions

For the purposes of this manual, the following relevant definitions apply:

ISO/IEC Guide 99; ISO/IEC 1700; ISO/IEC 17021-1:2015 ISO/IEC 17000:2004; ISO/IEC 17043:2010; ISO/IEC Guide 2: 2004; ISO/IEC Guide 30: 2015; ISO Council Committee on Conformity Assessment (CASCO); ISO 9000; ISO 10015:1999; ISO 5725-1:1994; ISO/IEC 17025:2017; the Food Laboratory Accreditation Working Group (FLAWG); AOAC; American Chemical Society (ACS); and International Vocabulary of Basic and General Terms in Metrology (VIM).

❖ **Accreditation** – Formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests (CASCO- Committee on conformity assessment).

❖ **Accuracy** – The closeness of agreement between a test result and the accepted reference value (ISO 5725-1: ISO Guide 30)

❖ **Calibration** - a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by the standard (VIM).

Notes

1. The result of a calibration permits either the assignment of values or measurements to the indications or the determination of corrections with respect to indications.

2. A calibration may also determine other metrological properties such as the effect of influence quantities.

❖ 3. The result of a calibration may be recorded in a document sometimes called a calibration certificate or a calibration report.

❖ **Certification** - procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements (ISO 8402).

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❖ **Certified Reference Material** – a reference material, one or more of, whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (ISO Guide 30).

❖ **Customer** – an entity (customer / client, agency, company, person, etc.) who receives a test result done according to specified requirements (FLAWG).

❖ **Complaint** - Expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.(ISO/IEC 17000).

❖ **Competence** – ability consisting of theoretical knowledge, practical skills, and attitudes (ISO 10015).

❖ **Corrective Action** – action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence (ISO 8402).

❖ **Decision rule** - Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

❖ **Holding Time** – elapsed time between sample collection and either sample preparation or analyses, as appropriate.

❖ **Inter laboratory comparison** – organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. (ISO/IEC 17043)

❖ **Intra laboratory comparison** - organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.

❖ **Impartiality:**

Presence of objectivity- Objectivity means that conflicts of interest do not exist, or are resolved so as not adversely influence subsequent activities of the laboratory. Impartiality

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include “freedom from conflict of interests”, “Freedom from bias”, “lack of prejudice”, “neutrality”, fairness”, “open-mindedness”, even-handedness”, “detachment”, “balance” (ISO/IEC 17021-1).

❖ **Inspection** - evaluation for conformity by measuring, observing, testing, or gauging the relevant characteristics (ISO/IEC Guide 2: 2004). Activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic. (ISO 8402).

❖ **Laboratory**- Body that performs one or more of the following activities

- Testing
- Calibration
- Sampling, associated with subsequent testing or calibration

❖ **Limit of Detection** – the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix containing the analyte(ACS). The mean value of the matrix blank readings plus 3 standard deviations of the mean, expressed in analyte concentration. For methods with less than 100% recovery the limit of detection should be corrected for recovery (AOAC).

❖ **Limit of Quantification** – lowest concentration of analyte that can be determined with an acceptable level of accuracy and precision. Determined by actual analysis of at least 6 fortified test samples per matrix. It is not determined by extrapolation (AOAC).

❖ **Linearity** – is determined by the analysis of samples with analyte concentrations spanning the claimed range of the method. The results are used to calculate a regression line against analyte calculation using the least squares method. It is convenient if a method is linear over a particular range but it is not an absolute requirement. Where linearity is unattainable for a particular procedure, a suitable algorithm for calculations should be determined (AOAC).

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- ❖ **Metrological traceability-** “Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty”. (ISO/IEC Guide 99).
- ❖ **Measurement Procedure-** Description of measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result. A measurement procedure is sometimes called a standard operating procedure.
- ❖ **Measurement Uncertainty** - Parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand (International Vocabulary of Basic and General Terms in Metrology).
- ❖ **Precision** - the closeness of agreement between test results obtained under stipulated conditions (ISO 5725-1, ISO Guide 30).
- ❖ **Preventive Action** - action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence (ISO 8402).
- ❖ **Proficiency Testing-** Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.(ISO/IEC 17043).
- ❖ **Quality Assurance** - All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO 8402).
- ❖ **Quality Control** - The operational techniques and activities that are used to fulfill requirements for quality (ISO 8402).
- ❖ **Quality Manual** - A document stating the quality policy, quality system, and quality practices of an organization (ISO 8402).
- ❖ **Quality System** - The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management (ISO 8402).

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❖ **Range** – the difference between the largest and smallest observed value of a quantitative characteristic. For quantitative analysis the working range for a method is determined by examining samples with different analyte concentrations and determining the concentration range for which acceptable accuracy and precision can be achieved. The working range is generally more extensive than the linear range. The working range is determined by the analysis of a number of samples of varying analyte concentrations and calculating the regression from the results, usually using the method of least squares. The relationship of analyte response to concentration does not have to be perfectly linear for a method to be effective (AOAC).

❖ **Reference Material** – a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (ISO Guide 30).

❖ **Reference Standard** – a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived (VIM). Generally, this refers to national traceable standards such as those from the National Physical Laboratory (NPL).

❖ **Repeatability (r)** – precision under the same conditions (same method, same test item, same operator, same apparatus, same laboratory, short interval of time) (ISO 5725-1).

❖ **Reproducibility (R)** – precision using the same method on identical items obtained by operators in different laboratories using different equipment (ISO 5725-1).

❖ **Ruggedness** – the ruggedness of a method is tested by deliberately introducing small changes to the method and examining the consequences. A large number of factors may need to be considered, but because most of these will have a negligible effect, it will normally be possible to vary several at once (AOAC).

❖ **Selectivity** – the extent that a specific analyte can be determined from a complex mixture without interference from the other components in the mixture. A method that is

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perfectly selective for an analyte or group of analytes is said to be specific. The applicability of the method should be studied using various samples, ranging from pure standards to mixtures with complex matrices. In each case the recovery of the analyte(s) of interest should be determined and the influences of suspected interference duly stated. Any restrictions in the applicability of the technique should be documented in the method (AOAC).

❖ **Sensitivity** – the difference in analyte concentration corresponding to the smallest difference in the response of the method that can be detected. It is represented by the slope of the calibration curve and can be determined by a least squares procedure, or experimentally, using samples containing various concentrations of the analyte (AOAC).

❖ **Skill** – ability to apply knowledge effectively and readily in performance (ISO 10015).

❖ **Standard Operating Procedure** – a document that specifies or describes how an activity is to be performed. It may include methods to be used and sequence of operations (FLAWG).

❖ **Test** - technical operation that consists of the determination of one or more characteristics of a given product, process, or service according to a specified procedure (ISO Guide 2).

❖ **Traceability** – the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons (VIM).

❖ **Training** – a process to provide and control competence to meet requirements (ISO 10015).

❖ **Validation** - Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled (ISO/IEC guide 99).

❖ **Verification**- Provision of objective evidence that a given item fulfills specified requirements. (ISO/IEC guide 99).

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4.1. Impartiality

This section explains about the Impartiality followed in our laboratory

Key Words

Impartiality

Risk to Impartiality

References

ISO/IEC/ 17025:2017 Section 4.0

4.1.1 Our laboratory activities are undertaken impartially. Our laboratory is structured and managed in such a manner so as to safe guard impartiality. The laboratory is the part of Christy Friedgram Industry Private Limited which carries out Food business operation and laboratory reports to the General Manager (Admin) who is in charge of the operations of this laboratory and production units. There is no potential conflict of interests between the laboratory and other departments, as the lab independently reports to the General Manager (Admin). Adverse influence against the laboratory's ability to operate in an independent manner is reduced by General Manager (Admin).

4.1.2 Our laboratory management system is committed to impartiality. Impartiality is explained to each employee and each employee of the laboratory signs the terms and conditions mentioned for Impartiality in the appointment order. Clause No. 6, 7 & 8 of Appointment order of the laboratory employee explains about impartiality.

4.1.3 Except the laboratory Head QA other employees of the laboratory is not allowed to directly deal with customer. Our laboratory is opened to In-house Testing for the raw materials, Processed Material, Semi-Processed materials, Finished Products and also follow the testing specification of material purchased and manufactured, partially opened to external customers or sister concerns. Our laboratory does not allow any commercial, financial or other pressures to compromise impartiality. Each and every activity is directly monitored by General Manager (Admin) and partiality of the laboratory activities is prevented.

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4.1.4 The laboratory identifies the risks to its impartiality on an on-going basis. The risk includes that arise from its activities or from the relationships of its personnel. The relationship that threatens the impartiality of the laboratory which arise from ownership, governance, management, personnel, shared resources, finances contracts, marketing and payable of a sales commission or other inducement for the referral of new customers etc. is identified and is controlled in such a manner that risks to its impartiality does not occur in laboratory activities.

4.1.5 Document of Identification, elimination or minimization of Risks to impartiality (CFIPL/NABL/DOC-01 (4.1.5)) demonstrates how the laboratory identifies, eliminates or minimizes if such risks to impartiality is identified.

4.2 Confidentiality

4.2.1 For the management of all information obtained or created during the performance of laboratory activities, our laboratory takes the responsibility, through legally enforceable commitments. The customers will be informed well in advance of the information that is intended to be placed in public domain. All the information is considered proprietary information and will be regarded as confidential, except for the information that the customer makes publicly available, or when agreed between us and the customer.

4.2.2 When our laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned will, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer will be maintained confidential between the customer and the laboratory. The provider (source) of this information will be maintained confidential to the laboratory and will not be shared with the customer, unless agreed by the source.

4.2.4 Our laboratory personnel, including our committee members, contractors, personnel of external bodies, or individuals acting on behalf of us will keep all information confidential which was obtained or created during the performance of laboratory activities, except as required by law.

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Annexures, Documents, Procedures & Records:

Annexures:

Nil

Documents:

1. Document of Identification, elimination or minimization of risks to impartiality (4.1.5) - CFIPL/NABL/DOC-01.
2. Document of Risk identification, assessment and management (CFIPL/NABL/DOC- (4.1.4, 4.1.5 & 8.5.2).

Procedures:

Nil

Records:

1. Risk identification, assessment and management record (4.1.4, .1.5 & 8.5.2) – Record No. F- 07.

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5.0 Structural Requirements

This section explains about the structural requirement of our laboratory

Key Words

Legal entity

Laboratory activities

Management structure

Responsibility

Authority

References

ISO/IEC/ 17025:2017 Section 5.0

5.1 Legal Identification /Registration

Name and address of the Laboratory:

Food Safety and Analytical Quality Control Laboratory,

Christy Friedgram Industry Private Limited

A-2, A-3, SIDCO Industrial Estate

Andipalayam, Thiruchengode-637214

TEL : 04288 – 288900, 288999.

FAX : 04288 – 285963

The laboratory is named as Food Safety and Analytical Quality Control Laboratory Christy Friedgram Industry Private Limited and is located in Tiruchengode, Namakkal District, which carries out food business operation. The laboratory is part of this company and the company is registered under Companies Act, 2013. The legal documents are enclosed in Annexure: 1

The Chemical and Microbiological laboratories of Food Safety and Analytical Quality Control Laboratory - Christy Friedgram Industry Pvt Ltd have been organized to satisfy the needs of the customer and regulatory authorities and to operate to the International Standard of IS/ISO/IEC 17025:2017. The laboratory functions as an In-house laboratory and is also partly open to others.

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5.2 Our laboratory has identified management that has overall responsibility for the laboratory. The laboratory reports to General Manager (Admin). The Head of the Department reports directly to General Manager (Admin).

5.3 The other staffs and workers of the laboratory reports to the Head of the laboratory. Our laboratory is In-house laboratory and partly open to others. The laboratory plays a vital role in online quality monitoring and quality assurance of food operations carried in its parent organization. The range of laboratory activities is well defined and documented in Doc. No. CFIPL/NABL/DOC: 2.

5.4 Our laboratory activities are carried out in such a way to meet the requirements of ISO/IEC 17025: 2017, our customer, regulatory authorities and organizations providing recognition. The management system covers activities in the laboratory's permanent facilities.

5.5. a) Organization and management structure

The organization and management structure of the laboratory, its place in the parent organization, and the relationships between management, technical operations, support services, and the Management System is defined through the aid of an organizational chart (see Annexure 2).

5.5. b) Responsibility and authority

Director (T.S.Kumarasamy & Satheeswaran)

- Develops primary goals, operating plans, policies, and short and long term objectives for the laboratory.
- Establishes organizational structure and delegating authority to subordinates.
- Leads the laboratory towards objectives, meets with and advises other executives, and reviewing results of business operations.
- Determines action plans to meet the needs of stakeholders.

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- Represents organization to major customers, government agencies, shareholders and the public.

General Manager (Admin)

- Develop, manage and guide the laboratory in operating, achieving primary goals, short and long term objectives.
- Guide the laboratory in implementing and following the policies and procedures.
- Review results of the laboratory.
- Evaluates the performance of laboratory personnel.
- Determines action plans to meet the laboratory activities.
- Participates in all senior-level administrative meetings of the organization as appointed by the Director (T.S.Kumarasamy & Satheeswaran).
- Authorized to take decision against any malfunction in performance of the laboratory staff. He is authorized by the Director (T.S.Kumarasamy & Satheeswaran) to remove or de-promote the persons who involved in such mal functions.
- Authorized to conduct surprise audits for evaluating the personnel in the laboratory
- Authorized to take decision on laboratory management

Head-QA (Manager -QA)

- Ensures that the Management System is established, implemented and maintained in accordance with the ISO/IEC 17025:2017 standard. Identifies deviation from the management system and from the procedures for performing laboratory activities.
- Provides the necessary resources (personnel, equipment, supplies) for quality assurance program, in order to ensure confidence in the laboratory's results.
- Manages the internal audit program. Records the minutes of MRM and implements

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the action plans.

- Coordinates all laboratory activities, certification and accreditation activities.
- Handles the maintenance and distribution of the Quality Manual and associated documents. Maintains a master list of current versions of quality documentation.
- Trains personnel on Management System activities
- Monitors the Laboratory Management System
- Reports on the performance of the Management System to senior management for review and as a basis for improvement of the Management System.
- Supervises the laboratory's inter-laboratory proficiency testing program.
- Ensures all equipment are maintained and calibrated, guides in validation and standardization of test methods, implements validated and standardized test methods.
- Verifies all reports and issues report to the respective department / customer.
- Assures the quality of all food products manufactured in the company.
- If any deviation is observed in both laboratory activities and quality of the food products, immediately intimates to the management for further corrective actions.
- Takes corrective action against all non-conformances observed and monitors its implementation for Preventive action.
- Head -QA is authorized to sign all the laboratory reports and other records.
- Head-QA is authorized to do surprise audits for evaluating the performance of the personnel in the laboratory. Recommends to the management for performance appraisal and if any mal functioned is observed, recommends for further action.

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- Authorized to take immediate decision in emergency situation in consultation with the General Manager (Admin).
- If any quality deviation is noted in the purchased raw materials or product manufactured, Head-QA is authorized to take decision on rejecting or recommending for reprocessing of the materials.
- Authorized to operate all the equipments in the laboratory.

Chief Analyst

- Is knowledgeable of the scope of all processes under his/her supervision.
- Ensures all equipment are maintained and calibrated, reporting all deficiencies (e.g. equipment malfunctions) in the appropriate manner substitutes when regular personnel are absent.
- Involves in standardization and implementation of testing methods, coordinates all laboratory activities.
- Verifies test procedures, testing and helps in performance evaluation of analysts.
- Maintains all laboratory records, stocks of chemicals and glasswares.
- Acts as custodian for all laboratory samples including counter samples.
- Initiates other laboratory works such as testing of Production samples from Govt. laboratories and/or FSSAI notified labs.
- Maintains other records of BIS & AGMARK certification.
- Authorized to operate all the equipment in the laboratory.
- Authorized to sign reports, relevant worksheets and chemical testing records.
- In absence of Head-QA, Chief Analyst is authorized to recommend for taking decision

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during quality deviation of the material received for production in consultation with Head-QA/ General Manager (Admin).

- In absence of Head-QA, Chief analyst, monitors the laboratory activities and reports to the management.
- Authorized to evaluate the performance of the senior analysts, analysts, junior analysts, sample collectors.

Senior analysts

- Maintains records of all quality activities as documented in SOPs and test methods.
- Handles samples and perform analysis according to SOPs and test methods.
- Prepare SOPs and test methods based on international approved standards.
- Maintains and calibrates equipment. Assist in maintaining the stocks of chemicals and glass wares.
- Act as Trainer for training the trainees & other analysts with regard to testing, handling & maintenance of equipment's.
- Report checking and cross verifying the results.
- Reports deficiencies or malfunction of the equipment and other things related to testing to the Head-QA.
- Identifies and records non-conformances on Corrective Action Requests.
- Identifies and records potential non-conformances on Preventive Action Requests.
- Corrects non-conformances and potential non-conformances.
- Improves laboratory and/or quality activities on a continuous basis.
- Online monitoring of Production process and collects sample from the production line.

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- Quality assurance of food products manufactured in the parent organization.
- Authorized to Sign reports.
- Authorized to access all equipments in the laboratory.
- Authorized to verify the results of Analysts and Junior Analysts.
- The senior analyst are authorized to verify the internal calibration records, maintenance and verification record of all equipment and chemical usage records.
- Authorized for recommending to stop testing / production during any emergency situations in consultation with Head-QA/General Manager (Admin).
- Identify the modification to be made in the quality system (Documents, Procedures, SOPs, worksheets, formats etc) and implement the same after getting approved form HEAD QA.
- Where ever approved by Head QA , the senior analyst are Authorized to verify the test reports to feed in the LIMS.

Analysts

- Handles samples and performing analysis according to SOPs and test methods.
- Maintains records of all quality activities as documented in SOPs and test methods.
- Online monitoring of Production process and collects sample from the production line.
- Quality assurance of food products manufactured in the parent organization.
- Authorized to access the particular equipment Specified by Head-QA/ Senior Analyst.
- Authorized to verify service maintenance of the equipment from outsiders and from the maintenance department.
- Train the new Joiner, as Authorized by Head-QA/ Senior Analyst.

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- Implement the corrective action during any deviation/non-conformance in consultation with Head-QA/ General Manager (Admin).
- Analysts are authorized to enter the data with regard to testing/Analysis in LIMS.

Junior Analysts

- Handles samples and perform analysis according to SOPs and test methods.
- Online monitoring of Production process and collects sample from the production line.
- Authorized to access the particular equipment approved by Head-QA/Senior Analyst.
- Authorized to verify the daily cleaning activity

Sample collectors

- Sample Collectors are trained in the area of sample collections stated in Quality Assurance procedure for sampling and sampling management.
- The responsibility of the Sample Collectors are to collect the raw materials or if any other materials as instructed by the Head-QA/Senior analyst.
- Samples are collected according the sampling plan and sampling procedure. Sampling management given by the laboratory.
- Performs the physical observation test for collected raw materials which is cross verified by the Senior Analyst / Head-QA.
- Receives the incoming samples from In-house production for testing and enters in the register.
- Sample collectors are authorized to access all equipment's necessary for physical observation of the sample collected.
- Sample collectors are authorized to access sample preparation rooms and testing areas except few restricted instrumentation rooms. Sample collectors are not authorized to

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access the computer in the laboratory.

5.5.c) To ensure the consistent application of the laboratory activities and the validity of the results, all the procedures given in the Quality System Procedures are documented with appropriate evidences to the extent necessary. The details of documentation for the respective procedures are given in the references of each QSP, STP & SOPs.

5.6. The Head-QA is appointed by the highest level of management. The Head-QA, who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the Management System is implemented, maintained and followed. The Head-QA identifies any deviation from the management system or from the procedures for performing laboratory activities. Initiates action to prevent or minimize such deviations, if any. The Head-QA has direct access to the highest level of management where decisions are taken on laboratory policy or resources and reports on the performance of the management system, any need for improvement and ensures the effectiveness of laboratory activities.

This statement notifies all laboratory personnel that S.Vimalan is the Head-QA as authorized by the Director (T.S.Kumarasamy & Satheeswaran). Any change in this position requires the reissue of this section to all holders of controlled copies of the Quality Manual.

Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent. If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

Personnel are aware of their role and importance in meeting the objectives of the management system. A thorough orientation and training program is adhered to all new employees which includes modules on organization's goals and objectives. Ongoing training for regular personnel is planned and carried out incorporating objectives relating to the area of work.

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5.7 The top management ensures the appropriate communication processes are established within the Laboratory and the communication is effective. Top management ensures that the integrity of the system is maintained when changes to the system are planned and implemented. Changes to the system which are likely to affect the integrity are absence of personnel for long periods, additional work load, equipment out of order etc.,. These would be reviewed and adequate steps taken to ensure that the system integrity is maintained.

Annexures, Documents, Procedures & Records:

Annexures:

1. Legal documents (5.3) – Annexure -1.
2. Organizational chart (5.5) – Annexure -2.

Documents:

1. Document of Range of Laboratory activities - CFIPL/NABL/DOC-02 (5.3).

Procedures:

Nil

Records

1. Roles and Responsibilities (5.5.b) - Record No.: F-04.

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6.0 Resource Requirements

This section explains about the resource requirement of our laboratory.

Key Words

Personnel

Facilities & Environmental Condition Equipment

Metrological Traceability

External Service Providers

References

ISO/IEC/ 17025:2017 Section 6.0

6.1 General

The laboratory has adequate number of staffs both in managerial and technical, facilities, equipment, systems, support services and other resources required to manage and perform the laboratory activities.

6.2 Personnel

6.2.1 All personnel of the laboratory act impartially. The laboratory identifies the risk arises from impartiality on an on-going basis. All the staffs of the laboratory are competent and work in accordance with the laboratory's management system.

6.2.2 Management ensures the competency of all specific equipment operators, those performing tests and/or calibrations, those evaluating results and sign test reports. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in test reports also have:

- Relevant technical knowledge for handling the instruments, products tested.
- Knowledge of the general requirements expressed in the legislation and standards.

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➤ An understanding of the significance of deviations found with regard to the normal use of the items, materials, or products concerned.

Management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. Competence requirements for each function influencing the results of laboratory activities are documented as prescribed in the cl.6.2.2. (Refer Document No. CFIPL/NABL/DOC-03).

6.2.3 Continued competence is monitored and where this is not achieved, the need to retrain personnel is considered. Where a method or technique is not in regular use, verification of personnel performance before they undertake tests, are verified. (Reference Record No. F-04- Competency Assessment and Monitoring Record (6.2.3, 6.2.5-a&f)).

6.2.4 The duties, responsibilities and authorities of the personnel are communicated. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to and implemented by the appropriate personnel.

The duties, responsibilities & authorities of the personnel are well explained in 5.5.b of this manual.

6.2.5 The laboratory have developed procedures and records are retained for determining the competence requirement, selection of personnel, training of personnel, supervision, authorization and monitoring competence of personnel. (QSP No.01 - Procedure for competency assessment, training, supervision, authorization and monitoring of competence of personnel CFIPL/NABL/QSP-01 (6.2.2)).

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Competent permanent employees are employed in the laboratory. The Head –QA / Senior Analyst ensures that technical employees, and key support personnel are supervised and work in accordance to the policies and procedures of this Quality Manual. (Reference Record No.- F-04- Competency Assessment and Monitoring Record (6.2.3, 6.2.5-a&f)).

Management has formulated goals with respect to the education and the skills of the laboratory personnel. The skills and knowledge are defined in the job description for each job function. Management compares the job description to the skills and knowledge of the new incumbent to determine the training needs. (Reference Record No. F-04-Appointment Order & Employee Qualification certificate (6.2.5-a, b,c,d,e,f)).

The training program is relevant to the present and anticipated tasks of the laboratory. Training in the laboratory includes all methods or parts of methods and techniques that personnel are asked to perform. For In-house training, a Senior analyst / senior analyst serves as the trainer. Minimally, the analyst must demonstrate competency by observation, by management and verification using replicate and/or check samples which ensures effectiveness of training provided. Re-verification of all personnel if necessary is performed on all methods or techniques pertinent to their job description. (Reference Record No. F-04(i)-Employee training Record (6.2.5-c)). Testing and supervision of testing is by an experienced person, qualified to degree level or as prescribed in the document of competence requirement. Personnel have relevant practical work experience (at least 6 months) before being allowed to perform accredited work.

Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained centrally in the administration area of the laboratory.

Minimum contents of job descriptions include:

- the duty of performing tests and/or calibrations

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- the act of planning tests and/or calibrations and evaluation of results
- The responsibility for reporting opinions and interpretations;
- the responsibility of developing and validating new methods as / when requested
- expertise and experience
- qualifications and training programs
- managerial duties

Job descriptions are dated and signed to demonstrate that each incumbent has read it and is in agreement. It is updated as and when new persons are appointed in the laboratory. (Reference Record No. F-04 Supervision of Personnel and Surprise Audit (6.2.5-a,b,c,d,e,f)).

The laboratory have well explained in the procedure, (QSP No.01 - Procedure for competency assessment, training, supervision, authorization and monitoring of competence of personnel CFIPL/NABL/QSP-01 (6.2.2)) for authorization of Personnel and the same is recorded (Reference Record No.-F-04- Authorized Personnel (6.2.5-e& 6.2.6))

The laboratory have developed procedure for monitoring the competence of personnel and the same is recorded (Reference Record No.- F-04- Competency Assessment and Monitoring Record (6.2.3, 6.2.5-a&f)).

6.2.6 The laboratory have authorized personnel to perform specific laboratory activities, including, development, modification, verification and validation of methods, analysis of results, including statements of conformity or opinions and interpretations, report, review and authorization of results. Management authorizes specific personnel to perform particular types of sampling, test and/or calibration, to issue test report, to give opinions and interpretations and to operate particular types of equipment. (Reference Record No.-F-04- Authorized Personnel (6.2.5-e & 6.2.6)).

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6.3 Facilities and environmental conditions

6.3.1 Laboratory facilities are appropriate to attain correct performance of tests and/or calibrations. This includes energy sources, lighting, heating, ventilation and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented. (Reference Record No.: F-08- Environment temperature monitoring record F-19(6.3.3).

This section deals with the test areas in the laboratory and premises for support such as sample receipt and storage. Central laboratory supplies and services, such as water purification systems, air supply and samples storage are appropriate to facilitate proper performance of tests.

6.3.2 Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Due attention is paid, for biological sterility, dust, air quality, humidity, electrical supply, temperature, and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

Laboratories are ventilated to reduce the levels of contamination, lower humidity, and control temperature. Chemical and Microbiological Laboratory test area where ever required is air-conditioned. The relative humidity in test areas is 30-75% and the temperature is 18°C-35°C except the hot areas where muffle, hot air oven, fume hoods, soxhlets are kept and these areas are maintained in room temperature.

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Bench tops and floors are made of impervious, smooth easily cleanable materials. There is at least two linear meters workspace per analyst while working. Walls and ceilings are made of materials that are smooth and easily cleaned. Critical work surfaces in microbiology laboratory are monitored for pathogens, the requirements for facilities and environmental conditions necessary for the performance of the lab activities are documented in document –CFIPL/NABL/DOC-04.

6.3.3 The laboratory monitors, controls and record environmental monitoring conditions in accordance with the document of Requirements for facilities and environmental conditions necessary for the performance of the lab activities - CFIPL/NABL/DOC-04 and recorded in environmental monitoring record (Record No.: F-19 – chemical testing & F-21 Biological testing (6.3.3).

6.3.4 Access to and use of areas affecting quality of the tests and/or calibrations is defined and controlled. Access to the laboratory is restricted to unauthorized personnel. The authorized personnel are made aware of the following items:

- The intended use of the area.
- The restrictions imposed on working within such areas
- The reasons for imposing the restrictions

Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary. Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements.

Laboratory is partitioned in such a way that the work is not affected and contaminated. Each division is separated from one another. The Layout of the laboratory (Annexure 3) explains the effective separation between areas affecting laboratory activities.

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Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

Reference materials and certified reference materials are kept separated from samples. Sample log-in and storage are segregated and include proper sanitation to exclude the possibility of cross-contamination. Segregation of activities is achieved through time and space allocations.

6.3.5 When the laboratory activities are performed at sites or facilities outside its permanent control, we will ensure that the requirements related to facilities and environmental condition as described in the document are met.

6.4 Equipment

6.4.1 Our laboratory has equipment such as measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus, etc. and the access to laboratory equipment is controlled to ensure that only authorized personnel use it. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel.

6.4.2 We ensure that the requirements for equipment of the document are met, when we use it outside our permanent control.

6.4.3 Methods and procedures for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration are given in QSP No.02-procedures for handling, transport, storage, use and planned maintenance of equipment- CFIPL/NABL/QSP-02 (6.4.3).

6.4.4 Before the equipment are placed or returned into services, we verify that the equipment conforms to the specified requirements (Reference Record. No. F-20- External

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Service Record (6.4.4 & 6.6.2)). Automated equipments are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. When received, equipment, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated.

The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

6.4.5 Equipment and software used for testing, calibration and sampling are capable of achieving the measurement accuracy and/or measurement uncertainty required to provide valid results and comply with specifications relevant to the tests and/or calibrations concerned.

6.4.6 Test and/or calibration equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling are calibrated before being put into service. All measurement and test equipment having an effect on the accuracy or validity of tests are calibrated and/or verified before being put into service. The QSP No.02, outlines an established program for the maintenance of equipment and includes calibration. Measuring equipment are calibrated when, the measurement accuracy or measurement uncertainty affects the validity of the reported results, calibration of the equipment is done when there is an requirement to establish the metrological traceability of the reported results.

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6.4.7 A detailed calibration programme is given in Document No. CF IPL/NABL/DOC-04 (6.4.7). The calibration programme is reviewed and adjusted as necessary in order to maintain confidence in the state of calibration.

6.4.8 Equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate.

Calibration labels have a write-on surface and a pressure sensitive adhesive. The areas that are filled out include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, and the equipment's identification number.

CALIBRATION BY _____ DATE _____ DUE _____ ID # _____
--

Measuring equipment that has failed calibration or is deemed out of service is labeled with one of the following labels:

CALIBRATION VOID

OUT OF SERVICE DO NOT USE

A piece of equipment that is not calibrated or checked and is used for reference purpose only is labeled with the following label:

FOR REFERENCE ONLY

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6.4.9 Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken as “out of service”, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly. Routine testing work is completely discontinued on equipment that even shows minor non-conformances. Not only we do this for ethical reasons in support of our client, but minor non-conformances are often indicative of major breakdowns of in-expensive equipment. These breakdowns are avoided wherever possible. Out of service equipment is clearly marked as outlined in section 6.4.8. The laboratory examines the effect of the defect or departure from specified limits on previous test and/or calibrations and institutes the “Control of Nonconforming Work” procedure as outlined in section 7.10.

6.4.10 when intermediate checks are required to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedure. Procedure for Intermediate checks of equipments (CFIPL/NABL/QSP-03 (6.4.10)) explains the same. Internal quality control checks are specified in individual test methods that are located in the appropriate laboratory areas. Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules as specified in (CFIPL/NABL/QSP-03 (6.4.10)).

The control check standards used to verify the accuracy of all the other standards are prepared independently. These control check standards are preferably prepared from a separate lot number or source. It is the responsibility of the Microbiologist / Chemists to establish and maintain the individual schedule for each SOP and/or test method.

6.4.11 Calibrations and reference material data that give rise to a set of correction factors are updated and implemented as appropriate to meet specified requirements, along with all

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copies of this data (e.g., in computer software).

The updating of correction factors including all copies is assured by following the appropriate test method or SOP. It is the responsibility of the Senior Analyst / HEAD QA to ensure that all copies are updated.

6.4.12 Safeguards against adjustment for laboratory equipment include:

- Detailed SOPs and manufacturer's manuals on the operation of the equipment
- Policies permitting only fully trained and competent personnel to operate equipment
- Access to the laboratory is restricted to authorized personnel Safeguards against adjustment for software include:
- Password protection for important files and packages
- Access to the laboratory is restricted to authorized personnel.

6.4.13 Records are retained for equipment that can influence laboratory activities, the records include the following;

- a. The identify of equipment;
- b. The manufacturer's name, type identification, and serial number or other unique identification;
- c. Evidence of verification that equipment conforms with specified requirements;
- d. The current location;
- e. Calibration dates, results of calibration, adjustments, acceptance criteria, and the due date of the next calibration or the calibration intervals;
- f. Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
- g. The maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
- h. Details of any damage, malfunction, modification to, or repair of, the equipment.

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(Reference: Records with Record Nos. From F-05 to F-20 – chemical testing & Record Nos. from F-21 – Biological testing are retained for equipment which can influence laboratory activities).

6.5 Metrological Traceability

6.5.1 We have established and maintaining metrological traceability of the measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. Test and/or calibration equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling are calibrated before being put into service. All measurement and test equipment having an effect on the accuracy or validity of tests are calibrated and/or verified before being put into service.

6.5.2 The measurement results are traceable to the International system of Units (SI) through:

Calibration done by competent laboratory. Calibration of all instruments are done in NABL accredited laboratory, who fulfils the requirements of IS/ISO/IEC 17025:2017. Certified values of Certified Reference materials are procured from a competent producer only. Direct realization of the SI units is ensured by comparison, directly or indirectly with national or international standards.

6.5.3 When metrological traceability to the SI units is not technically possible, we demonstrate metrological traceability to an appropriate reference. The certified values of CRM/SRM materials by the competent producers are received with CRM /SRM or COA certificate. (Reference Record No.S-01 -CRM/COA certificate (as soft copy) (6.5.3))

Results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended uses are ensured by suitable comparisons. As mentioned in section 6.4.10 and QSP (CFIPL/NABL/QSP-03 (6.4.10)). Outlines an established program for the maintenance of

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equipment and includes calibration.

The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform tests and calibrations

Procedures are documented where appropriate. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained for each standard. These records include details, as applicable:

- Supplier, grade, batch#
- Dates of preparation or verification
- Measurement of weights, volumes, time intervals, temperatures, and reassures and related calculations
- Relevant processes (e.g., pH adjustment, sterilization)
- Verification results
- Identification of personnel involved

(Reference Record No.: F-08 CRM usage record (Chemical Testing) (6.5.3 & 7.7.1.a.)

Records are maintained for each lot of test organisms. These records include, as applicable:

- source, including age, species, and lot#
- date of arrival
- arrival condition
- culture and/or holding conditions
- feeding history
- health history including mortality, disease and treatment

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- acclimation history

(Reference Record No.: F-08 - CRM Viability Check (Biological Testing) & Record No.: F-08- CRM usage record (Biological Testing) (6.5.3 & 7.7.1.a.).

Disposal of test organisms is carried out after decontamination and conforms to applicable legal requirements.

Reagents prepared in the laboratory are labeled to identify substance, strength, solvent (where not water), any special precautions or hazards, restrictions of use, and date of preparation and/or expiry. The person responsible for the preparation of the reagent is identified from the label and from records. (Reference Record No.: F-12- Chemical quality check record (6.5.3&7.5.1), Record No.:12- Reagent Preparation and Standardization record (6.5.3 & 7.5.1), Record No. F-12 - Media preparation record (6.5.3 & 7.5.1) and Record No.: F-12 - Media quality check record (6.5.3 & 7.5.1), (7.5.1).

6.6 Externally provided products and services

6.6.1 The laboratory uses only suitable externally provided products and services, which are intended for incorporation in to the laboratory's own activities, which are provided in part or in full, directly to the customer as received from the external provider and when used to support the operation of the laboratory. The Laboratory seeks external provided services if necessary due to the following reasons;

- Unforeseen circumstances such as heavy work load, temporary incapacity or on a continuing basis (permanent subcontracting or franchising arrangements) this work shall be placed with a competent subcontractor.
- If any external provided services is done, the service providers will be selected on competent basis, who complies with this national or International standard for the specific work is question. The competence of external service providing laboratories will be assessed and the work will be allotted to the lab who fulfills the audit criteria. The testing will be given to the NABL accredited labs and preference will be given to FSSAI notified labs

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- It is the responsibility of the HEAD QA to assess and approve the competence level of subcontractor laboratories.

6.6.2 The laboratory uses QSP No.04-Procedure for Externally provided products and services (CFIPL/NABL/QSP-04 (6.6.2)) for

- Defining the criteria, reviewing and approving the laboratory's requirements for externally provided products and services. (Reference Record No.F-47-External Service Provider record).
- Defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers, that critically affect the quality of the tests/calibrations.
- Ensuring quality of externally provided products and services shall be followed when authorizing the use of externally provided products and services and when responding to conform to the laboratory's established requirements, or when applicable to the relevant requirements of ISO/IEC/IS 17025:2017, before they are used or directly provided to the customer.
- Taking any actions arises from evaluation, monitoring of performance and re-evaluation of the external providers. This procedure describes the process for selection, purchase, reception and storage of equipment, services and supplies including reagents, and laboratory consumables used for tests/calibrations. Consumable materials are stored according to the appropriate test method, SOP, or work instruction. External provided services are done after assessing the competence of them.

6.6.3 Requirements are communicated then and there to authorized providers according to the procedure given in QSP No.04-Procedure for Externally provided products and services (CFIPL/NABL/QSP-04 (6.6.2)) for the products and services to be provided by the external providers, the acceptance criteria, competence, including any required qualification of personnel, activities that the laboratory or its customer, intends to perform at the external provider's premises.

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Annexures, Documents, Procedures and Records

Annexures:

1. Layout of the laboratory - Annexure 3.

Documents:

1. Document of Competence requirements - CFIPL/NABL/DOC-03 (6.2.2).
2. Document of Requirements for facilities and environmental conditions necessary for the performance of the lab activities CFIPL/NABL/DOC-04 (6.3.2).
3. Document of Calibration Programme - CFIPL/NABL/DOC-05 (6.4.7)

Procedures:

1. Procedure for competency assessment, training, supervision, authorization and monitoring of competence of personnel CFIPL/NABL/QSP-01 (6.2.2).
2. Procedures for handling, transport, storage, use and planned maintenance of equipment- CFIPL/NABL/QSP-02 (6.4.3).
3. Procedure for Intermediate checks of equipments -CFIPL/NABL/QSP-03 (6.4.10).
4. Procedure for Externally provided products and services - CFIPL/NABL/QSP-04 (6.6.2).

Records:

1. Appointment Order & Employee Qualification certificate(6.2.5-a,b,c,d,e,f)-Record No.F-04.
2. Employee training Record (6.2.5-c) - Record No. F-04(i).
3. Supervision of Personnel and Surprise Audit (6.2.5-d) - Record No. F-04.
4. Authorized Personnel (6.2.5-e & 6.2.6) - Record No.-F-04.
5. Competency Assessment and Monitoring Record (6.2.3, 6.2.5-a & f) - Record No. F-04.
6. Environment monitoring record (6.3.3) - Record No.: F-19 – chemical testing & F-19– Biological testing.
7. Records for equipment - Record Nos. From F-05 to F-20 – chemical testing & Record

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Nos.F-21– Biological testing (6.4.4, 6.4.7, 6.4.10, 6.4.11, 6.4.13, 7.6.2, 7.7.1.e).

8. External Service Record (6.4.4 & 6.6.2) - Record. No. F-05.

9. Chemical quality check record (6.5.3 & 7.5) - Record No.: F-12.

10. Reagent Preparation and Standardization record (6.5.3 & 7.5) -Record No.: F-12.

11. List of Equipment and Calibration Certificate File (6.4.4 & 6.6.2) – Record No.: F-05.

12. List of Reference materials and CRM usage record (Chemical Testing) (6.5.3 & 7.7.1) -
Record No.: F-05 & F-08.

13. CRM Viability Check (Biological Testing) (6.5.3 & 7.7.1.a) - Record No.: F-08

14. CRM usage record (Biological Testing) (6.5.3 & 7.7.1.a) - Record No.: F-08

15. CRM/COA certificate (as soft copy) (6.5.3) - Record No.S-03

16. Media quality check record (6.5.3 & 7.5.1) - Record No. F-12

17. Media preparation record (6.5.3 & 7.5.1) - Record No.: F-12

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7.0 Process Requirements

This section explains about the process requirement of our laboratory.

Key Words

Review
 Verification
 Validation
 Sampling
 Measurement Uncertainty
 Report
 Conformity
 Interpretation
 Complaints
 Non Conformance

References

ISO/IEC/ 17025:2017 Section 7.0

7.1 Review of request, tenders and contracts

7.1.1 The laboratory has established a procedure and follows the procedure given in CFIPL/NABL/QSP-05 (7.1.1) for the review of requests, tenders and contracts.

➤ This laboratory caters exclusively to the needs of the in-house customers and there is no formal review for the routine tests being that is being carried out as the user department's needs are well known and understood, including the methods to be used.

An annual review of the requirements of the user departments is undertaken to ascertain and document the need for any additional tests or to alter the frequency of tests performed and accordingly the same is documented in the record. (Reference Record No. F-05, Review of request, tenders and contracts (7.1-7.1.1))

➤ The laboratory follows the requirements specified in clause 6.6, when external providers are used. The laboratory has the capability and resources to meet the requirements as the facilities and resources have been planned to meet the demands of

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the user department. The appropriate test method is selected and capable of meeting the external customer's requirements also.

- The review also establishes that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests in question.
- It is the policy of our laboratory to ensure that Test methods, including methods for sampling, meet the needs of the user department and are appropriate for the tests and/or calibrations we undertake. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application. Methods that have been published either in international, national, or regional standards, or by reputable technical organizations, or in relevant scientific texts or journals. These methods are adopted from the {BIS, IP, ISO, FSSAI, Food chemical codex, AOAC, APHA, APHA Compendium of Methods for the Microbiological Examination of Foods, ISO). The ability of the laboratory to achieve satisfactory performance against documented performance characteristics is verified before samples are analyzed. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The Test methods that are followed by the laboratory are given as Standard Testing Procedures (STPs) soft copy and relevant IP, AOAC Books are hard copies. (Reference Record No. S-05- Standard Testing Procedures (7.1.1).

7.1.2 The customer is informed as to the method chosen. The laboratory confirms that it can properly operate standardized methods before introducing the tests. If the standardized method changes, the confirmation is repeated. The customer is informed when the method proposed by the customer is considered to be inappropriate or out of

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date. Head QA/Senior Analyst is responsible for issuing, amending, updating, retrieving and approval of test and calibration methods.

7.1.3 In case of internally or externally received samples, unless the user department or customer request for a statement of conformity either in written or through other means of communication, the statement of conformity will not be applied. Where ever essential, the in-house or external test reports are issued with a statement of conformity to a specification or standards whichever is requested by the user department/customer(in case of external samples), decision rule for providing such statement will be based on the measurement uncertainty value of that particular parameter and matrix. The level of risk associated with decision rule is taken in to account. If the statement of conformity is applied, the same is communicated to, and agreed with, the customer. (Reference:- Record No.: F-18 & S-08– Work Sheets and Analytical Reports (7.1.3, 7.5.1, 7.5.2 & 7.8).

7.1.4 As mentioned in 7.1.1, the laboratory caters their work to the In-house requirement, the request are discussed in the annual meeting, and if any immediate changes in the request or any differences on the request arises the same is discussed by conducting intermediate meeting with the user department and the same is communicated to the management. In case of any difference between the request or tender and the contracts with the external customer of external service provider, the same is resolved before the laboratory initiates the activities in such a way that the deviations requested by the customer will not impact the integrity of the laboratory or the validity of the results. (Reference Record No. F-05, Review of request, tenders and contracts (7.1.1, 7.1.4, 7.1.8, 7.2.1.7 & 7.4.3).

7.1.5 The laboratory intimates the customer at the time of any deviations from the contracts.

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7.1.6 In case of any amendments after work has commenced, the contract review will be repeated and the amendments which is done will be communicated to all affected personnel.

7.1.7 The laboratory provides reasonable access to the relevant areas of the laboratory to witness customer specific laboratory activities. The laboratory or the authorized person of the laboratory clarifies the customer's request at any point of view and co-operates with the customer in monitoring the laboratory's performance in relation to the work performed.

7.1.8 Records of review of requests, tenders and contracts, discussion with the customers and the results of the laboratory activities are maintained. (Reference Record No. F-05, Review of request, tenders and contracts (7.1.1, 7.1.4, 7.1.8, 7.2.1.7 & 7.4.3)).

7.2 Selection, Verification and validation of methods

7.2.1.1 Laboratory uses various methods and procedures for all laboratory activities which are documented in the form of procedures and documents. Methods and procedures used for all tests and/or calibrations are appropriate as per:

Sampling, handling, transport, storage, and preparation of items to be tested.

An estimation of the measurement of uncertainty as well as statistical techniques for analysis of test and/or calibration data where appropriate. (Reference CFIPL/NABL/QSP-06 (7.2.1.1) - Procedure Selection and Verification of Methods).

7.2.1.2 All methods, Procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and are made readily available to personnel. Any amendments are requested in change request form and the same is reviewed and implemented. (Reference Record No.: F-13-Change request record (7.2.1.2)).

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7.2.1.3 The laboratory ensures that the latest valid version of methods are used unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application. International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations are not necessarily supplemented or rewritten as an internal procedures, when they are written in a way that can be used as published by laboratory staff. When necessary for providing additional documentation for optional steps in the method or additional details.

7.2.1.4 When the customer not specifies the method, the laboratory selects an appropriate method and informed to the customer of the method chosen. Methods that have been published either in international, national, or regional standards, or by reputed technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or modified methods adopted by the laboratory are also used.

7.2.1.5 The laboratory confirms that it can properly operate standardized methods before introducing the tests or calibrations through repeatability, reproducibility test and the laboratory performs Inter lab comparison before it introduces newly standardized methods to regular testing. The laboratory monitors the efficiency of result out puts on regular basis and verifies the same on regularly. (Reference Record No.: F-16- Method verification record (7.2.1.5))

7.2.1.6 Whenever method development is required, it is planned and the same is assigned to Senior analysts / senior analysts or analyst, if necessary and the same is monitored by Head-QA. Adequate equipments and other resources required for method development

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are made available by the Head - QA. Once the method is developed the method is validated and Periodic review is done before it is introduced for regular testing. Any modifications to the method development plan are approved and authorized by Head-QA. (Reference Record No.: F-16-Method validation record (7.2.1.6, 7.2.2.2 & 7.2.2.4)

7.2.1.7 Deviation from test and calibration methods are permitted only after it is technically justified, authorized, accepted by the customer and it is documented. (Reference Record No. F-05, Review of request, tenders and contracts (7.1.1, 7.1.4, 7.1.8, 7.2.1.7 & 7.4.3)

7.2.2 Validation of methods

7.2.2.1 Laboratory validates the non-standard methods, laboratory developed methods and standard methods when used outside our intended scope. The validation is done to meet the needs of the given application or field of application. Validation of test methods are done as per the standard operating procedure given in Procedure for Validation of Test methods CFIPL/NABL/SOP-02(7.2.2.1) Validation includes the procedures for sampling, sample handling and transportation of test or calibration items. The techniques of a validation method include:

- Calibration or evaluation of bias and precision using reference standards or reference materials.
- Systematic assessment of the factors influencing the result.
- Testing method robustness through variation of controlled parameters such as incubator temperature, volume dispensed.
- Comparison of result with other validated methods.
- Inter laboratory comparisons.
- Evaluation of measurement uncertainty.

7.2.2.2 Whenever changes are made to the validation method changes, the influence of such changes are determined and if the changes affects the original validation, new

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method validation is done and the same is recorded. (Reference Record No.: F-16-Method validation record (7.2.1.6, 7.2.2.2 & 7.2.2.4).

7.2.2.3 Performance characteristics of validated methods are assessed for the intended use, and relevant to the customers need and consistent with specified requirements.

Performance characteristics can include, but are limited to

- Measurement range
- Accuracy
- Measurement uncertainty of the results
- Limit of detection, limit of quantification,
- Selectivity of the method,
- Linearity, repeatability or reproducibility,
- Robustness against external influences or cross –sensitivity against interference from the matrix of the sample or test object and bias.

(Reference - Procedure for Validation of Test methods CFIPL/NABL/SOP-02 (7.2.2.1)

7.2.2.4 The laboratory retains the following records of validation

- Validation procedure used
- Specification of the requirements
- Determination of the performance characteristics of the method
- Results obtained
- Statement on the validity of the method, detailing its fitness for the intended use.

(Reference Record no: F-16 Method Validation Record (7.2.1.6, 7.2.2.2 & 7.2.2.4))

7.3 Sampling

7.3.1 The laboratory have developed sampling plan and sampling method for carrying out sampling of substances, materials or products for subsequent testing. (Reference CFIPL/NABL/SOP-03 (7.3) - procedure for sampling plan and sampling methods.

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Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide for testing or calibration as a representative sample of the whole. Sampling can also be required by the appropriate specification for which the substance, matrix, material or product is to be tested or calibrated. The sampling plan describes the allocation, withdrawal and preparation of a sample or samples from a substance, matrix, material or product to yield the required information. All samples are collected and placed in sealed containers.

7.3.2 As main function of the laboratory is testing of in-house samples, the samples are drawn by the user department in front of the analyst at the time of online (production process) monitoring. The laboratory does not collect the samples of external customer. The laboratory clearly specifies the sampling plan in the report.

7.3.3 The laboratory have trained sample collectors who are utilized for collection of in-house samples such as raw materials of and finished products. All the analysts are trained on sample collection for collecting the in house samples. The laboratory verifies sampling parameters such as sample quantity, lot size, no of bags sampled, etc., during sample receipt according to sampling plan. The procedure for sampling plan and sampling methods(Reference CFIP/L/NABL/SOP-03 (7.3))

The laboratory retain records of sampling data that forms the part of testing. The record includes the following;

- Reference to the sampling (specified in test reports).
- Date and time of sampling
- Data to identify and describe the sample
- Identification of the personnel performing sampling
- Identification of equipment used
- Environmental conditions

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- Identify the sampling location
- Deviations, additions to or exclusions from the sampling method and sampling plan.

(Reference Record No.: F-14-Sample register & Sampling Report (7.3.3, 7.4.3 & 7.5.1)

7.4 Handling of test or calibration items

7.4.1. The laboratory have established procedures for the transportation, receipt, handling, protection, storage, retention and disposal or return of test or calibration items, including the provisions necessary to protect the integrity of the test or calibration item, and the interests of the laboratory & the customer. Samples, reagents, and standards are stored so as to ensure their integrity` by preventing against deterioration, contamination, and loss or damage to the item during handling, transporting, storing/waiting and preparation for testing or calibration. The Personnel follow the handling instructions provided with the items. (Reference CFIPL/NABL/QSP-07 (7.4.1) - Procedure for Handling of test or calibration items).

7.4.2. The laboratory have a system for the unambiguous identification of test or calibration items. Test items are systematically identified as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

Sample labelling indicates the unique identification and conforms to applicable legal requirements. Samples received for chemical testing and Biological testing are entered separately in the sample register with unique identification number, which is referred as "Sample Code".

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7.4.3 Upon receipt of the test or calibration item, any abnormalities or departures from normal or specified conditions, as described in the relevant test or calibration method, are recorded. When there is any doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, the Laboratory consults the customer for further instructions before proceeding and record the result of this discussion. The laboratory includes a disclaimer in the test report indicating that the result may be affected by the deviation. The customer (Reference Record No. F-05, Review of request, tenders and contracts (7.1.1, 7.1.4, 7.1.8, 7.2.1.7 & 7.4.3)

When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded. (Reference Record No.: F-17 –Counter Sample Storage and Disposal record (7.4.4)

7.5 Technical records

7.5.1 Laboratory ensures that technical records for each test or calibration contains sufficient information to facilitate identification of factors affecting the measurement results and associated measurement uncertainty and to enable to repeat the test under conditions as close as possible to the original. The records include the identity of personnel responsible for sampling, performing of each test calibration and checking of results. Access to technical record is controlled to ensure that only authorized personnel use technical records for checking data and results. Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific job at the time they are made.

Reference records:

Record No.: F- 05 Equipment and Chemical/Media Purchase record-C/M (6.4.2), Record No.: S-07 - Chemical/Media Stock register C/M (7.5.1),

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Record No.: F-12 - Chemical/ Media Quality Checking record (7.5.1),

Record No.: F-12 – Reagent Preparation and Standardization record (7.5.1),

Record No.: F-14-Sample register (7.3.3, 7.4.3 & 7.5.1),

Record No.: F-18 & S-08 – Work Sheets and Analytical Reports (7.1.3, 7.5.1, 7.5.2 & 7.8),

Record No.: F-11 – Waste Disposal Record (7.5.1)

Record No.: F-19-Environment Monitoring Record (6.3.3)

Record No.: F-17- Counter sample Storage & Disposable record (7.4.4)

Record No. F-19-Water Purification Record (6.3.3)

7.5.2 Whenever amendments to technical records are made, the laboratory maintains both the original and amendment data and files are retained with traceability to the previous data, date of alteration done, indications or details of altered aspects and the personnel responsible for alterations. The altered data are verified and signed by the authorized signatory. Change request record No.F-13 (7.2.1.2).

7.6 Evaluation of measurement uncertainty

7.6.1 Evaluation of measurement uncertainty is done as per the procedure described in CFIPL/NABL/QSP-06 (7.2.1.1) (Procedure for Procedure Selection and Verification of Methods).

7.6.2 The laboratory uses the uncertainty of its own equipment derived during calibration of the equipment. Instruments and glasswares are calibrated by qualified external service provider as per the calibration programme. The uncertainty of measurement available on the certificate of analysis or calibration certificate from the external service provider is used for calculating measurement uncertainty.

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7.6.3 The Procedure for measurement uncertainty (CFIPL/NABL/QSP-06 (7.2.1.1)) is utilized to estimate uncertainties of measurement in testing, except when the test methods preclude such rigorous calculations.

7.6.4 In certain cases it is not possible to undertake metrologically and statistically valid estimations of uncertainty of measurement. In these cases the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope and makes use of previous experience and validation data.

The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- Requirement of the test method
- Requirement by the customer
- If there are narrow limits on which decisions on conformance to a specification are based

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement and follows the reporting instructions. The calculated measurement uncertainty for test methods are stored as soft copies. (Reference Record No.: S-03-Measurement uncertainty (7.6.3)).

7.7 Ensuring the validity of results

7.7.1 Quality control Procedure for ensuring the validity of results is given in CFIPL/NABL/QSP-08 (7.7.1). The procedure for each test method utilized in the laboratory. The resulting data are recorded so that trends are detectable and where practicable, statistical techniques are applied to the reviewing of results. This monitoring

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is planned and reviewed and may include, but not limited to, the following:

- Use of reference materials or quality control materials;
- Use of alternative instrumentation that has been calibrated to provide traceable results;
- Functional checks of measuring and testing equipment;
- Use of check or working standards with control charts, where applicable;
- Intermediate checks on measuring equipment;
- Replicate tests or calibrations using the same or different methods;
- Retesting or recalibration of retained items;
- Correlation of results for different characteristics of an item;
- Review of reported results;
- Intra-laboratory comparisons;
- Testing of blind samples;

For routine analysis, the level of internal quality control is typically 5% of the sample throughput. The use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the sample and spiked sample. The use of certified reference materials and reference materials to evaluate test performance on a regular basis for control checks.

When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically.

Replicate tests may be used if suitable reference material is available. These materials and proficiency test materials are available for improving repeatability.

Retesting of test items is performed occasionally when the test results are deviate from the previous data. (Reference Record No.: F-03 IQC Record (7.7.1.f.g.h & 7.7.3)).

Testing of blind sample shall be analysed to check the performance of the QA. (Reference Record No.: F-03 IQC/ Blind Sample Record (7.7.1.k & 7.7.3))

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7.7.2 The laboratory monitors the performance by participating in Proficiency test (PT) and Inter Laboratory comparisons (ILC) annually as per the ILC and PT plan. The results are reviewed and the same is recorded. If any deviations are noted in the Z score of PT participation, the laboratory initiates ILC for the same matrix and analyte and the same is recorded in Proficiency Testing participation record (Reference Record No.: F-02 (7.7.2,a,b & 7.7.3) and ILC record (Reference Record No.: F-02 (7.7.2,a,b)).

7.7.3 Data from monitoring activities are analyzed and the analyzed reports are used to control and improve the laboratory activities. Appropriate actions are taken to prevent incorrect results from being reported. The results of quality control data that are found to be outside pre-defined criteria (acceptance + 10%) planned actions will be taken to account and second sampling will be done for the acceptance level of + 10%, if again any data are reported outside the pre-defined data, the root cause for the same is done and the reason for the same is identified and necessary actions will be taken to prevent it. (Reference Record No.: F-03 IQC/Blind sample Record (7.7.1.a,b,f,g,h & 7.7.3 & 7.7.1.k))

7.8 Reporting of Results

7.8.1 General

7.8.1.1 The results are reviewed by the Head- QA or Senior analyst in case of chemical testing and for Biological testing the results are reviewed by Senior Analyst or Head- QA or by the authorized signatory deputed for reviewing the result. The worksheet are reviewed and signed by the authorized Personnel. (Reference Record No. F-04).

7.8.1.2 The results of each test are reported accurately, clearly, unambiguously and objectively usually in a report form. The results are reported normally in a test report and the report includes all the information requested by the customer, necessary for the interpretation of the results and information required by the method used. Test reports are issued as either hard copy or by electronic data transfer. The test reports also includes

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all the necessary information which is made mandatory by the accreditation body (NABL) or regulatory bodies. The test report formats will also be amended then there as per any amendments made in the standard or as suggested by the accreditation body or regulatory bodies. Amendment record (Reference Record No. F-13)

7.8.1.3 When agreement with customer, the results will be reported in a simplified way. The information listed in section 7.8.2 to 7.8.7 and not reported, is kept readily available.

7.8.2 Common requirements for test reports (test, calibration or samples)

7.8.2.1 Test reports include following information as appropriate

- a. A title (e.g. Test report)
- b. The name and address of the laboratory
- c. Location of performance of the laboratory (performed at customer facility or away from permanent facility or temporary or mobile facility).
- d. Unique identification of the test report including sample condition and clear identification of the end of the test report.
- e. Name and contact information of the customer
- f. Identification of the method used.
- g. Description, unambiguous identification and condition of the item tested.
- h. Date of receipt of test or calibration items and the date of sampling, where this critical to the validity and application of the results.
- i. Dates of performance of the laboratory.
- j. Date of issue of the test report.
- k. Reference to sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results.
- l. Where relevant a statement to the effect that the results relate only to the items tested.
- m. Test results with, where appropriate, units of measurement.
- n. Additions to deviations or exclusion from the method.

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o. Identification of the person(s) for authorizing the test report.

p. Clear identification when results are from external providers

The results from External providers will be identified with a mark of '+' followed by a note stating that '+' sign indicates that the particular report is from external providers/Lab.

A statement is included specifying that the test report is not to be reproduced except in full, without approval of the laboratory and provide assurance of a report are not taken out of context.

7.8.2.2 The laboratory is responsible for all information provided in the test report except when the information is provided by the customer. If the data provided by the customer is given in the report, it will be clearly identified. In addition, a disclaimer is made on the test report when information provided by the customer can affect the validity of test results. When the laboratory is not responsible for sampling and is provided by the customer, a statement is made on the test report stating that the sample not drawn by us, and the results apply to the sample as received.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2 test reports include the following, where necessary for the interpretation of results;

- Information on specific test conditions, such as environmental conditions,
- Where relevant, a statement of compliance/non-compliance with requirements and or specifications.
- Where applicable, a statement on the estimated uncertainty of measurement of the test result, information on uncertainty is provided in test reports when

It is relevant to the validity or application of the test results

When a customer's instruction so requires

When measurement uncertainty affects conformity to a specification limit.

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d. Where appropriate, opinions and interpretations.

e. Additional information required by specific methods, customers, or groups of customers.

7.8.3. 2 The laboratory responsible for the Sampling plan, sampling procedure, and test reports could meet the requirements listed in section 7.8.5 include the following, where necessary for the interpretation of results.

7.8.4 Specific requirements for calibration certificates

As the laboratory is a testing laboratory, clause from 7.8.4.1 to 7.8.4.3 is not applicable.

7.8.5 Reporting Sampling-specific requirements

The laboratory if necessary does sampling as per the management requirement. If sampling is done by the laboratory the laboratory abides this class in reporting the results. In addition to the requirements listed in 7.8.2, the report will include the following, where necessary for the interpretation of results.

- Date of sampling.
- Unique identification of the item or material sampled (including name of manufacturer, model or type of designation and serial numbers as appropriate).
- Location of sampling, including any diagrams, sketches or photographs.
- Reference to sampling plan and sampling method.
- Details of any environmental conditions during sampling that may affect the interpretation of the test results.
- Information required to evaluate measurement uncertainty.

7.8.6 Reporting statements of conformity

7.8.6.1 When statement of conformity to a specification or standard is provided, decision rule for providing such statement will be based on the measurement uncertainty value of

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that particular parameter and matrix. The level of risk associated with decision rule is taken in to account (Refer clause 7.1.3).

7.8.6.2 The statement of conformity report provided by the laboratory clearly identifies:

- The statement of conformity applied to which report.
- Which specifications, standards or parts thereof are met or not met;
- Decision rule applied (unless it is existing in the requested specification or standard).

7.8.7 Reporting opinions and interpretations

7.8.7.1 Head QA or the Authorized signatory expresses the opinions and interpretations and release the respective statement. When Opinions and interpretations are included in the test report, the basis upon which the opinions and interpretations have been made in documented.

7.8.7.2 The opinions and interpretation expressed as statement will be based on the test results obtained from tested item and that are clearly identified in the test report.

7.8.7.3 When opinions and interpretations are directly received by oral communication or by dialogue with the customer, the communication is recorded in the communication record and is retained. (Reference Record No.: F-15 – Communication record (7.8.7.3 & 7.8.8.1) & Record for documenting statement of conformity, opinions and interpretation -F-04).

7.8.8 Amendments to reports

7.8.8.1 When an issued test report needs to be changed, amended or reissued, amended test reports are issued and the change or amendments are clearly identified and the reason for the same is recorded. (Reference Record No.: F-15 – Report communication record (7.8.7.3 & 7.8.8.1)

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7.8.8.2 Material amendments to a test report after issue are made only in the form of a further document, or data transfer, which includes the statement “Supplement to Test Report / Amended Report with serial number...[or as otherwise identified]”, or an equivalent form of wording. Such amendments meets all the requirements in this document

7.8.8.3 When necessary to reissue a complete new report, unique identification number and reissue date is given along with the old (original/ earlier) report number and issue date of old report.

7.9. Complaints

7.9.1 The laboratory have a documented process to receive, evaluate and make decisions on complaints. (Reference CFIPL/NABL/DOC-07(7.9.1).

7.9.2 The description of handling process for complaints are made available to any interested party on request. Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities and if so the laboratory deals with the complaint. The laboratory takes the responsibility of all decisions taken at all levels of the handling process for complaints.

7.9.3 The process for handling complaints includes the following elements and method:

- Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
- Tracking and recording complaints, including actions undertaken to resolve them;
- Ensuring that appropriate action is taken

7.9.4 After the complaint is received, the laboratory gathers and verifies all the necessary information to validate the complaint.

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7.9.5 Once the complaint is received the laboratory acknowledges the receipt of complaint and provides the complainant with progress reports and the outcome.

7.9.6 The outcome to be communicated to the external complainant are reviewed and approved by our General Manager (Admin).

7.9.7 Whenever possible the laboratory gives formal notice of the end of the complaint handling to the complainant.

(Reference Record No.: F-07 – Customer Complaint Register, non-conforming work, and corrective action record (7.9 & 8.7)).

7.10 Non - Conforming work

7.10.1 The laboratory have implemented procedure (CFIPL/NABL/QSP-09 (7.10 & 8.7) - Procedure for non-conforming works) for non -conforming works which does not conform with the own procedure or agreed requirements of the customer such as procedure used to control any aspect of testing, or the results of this work, when they do not conform to the test methods or the agreed requirements of the customers (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria).

The CFIPL/NABL/QSP-09 (7.10 & 8.7) explains how the laboratory react to the non-conformity, action taken to control and correct it and how the laboratory address the consequences, used to control any aspect of testing, or the results of this work, when they do not conform to the test methods or the agreed requirements of the customer.

The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and when nonconforming work is identified, actions (including halting of work and withholding of test report as necessary) are taken by considering the risk levels established by the laboratory.
- An evaluation of the significance of the nonconforming work is made by

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considering the impact of previous analysis and a decision is taken on the acceptability of the non - conforming works.

- Remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming works.
- Where necessary, the customer is notified and the work is recalled.
- The responsibility for authorizing the resumption of work is defined. Identification of nonconforming work or problems with the Management System or with testing activities may come from various locations within the Management System and technical operations such as:
 - Complaints
 - Quality control
 - Instrument calibration
 - Checking of consumable materials
 - Staff observations or supervision
 - Test report checking
 - Management reviews
 - Internal or external audits

7.10.2 The laboratory retains records of non-conforming works and action specified in 7.10.1 (Reference Record No: F-07- customer Complaint Register, non-Conforming work and corrective action record (7.9, 7.10 & 8.7).

7.10.3 Corrective action is implemented by the laboratory as per the procedure for corrective action - CFIPL/NABL/SOP-01 (8.7), when the evaluation of complaint indicates that the non-conforming works could reoccur or there about the conformity with the laboratory's operations with its management system.

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7.11 Control of data and information management

7.11.1 The laboratory have access to the data and information needed to perform testing and other laboratory activities. The access to the laboratory activities is defined in section 5.5.

7.11.2 The laboratory information management system used for collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces with in the LIMS. Whenever any changes are made in the LIMS including the laboratory software configuration or modifications to commercial off-the-shelf software, they are authorized, documented and validated before implemented.

7.11.3 The laboratory information management system are:

- Protected from unauthorized access;
- Safeguarded against tampering and loss;
- Operated in an environment that complies with provider or laboratory specifications or in the case of non-computerized systems, conditions provided which safeguard the accuracy of manual recording and transcription;
- Maintained in a manner that ensures the integrity of the data and information;
- Includes recording system failures and the appropriate immediate and corrective action;

7.11.4 When a laboratory information system is managed and maintained off-site or through an external provider, the laboratory ensures that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory manuals, instructions and reference data relevant to LIMS are readily available to personnel.

7.11.6 Calculations and data transfer are checked in an appropriate and systematic manner. (Reference Record No.F-05- LIMS Monitoring Record (7.11)).

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Annexures, Documents, Procedures & Records:

Annexures:

Nil

Documents:

Document of process to receive, evaluate and make decisions on complaints - CFIPL/NABL/DOC-07 (7.9.1).

Procedures:

1. Procedure for Selection and Verification of Methods - CFIPL/NABL/QSP-06 (7.2.1.1).
2. Procedure for Validation of Test methods - CFIPL/NABL/SOP-02 (7.2.2.1).
3. Procedure for sampling plan and sampling methods (CFIPL/NABL/SOP-03 (7.3)
4. Procedure for Handling of test or calibration items - CFIPL/NABL/QSP-07 (7.4.1)
5. Procedure for ensuring the validity of results - CFIPL/NABL/QSP-08 (7.7.1).
6. Procedure for non-conforming works - CFIPL/NABL/QSP-09 (7.10 & 8.7).
7. Procedure for corrective action - CFIPL/NABL/SOP-01 (8.7).

Records:

1. Standard Testing Procedures (8.3.2) - Record No. S-04.
2. Review of request, tenders and contracts (7.1.1, 7.1.4, 7.1.8, 7.2.1.7 & 7.4.3) - Record No. F-05.
3. Change request record (7.2.1.2) - Record No.: F-13.
4. Method verification record (7.2.1.5) - Record No.: F-16.
5. Method validation record (7.2.1.6, 7.2.2.2 & 7.2.2.4) -Record No.: F-16.
6. Counter Sample Storage and Disposal record (7.4.4) - Record No.: F-17.
7. Chemical/Media and Equipment Purchase Record (7.5.1) - Record No.: F- 05
8. Chemical/Media stock register (7.5.1) - Record No.: S-06
9. Chemical/Media Quality Checking record (7.5.1) - Record No.: F- 12
10. Reagent Preparation and Standardization record (7.5.1) - Record No.: F-12

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11. Sample register (7.3.3, 7.4.3 & 7.5.1) - Record No.: F-14 (Chemical Testing) / (Biological testing)
12. Work Sheets and Analytical Reports (7.1.3, 7.5.1, 7.5.2 & 7.8) - Record No.: F-18 (Chemical Testing) / (Biological testing)
13. Copier Formats (7.5.1) - Record No.: F-10 (Chemical Testing) /(Biological Testing)
14. Waste Disposal Record (7.5.1) - Record No.: F-11(Chemical testing) / (Biological Testing).
15. Measurement uncertainty-C/M (7.6.3) - Record No.: S-04
16. LIST OF CRM and CRM Usage Record (7.7.1.a) - Record No.: F-08
17. Alternative equipment Record (7.7.1.b) - Record No.: F-05
18. IQC Record/Blind Sample Record (7.7.1,a,b,f,g,h & 7.7.1,k) - Record No.: F-03
19. Proficiency Testing participation record (7.7.2,a,b & 7.7.3)- Record No.: F-02
20. ILC record (7.7.2, a,b) - Record No.: F-02
21. Communication record (7.8.7.3 & 7.8.8.1) - Record No.: F-15
22. Customer Complaint Register, Non -Conforming work and corrective Action record (7.9) - Record No.: F-07
23. LIMS Monitoring Record (7.11) - Record No.F-05.
24. Record for documenting statement of conformity, opinions and interpretations - record No.F-04 (7.8.6 & 7.8.7).

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8.0 Management system requirements

This section explains about the management system requirements of our laboratory.

Key Words

Documents Records

Risks & Opportunities

Improvement

Corrective actions

Internal Audit Management Review

References

ISO/IEC/ 17025:2017 Section 8.0

8.1. Option

8.1.1. General

Our laboratory had established, documented, implemented and maintaining a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meet the requirements of Clauses 4 to 7, our laboratory had implemented a management system in accordance with Option A.

8.1.2 Option A

Our management system of the laboratory had addressed the following: —

- management system documentation
- control of management system documents
- control of records
- actions to address risks and opportunities

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- improvement
- corrective actions
- internal audits
- Management reviews

8.2 Management system documentation (Option A)

8.2.1 The Management System is established, documented, implemented and maintained in the laboratory. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel. The Management System is appropriate to the scope of its activities and in accordance with ISO/IEC 17025:2017 and NABL Documents. The purpose of our Management System is to ensure that all services and products satisfy the customer's requirements and have been designed, manufactured, and delivered under controlled conditions.

The effectiveness of the Management System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the Management System.
- by regular management reviews of the suitability and effectiveness of the Management System.
- by analysis of potential and actual problems as shown by customer complaints and supplier assessments.

This Quality Manual and associated documents (including procedures) and records serve as the quality plan for the laboratory. Other documents and records include:

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- Standard Operating Procedures (SOP)
- organizational charts

8.2.2 Policy

The policies and objectives for laboratory operations are documented in this Quality Manual. The overall intentions regarding quality are set out in the Quality Policy Statement. The Quality Policy Statement is issued under the authority of the Head-QA on the effective date.

Quality Policy Statement

- Ensure that all personnel's are competent to perform the tasks they perform and familiarize themselves with management system documentation and implement the policies and procedures in their work at all times.
- Ensure that our laboratory management system is committed to impartiality and the risk to impartiality is identified, eliminated or minimized, if risks to impartiality is identified.
- To ensure accurate and timely testing of samples. Consistently provide quality testing services that conform to customer and regulatory requirements. All the personnel's shall perform the testing professionally and effectively to achieve accuracy and precision.
- Tests are always carried out in accordance with stated standard methods and customers' requirements. Requests to perform tests that may jeopardize an objective result or have a low validity are rejected.
- Excellence in the workplace is promoted by providing all employees with the knowledge, training, and equipment necessary to allow for the completion of accurate and timely work.
- The Management is committed to complying with *IS/ISO/IEC 17025* and this continually improves the effectiveness of the Management System. This Quality Manual is to document the compliant policies and associated procedures that are integrated into our daily activities.

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Objectives:

- Ensure accuracy and reliability of test results through national, international & validated methods.
- Ensure that false positives or false negative are not reported.
- Maintain independence and confidentiality in all laboratory operations.
- Train staff regularly and maintain calibrated equipment.
- Conduct audits, reviews, and corrective actions for sustained excellence
- Improving customer satisfaction by ensuring the accurate and timely issuance of test reports in accordance with customer requirements and quality standards.
- Ensure effective internal quality control and satisfactory proficiency testing performance to deliver accurate, reliable, and consistent laboratory results.

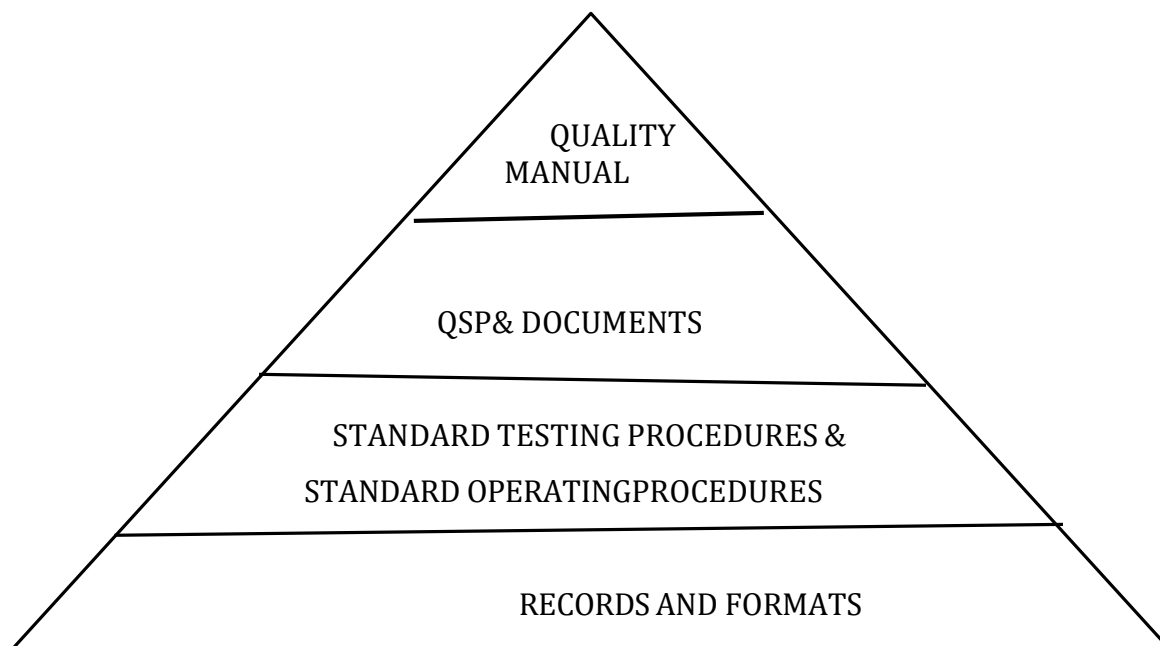
8.2.3 Evidence of Management's commitment to the Management system and its continual improvement in effectiveness is demonstrated by but not limited to participation of Managers in review, performance of internal audits, proficiency testing and the analysis of quality control samples.

8.2.4 This Management System is structured in four tiers of documentation. The tiers are as follows

1. Quality manual
2. Quality System Procedure & Documents
3. Standard Testing Procedure & Standard Operating Procedure
4. Formats and Records

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This Quality Manual makes reference to supporting procedures including technical procedures and is maintained up to date. For most customers, this Quality Manual and the associated documents form a general Quality Plan. If necessary, specific Quality Plans will be prepared on a 'per-customer' basis. These Quality Plans will modify the general requirements stated in the Manual and associated documents.

All of the above documents are controlled documents.

The details of records are given in the list of records and directive documents are referenced in the Quality Manual and also maintained separately. All documentation, processes, systems, records, related to the fulfillment of the requirements of this document had been included in, referenced from, or linked to the management system.

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8.2.5 All personnel involved in the laboratory activities have an access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents (Option A)

These include documents of external origin, such as regulations, standards, other normative documents, test and/or Internal calibration methods, as well as drawings, specifications, instructions, and manuals.

8.3.1 Method adopted for Control of all Management System documents (internally generated and from external sources) are discussed below.

Document means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. All these documents are given unique number for identifications, which includes document number, date of issue, amendment /revision number, page numbering, total number of pages, approving authority and issuing authority. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:

- Quality Manual
- Standard Operating Procedures and test methods
- List of Formats
- Reference materials
- IS,IP, ISO Standards & AOAC
- Developed and non-developed methods
- Internal audit
- MRM
- Audit Non-conforming Reports/Corrective action reports

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- Complaint register, communication records
- Enclosures
- Test reports
- Any relevant documents that are maintained as soft copies or any other documents which are covered in Laboratory Management System.

8.3.2

a) All documents issued to personnel in the laboratory as part of the Management System are reviewed and approved for use by authorized personnel prior to issue (i.e., reviewed by personnel knowledgeable in the documented activity and then approved by management). All the documents are approved by Head (QA) and the reports are approved by Authorized signatories.

b) Documents are reviewed three years once for verifying its suitability to the system and where necessary, revision are done to ensure continuing suitability and compliance with applicable requirements.

c) A master list identifying the current revision status and distribution of documents in the Management System is readily available in order to preclude the use of invalid and/or obsolete documents. A revision history of documents is also maintained. The documents related to the Quality Manual and Quality System Procedure, Standard Testing Procedure and Standard Operating Procedure are reviewed based on the following steps.

- The users of the document can request for change in the document through a note to the Head-QA, who shall review the request.
- If the reasons cited are found valid, the request are agreed to if the change do not affect any other aspect of the system. In case it is felt that other aspects of the system can be affected due to this change, this will be discussed at the management review and all necessary changes will then be taken up.

The document is suitably amended and reissued and the issue no. of the document is changed to the next number. The changed text is identified by and amendment record is issued along

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with the modified document. Changes to documents are reviewed and approved by the same function (i.e., personnel or position) that performed the original review. Developments in policies and procedures require documents to be changed from time to time. Changes to documents receive the same level of review and approval as the originals. The Quality Manual, Quality System Procedure, Documents, Standard Testing Procedure and Standard Operating Procedures are reviewed whenever amendments are made on the International/Indian standards whichever followed by the laboratory. Records are kept off this review.

The master list shows the current status of all controlled documents of Quality System Procedures, Standard Testing procedures and standard operating Procedures. The master list document is organized with the following information:

- Document #
- Title, Document name
- Master list Issue No & Date, Revision no & Date
- Location & details of Document Holder(Distribution list)

When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that

1. Computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use.
2. Procedures are established and implemented for protecting the integrity of data, such procedures included, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing.
3. Computers of automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.
4. Data is securely maintained by preventing unauthorized access to, and unauthorized

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amendment of, computer records.

5. All the data's maintained in computer are password protected and authorization is given to designated person to access the data maintained in the computer.

6. Controlled documents are approved before issue.

d) Authorized editions of appropriate documents are available at all the relevant locations where operations essential to the effective functioning of the laboratory are performed. Personnel concerned with the operation of the relevant aspects of the QMS are identified and it is ensured that the documents are distributed to them and the list of controlled copy holders and master list of all documents is given manual. The master copy of the documents containing the original digital signature is maintained by Laboratory Manager duly identified. Copies are made from the master and issued as controlled copies.

e) The documents are maintained in files so that they remain legible and no hand written correction is permitted. The unique number of each document identifies the files. The external documents relevant to the laboratory operations have been identified and listed in the master list of documents Record No.F-26). The Head-QA receives the external documents and if necessary, copies of the same are sent to the relevant areas of operation.

All Management System documentation is identified by:

- Document No.
- Date of issue & Issue No. and/or Date of Revision & Revision number
- Page numbering
- Total number of pages (e.g., page 5 of 5)
- Issuing authority (i.e., approval signature)
- Obsolete documents are withdrawn, but are retained for archive purposes and clearly labeled as obsolete. Invalid or obsolete documents are promptly removed from all points of issue or used to assure against unintended use.
- It is the responsibility of controlled copy holders to return the old document whenever

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the revised documents are issued. One copy of the old version is maintained by Head-QA duly stamped as obsolete. Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked (i.e., stamped "OBSOLETE").

In general, changes are recorded in the amendment record the quality manual with details of page Number and the corresponding section. Revision history is recorded at the end of the section. Hand-written amendments to documents are not permitted.

8.4 Control of records (Option A)

8.4.1 Our laboratory have established and retaining records to demonstrate fulfillment of the requirements in this document. Records are available to demonstrate conformance to requirements and effective operation of the Management System. Records are in the form of any type of media, such as hard copy or electronic media. Quality records include reports from internal audits and management reviews as well as corrective and preventive action records. All records are legible and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. The retrieval is facilitated by the numbering system and suitably indexed for storage. All records, including test reports, are safely stored and held secure in locked areas, and in confidence to the client. Records are maintained in the designated archival area. All the data's in the form of records maintained in computer are password protected and authorization is given to designated person to access the data maintained in the computer.

The retention times for records are generally set up to the extent of shelf life of the products for the in-house samples or the maximum of one year. On completion of the retention period the records are removed from its identified location and disposal off by shredding after obtaining clearance.

- A master list of records and formats is maintained by Head –QA.
- The master list of records is organized with the following information:

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- Name of the record
- Revision
- Record ID (No. / Form No.)
- Record type- Filing Method (loose forms filed monthly, quarterly, semi-annual, annual or electronic)
- Files (Active / Inactive) - Active Files (files referred to within the work area) / Retention Period / Location & Inactive Files (files referred to but not often and kept in storage) / Retention.
- Preparation (Prepared by)
- Review and Approved by
- Location

Reference (Record No.: F-01 & F-05 Master List of documents list of records, List of reference materials)

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The laboratory has considered the risks and opportunities associated with the laboratory activities in order to give assurance that the management system achieves its intended results; enhance opportunities to achieve the purpose and objectives of the laboratory; prevent, or reduce undesired impacts and potential failures in the laboratory activities; achieve improvement.

8.5.2 Our laboratory has planned actions to address the risks and opportunities; in order to integrate and implement these actions into its management system; the effectiveness of these actions are evaluated at planned intervals. The laboratory have identified the possible risks and opportunities associated with the laboratory activities and the details of Risk assessment, plan of action and evaluation of the risk is discussed in detail in the Document of Risk identification, assessment and management (CFIPL/NABL/DOC-(4.1.4, 4.1.5 & 8.5.2)

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8.5.3 Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results. (Refer Document- Risk identification assessment and management methodology (Document No.: CFIPL/NABL/DOC-06).

8.6 Improvement (Option A)

8.6.1 Whenever there is an availability, the laboratory identifies and selects the opportunities for improvement and implements any necessary actions. The quality policy is reviewed for its suitability and its continued effectiveness during management reviews. The achievement of objectives established is the prime concern of all employees. This is monitored and reviewed annually. All information relating to complaints and feedback are analyzed and actions taken are presented to the management. Results obtained in Proficiency test programme, internal Quality control checks are tabled at the management review and corrective and preventive actions arising out of it is documented and followed up. Opportunities for improvements needed and potential sources of non-conformances, either technical or with the Management System are identified. If action is required, action plans are developed, implemented and monitored, to reduce the likelihood of occurrence of such non-conformances and to take advantage of the improvement opportunities.

8.6.2 Positive and negative feedback are obtained passively through ongoing communications. The feedback is analyzed and used to improve the Management System, testing activities, and customer service. Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers. (Reference Record No.: F-07-Customer Feedback record (8.6.2).

8.7 Corrective actions (Option A)

Determination of an ideal corrective action and Implementation of the same will receive our

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utmost attention in any non-conformances that occur.

The Procedure for corrective action - CFIPL/NABL/SOP-01 (8.7) is utilized for implementing corrective action when nonconforming work or departures from policies, process and procedures in the Management System or technical operations have been identified. Appropriate authority is been designated for the implementation of corrective actions. The CFIPL/NABL/SOP-01 (8.7) includes cause analysis, selection and implementation of corrective action, and monitoring of actions.

Problems with the Management System or technical operations of the laboratory are identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feed-back from customers, or staff observations.

Corrective action investigations are documented and required changes to operational procedures are implemented. The Corrective Action Request investigation and resolution are recorded on a change request form.

8.7.1 When a Non conformances arises or occurs, the laboratory follows the CFIPL/NABL/QSP-09 (7.10 & 8.7) - Procedure for Non-conforming works to implement at the occurrence of Non conformances. Our laboratory reacts to the non-conformity and take actions to control and correct it. Corrective action always begins with an investigation to determine root cause(s) of the problem. The non-Conformity is reviewed and analyzed. Since the root cause of the problem is not obvious a careful analysis of all potential causes is required. Potential causes of the problem could include customer requirements, the samples, sample specifications, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration. The action taken against the corrective action is implemented, the effectiveness of the corrective action is reviewed at the time of management review. The risk and opportunities identified as a new one are included in the risk assessment list and is considered at the time of evaluation of the risk assessment and planning. If

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necessary, changes to the management system are done. (Record No:F-07- Customer complaint register, non - conforming works and corrective action record (7.10 & 8.7)).

8.7.2 After determining the cause(s) of the problem, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the problem and to prevent recurrence. It should be noted that any corrective action taken to eliminate the cause(s) of nonconformance or other departures are to an appropriate degree to address the magnitude of the problem and commensurate with the risks encountered. Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

8.7.3 After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the problems originally identified. Monitoring is assigned to an appropriate individual such as the originator of the CAR or the originator's manager. Changes resulting from corrective action are documented and the same are retained. When the identification of non-conformances or departures casts doubts on compliance of policies, procedures or process, regulations, international or Indian standards that are followed, the appropriate areas of activity are promptly audited. (Reference Record No: F-07-Corrective action Record (7.10 & 8.7)).

8.8 Internal audits (Option A)

8.8.1 The internal audit program involves periodic audits conducted according to a predetermined schedule for each year. These audits are performed to verify operations continue to comply with the requirements of the Management System including the laboratory activities and the requirements of the standards is effectively implemented and maintained.

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All elements of this Quality Manual, procedures, documents, process and all the relevant supporting documents will be audited ONCE IN SIX MONTHS/ whenever required. This program is defined on an annual basis and conducted as outlined in this section. The purpose of internal auditing is to ensure that the Quality Management is being operated correctly and effectively, by performing planned and documented checks, designed to ensure that:-

- The quality system documentation adequately defines the needs of the laboratory.
- The documented procedures are practical, understood and implemented.

8. 8.2 It is the responsibility of the Manager to plan and organize audit required by the schedule and requested by management. The CFIPL/NABL/SOP-04(8.8.2) Procedure for Internal audits define the procedure for performing and reporting internal audits. Audits are carried out by trained and qualified personnel who are independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out. Audits are performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit. The audit criteria and scope for each audit will be defined at the time of conducting the audit. Generally, the types of audits include:

- Quality Management System
- Processes and Procedures
- Services, and Reports

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken as per corrective action procedure CFIPL/NABL/SOP-01(8.7).

The results of each audit are to be reported to the relevant authorities of the section and simultaneously to the manager and the manager should bring the findings to the knowledge of the Head, to whom the laboratory is reporting. Clients are notified if investigations show

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that laboratory results may have been affected.

Non-conformances that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Non-conformances that require a more involved resolution are recorded on a CAR and resolved as described in section 8.7.1.

Corrective actions and customer modifications are kept in the (Record No:F-07- customer complaint register, non - conforming works and corrective action record (7.10 & 8.7) for each audit deviation that casts doubt as described in this section. Records are made of the activity being audited, the audit findings, and corrective actions that arise.

A report is prepared by the auditors and distributed to those audited and/or the area manager/supervisor within an appropriate and agreed timeline. The audit report may include the following sections, as appropriate:

- audit objective and scope
- area or section audited
- personnel involved – auditors and auditees
- date of audit
- reference documents
- observations including non-conformances and commendations
- opening and closing meetings
- recommendations
- audit report distribution

The auditee is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are kept in the laboratory.

Follow-up audits are performed to verify and record the implementation and effectiveness of the corrective action taken.

The follow-up audit is performed at a mutually acceptable time between the area

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implementing corrective action and the auditor. This time is determined when the Change request form is issued. (Reference – Record No.: F-07- Internal audit record (8.8).

8.9 Management reviews (Option A)

8.9.1 The laboratory management is reviewed ANNUALLY, in accordance with a predetermined schedule and conducts a review of the laboratory's Management System and testing activities to ensure the continuing suitability, adequacy and effectiveness, including the stated policies & objectives related to fulfilment of ISO/IEC/IS 17025: 2017 and to introduce any necessary changes or improvements.

8.9.2 The inputs to management review are recorded and includes information related to and the review takes account of:

- a) Changes in internal and external issues that are relevant to the laboratory;
- b) Fulfilment of objectives;
- c) Suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) Outcome of recent internal audits;
- f) Corrective actions;
- g) Assessments by external bodies;
- h) Changes in the volume and type of the work or in the range of laboratory activities;
- i) Customer and personnel feedback;
- j) Complaints;
- k) Effectiveness of any implemented improvements;
- l) Adequacy of resources;
- m) Results of risk identification;
- n) Outcomes of the assurance of the validity of results; &
- o) Other relevant factors, such as monitoring activities and training.

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8.9.3 Findings from management reviews and the actions that arise are recorded in the minutes of the meeting. Management will ensure that the actions are discharged within an appropriate and agreed timeline. The output of the management review recorded are related to the effectiveness of the management system and its processes; improvement of the laboratory activities related to the fulfilment of the requirements of ISO/IEC/IS 17025: 2017; provision of required resources & any need for change. The outputs from the management reviewed record all decisions and actions related to at least:

- The effectiveness of the management system and its processes;
- Improvements of the laboratory activities related to the fulfilment of the requirements of this document;
- Provision of required resources;
- Any need for change.

(Reference Record No.:07- Management review meetings record (8.9).

Annexures, Documents, Procedures and Records

Annexures:

Nil

Documents:

- Document of Risk identification, assessment and management (4.1.4, 4.1.5 & 8.5.2) - CFIPL/NABL/DOC-06).

Procedures

- Procedure for corrective action (8.7) - CFIPL/NABL/SOP-01.
- Procedure for non- conformity (8.7.1) - CFIPL/NABL/SOP-02.
- Procedure for Internal audits (8.8.2) - CFIPL/NABL/SOP-03.

Records

- Risk identification, assessment and management record (4.1.4, 4.1.5 & 8.5.2) - Record

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No. F- 07.

2. Record of Complaint register, non - conforming works and corrective action record (7.10, 8.7) - Record No: F-07.
3. Master List of Records (8.4) -Record No.: F-01 (Chemical & Biological).
4. Customer Feedback record (8.6.2) -Record No.: F-07.
5. Internal audit record (8.8) - Record No.: F-07.
6. Management Review meetings record (8.9) - Record No.: F-07.

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