

**PROJECT TITLE**  
**PLANNING AND IMPLEMENTATION OF 5S AND GOOD**  
**LABORATORY PRACTICES (GLP) IN QUALITY CONTROL LAB**

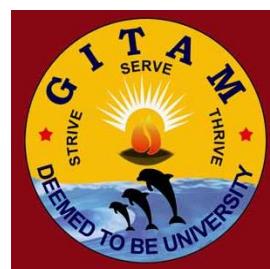
*A Project Dissertation*  
*submitted in partial fulfilment for the award of degree of*

**MASTER OF SCIENCE**  
**IN**  
**FOOD SCIENCE AND TECHNOLOGY**

**JULY - 2021**

**by**

**POULOMI GHOSH**  
**(Reg No: 121922802016)**



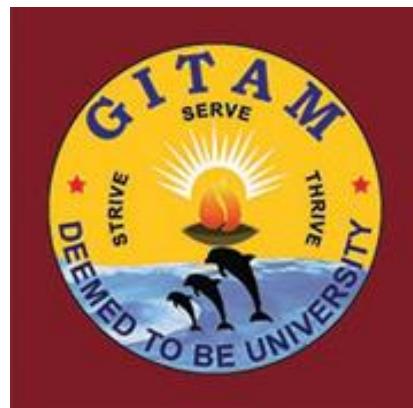
**DEPARTMENT OF MICROBIOLOGY AND FOOD SCIENCE AND TECHNOLOGY**

**GITAM INSTITUTE OF SCIENCE,**  
**GITAM (DEEMED TO BE UNIVERSITY)**

**VISAKAHPATNAM**

**2021**

# CERTIFICATE



This is to certify that the project work entitled "**“Planning and Implementation of 5S and Good Laboratory Practices (GLP) in Quality Control lab”**" has been done by **Ms. Poulomi Ghosh (Reg No: 121922802016)** a Bonafede student of the Department of Microbiology and Food Science and Technology, in partial fulfilment of her Master of Science in Food Science and Technology degree during the academic year 2019-2021.

Place: Visakhapatnam

Date: 19.07.2021

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## **CERTIFICATE**

This is to certify that the project work entitled "Planning and Implementation of SS and Good Laboratory Practices (GLP) in Quality Control lab" has been done by **Ms. Poulomi Ghosh (Reg No: 121922802016)** a Bonafede student of the Department of Microbiology and Food Science and Technology, GITAM under my supervision as a requirement for the completion of her Master of Science in Food Science and Technology degree.

The project was completed successfully and the objectives were met during the course of the dissertation.

I wish her every success in her future endeavour.

For Allied Blenders and Distillers Pvt Ltd.

A handwritten signature in black ink, appearing to read 'Lasat Tanu Basu'.

(Lasat Tanu Basu)  
Regional Head – QC & Process Excellence (East)  
Allied Blenders and Distillers Pvt Ltd.

Dated : 18<sup>th</sup> June 2021

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## **DECLARATION**

I, hereby declare that the project work entitled “**Planning and Implementation of 5S and Good Laboratory Practices (GLP) in Quality Control lab**” submitted by **POULOMI GHOSH** to the Department of Microbiology & Food Science and Technology, GITAM Institute of Science, GITAM (Deemed to be University), in partial fulfilment for the degree of Master of Science in Food Science and Technology is a record of original work carried out under the guidance and supervision of **LASAT TANU BASU**, Regional Head - QC and Process Excellence (East), Allied Blenders & Distillers Pvt Limited.. This work is original and is not been submitted elsewhere for any other academic qualifications.

Poulomi Ghosh

Date: 19.07.2021

Reg No: 121922802016

Place: Visakhapatnam

## **ACKNOWLEDGEMENT**

I would like to express my gratitude to my supervisor **Lasat Tanu Basu**, Regional Head QC and Process Excellence (East), Allied Blenders and Distillers Pvt Ltd, who gave me the golden opportunity to work on this project, titled "**Planning and Implementation of 5S and Good Laboratory Practices (GLP) in Quality Control lab**". Under his guidance and constant supervision, I am come across many new things which has enhanced my knowledge.

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I also want to express my deepest thanks to my Mentor **Dr. A. Rajani Chowdary**, Assistant Professor, Department of Microbiology and Food Science and Technology, GITAM Institute of Science, GITAM (Deemed to be University) for helping me and guiding me on the research aspects of the thesis which had made possible to accomplish this stupendous task.

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I consider it has a great privilege and an opportunity to do work in **Allied Blenders and Distillers Pvt Ltd**, Unit - Kalyani.

Lastly, I would like to thank my beloved parents as well with whose support I have been able to carry out the work in the limited time frame.

**POULOMI GHOSH**

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## **ABSTRACT**

In the present era of rapidly evolving technology and evidence-based medicine, Good Laboratory Practice play an important role in ensuring, consistency, reliability, reproducibility and quality of laboratory tests. GLP embodies a set of principles that provides a frame work within which laboratory studies are planned performed, monitored, and archived and reported. The purpose of the Principles of GLP is to promote the development of quality test data and provide a tool to ensure a sound approach to the management of laboratory studies, including conduct, reporting and archiving.

The concept of GLP originated in the USA in the 1970s because of concerns about the validity of non-clinical safety data submitted to FDA in the context of New Drug Applications (NDA). All GLP texts, irrespective of their origin, stress the importance of the following five points: 1. Resources: organization, personnel, facilities and equipment 2. Characterization: test items and test systems 3. Rules: study plans (or protocols) and written procedures 4. Results: raw data, final report and archives 5. Quality assurance.

The implementation of GLP at any place is correlated with the successful incorporation of 5S, since without 5S, GLP remains incomplete. The 5S Method is a standardized process that when properly implemented creates and maintains an organized, safe, clean and efficient workplace. It comprises of 5 S (Seiri / Sort, Seiton / Set in order, Seiso / Shine: Cleaning the work area, Seiketsu / Standardize and Shitsuke / Sustain.

An industrial quality Control laboratory was selected for stage wise implementation of 5S along with GLP, and review the effectiveness of implementation through checklist and user satisfaction survey.

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*Key words: GLP, Quality Assurance, FDA, Safety.*

# **CHAPTER 1**

# **INTRODUCTION**

Definition of **Quality** basically says "meeting or exceeding customer expectations." Actually, it is Cumulative characteristics of good service and Cumulative characteristics of production of goods and services.

**TQM (TOTAL QUALITY MANAGEMENT)** is sometimes defined as the implementation of QC circle activities across the organization; it is essential approach aiming at comprehensive quality management that utilizes capacity throughout the organization at maximum (aggregation of systemized methods). Constraint theory and Six Sigma are one of TQM approaches, and International Organization for Standardization (ISO) implementation is one example of its practice.

In most cases, indicating Continuous Quality Improvement (CQI) activities by Quality Control (QC) circles, but it also includes KAIZEN recommendations and field improvement activities (GEMBA KAIZEN). It is generally conducted through PDCA cycle, so that it can be called problem solving through participation by service providers.

**5S:** It is to implement Sort (S1): to eliminate what is unnecessary, set (S2): to align in the position easy to use, Shine (S3): to make things clean without trash or dust, and Standardize (S4): to maintain S1 to S3, and Sustain (S5): to voluntarily continue S1 to S4. Its original purpose is to delete the defect from finished goods with defect or dirt, and later utilized in the various purposes such as improving the work environment, organizational revitalization and management system improvement.

5S is a principle institutionalised in Japan and has yielded significant results in industrial and service sectors. These results are briefly known as incidents prevention, delays reduction and productivity enhancement in work environment. The ultimate goal of 5S is to prevent losses. Despite seeming simplicity of 5S in concept and implementation, organisations have great difficulty in its execution. In fact, managers and executive personnel are not well aware of goals of 5S. Therefore, it is quite difficult to set appropriate ground for implementing 5S, unless

its principles are well comprehended. These principles are known in form of five Japanese words, beginning with letter S, which later formed the term 5S.

The perceived benefits arising from successful 5S implementation include: less searching, improved cleanliness, easier recognition of defects, decreased walking and motion, reduced downtime, fewer safety hazards and accidents, improved flow, fewer mistakes, improved workplace visual management and better utilisation of space. These benefits add up to overall improvements in productivity, quality, cost, delivery, safety and morale.

### **HISTORY OF 5S**

The use of 5S as a strategy for achieving business excellence has been evident in Japan since the Second World War (De Mente, 1994). Osada (1989) introduced 5S in early 1980's for considerably enhancing the environmental performance in production and services. Since its introduction and acceptance by Japanese's firms in Japan, 5S practice has been successfully deployed in many western countries including USA. Firstly, 5S was implemented at Toyota Motor Corporation as part of their production system, namely TPS. The 5S has also been widely used in TQM systems, where it has been referred to as part of a series of quality initiatives (Yusof and Aspinwall, 2001; Ahmed and Hassan, 2003). 5S has evolved as an efficient housekeeping tool and a system for maintaining a good working environment (Ho, 1999a; Krasachol and Tannock, 1999). Now-a-days in this dynamic and technological world, 5S approach is essentially required for each and every company for their survival in its products and services.

### **NEED OF 5S IN INDUSTRY**

In contemporary competitive environment, industry has to increase its demand without increasing the sale price of their product. This has forced the manufacturing and service organisations to improve the effectiveness of production and other related operations to

improve the bottom line by reducing their costs. Thus to achieve the aforesaid targets, there is an emergent need of holistic adopting 5S principles in the industry. 5S has emerged as an effective foundation for various lean manufacturing improvement drives for eliminating waste from the manufacturing process and improve the organisation's bottom line by affecting sustained improvement in organisational functions.

5S initiatives provide an organisation with the framework and discipline needed to successfully implement various lean manufacturing continuous improvement initiatives. The four key objectives of a 5S deployment program include: developing kaizen-minded people at workplace; evolving teamwork through entire workforce participation; developing managers and supervisors for practical leadership; and improving infrastructure for adoption of advanced kaizen technologies (Tsuchiya, 1999).

5S can be used for setting in order materials, products, tools and documents (Chiarini, 2013). Tsuchiya (1999) has portrayed significant benefits of 5S as PQCDSM, that is, productivity – enhanced competitiveness; quality – eliminating defects; cost – eliminating waste; delivery – ensuring 100% customer order compliance; safety – eliminating accidents; and morale – good teamwork

## **GOOD MANUFACTURING PRACTICE**

**Good Manufacturing Practice (GMP)** is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

**GMP** covers all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff. Detailed written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide

documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

## **GOOD LABORATORY PRACTICE**

**Good laboratory practice** or good laboratory practices are accepted methods to carry out activities or operations in a laboratory. The authorities and laboratory organizations say that these practices help ensure safety. They also have a positive influence on the quality of the result. For pharmaceutical companies, for example, GLP compliance is extremely important.

Good laboratory practice is not only concerned with production, but also quality control.

“The principles of Good Laboratory Practice (GLP) promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices.”

GLP, commonly utilized in nonclinical or preclinical research studies, is a quality control system for management of research and development laboratory methods. Good Laboratory Practices by the FDA ensure high consistency, uniformity, reproducibility, reliability, integrity, and quality in nonclinical safety tests, toxicity tests, and physiochemical property studies.

In the preclinical research and development, GLP labs assess the safety profile, therapeutic dose, and chemical efficacy of the drug being tested on animal models. Note that good laboratory practices should not be mistaken with necessary laboratory safety during nonclinical studies such as effective utilization of appropriate personal protective equipment (PPE). Instead, good laboratory practices provide guidelines such that the studies are conducted under proper conditions, documented correctly, and provide reliable results.

As GLP lab, a facility must have (a) sufficient scientific staff with specific responsibilities, (b) an independent Quality assurance unit, (c) appropriate test facility to perform all research (d) all necessary equipment that is well maintained and calibrated, and (e) comprehensive SOPs to cover all operations. Studies must be performed under a defined study plan, and all documents related to studies must be archived and saved for at least 20 years.

**The purpose of the Principles of GLP is:**

- To promote the quality of test data;
- To avoid duplication of research;
- To improve the protection of human health and environment;
- To facilitate international acceptance of test data;
- To prevent the creation of technical trade barriers.

## **CHAPTER 2**

## **OBJECTIVE**

The main objectives of this project was to successfully implement the basic GLP standards and 5S -

- to promote the quality of test data;
- to avoid duplication of work
- to improve the protection of human health and environment;
- to prevent the creation of technical trade barriers.
- to remove unnecessary items and create an efficient workplace, thus increasing the productivity and leading to minimal wastage in and around the workplace.
- to decrease the unsafe working conditions, thus promoting safety at work

**CHAPTER 3**  
**REVIEW OF LITERATURE**

Osada (1991) views 5S as a strategy for organisational development, learning and change, whereas Hirano (1995) considers 5S to be an industrial formula that differentiates a company from its competitors (Bayo-Moriones et al., 2010). Esain et al. (2008) have identified 5S as a structural method to speed up operational change and focused on overseeing workplace discipline and control (Abdul Aziz et al., 2014).

5S methodology has become the topic of research in the recent times. Many researchers have investigated and formulated the methodologies of 5S, which have helped in optimising production and management in modern industries. The research and development efforts over the last three decades have resulted in improvement and increase effectiveness of processes. The literature of 5S methodologies has been reviewed thoroughly and it has been presented and discussed below:

Suehiro (1981) has concluded that the integrated visual control system (me-demirukanri) is necessary for successful 5S implementation. The Japanese approach to quality, just-in-time (JIT), kaizen (continuous improvement) and TPM have also been developed and formalised concurrently as a management method to commensurate with 5S principles.

Womack et al. (1990) have investigated the correlation between a 5S implementation and productivity, quality and cycle time measurements in a large manufacturing plant. The study concluded that lean uses less of everything compared to traditional manufacturing.

Osada (1991) has found 5S as a foundation to a total quality environment. According to Osada, 5S initiatives result in reducing waste and optimising productivity and quality by improving workplace efficiency and enhancing visual workplace management for realising significantly consistent operational performance. 5S leads to embedding the values of organisation, neatness, cleaning, standardisation and discipline into the workplace basically in its existing configuration.

Suzuki (1992) has claimed that 5S implementation autonomy have direct relationship with each other. In the Japanese context, 5S is a strong platform for the development of an integrated management system.

Sarthi (1996) has stated that improvement in the performance of Indian organisations have been stagnated over the years. Since 5S and TQM philosophies have proved its success world-wide and Indian organisations are also taking the same route for focusing on 5S and TQM tools extensively, one of the major reasons for dismal performance of Indian organisations in the world market may be attributed to the poor focusing on competency-based training for the improvement of 5S and TQM.

Chaneski (2004) observed that integration of 5S into the organisations can facilitate realisation of significant organisational achievements. The strategic initiatives for successful 5S program include highlighting the benefits of 5S program, ensuring total employee involvement, communicating progress made, addressing non-compliance and recognising the need for ongoing reinforcement.

Khamis et al. (2009) has concluded that effective implementation of the 5S activity depends on commitment of top-level management, total involvement of staff at all levels within the company, function and background of the business, publicity given to the 5S activity and finally the conducted for the organisation in implementing the 5S practices.

Goetsch and Davis (2010) have outlined that in order to have a dedicated and committed employee towards the implementation of 5S programs, the top management levels need to be proactive in introducing and promoting the importance of exercising 5S practices among their subordinates.

Ghodrati and Zulkifli (2013) have conducted a study to determine performance factors and characteristics in industrial organisations and identifying the effectiveness of 5S

implementation on organisational performance as well. The results show that 5S is an effective tool for improvement of organisational performance, regardless of organisation type, size, its production or its service. Consequently, 5S techniques had strongly supported the objectives of organisation to achieve continuous improvement and higher performance.

Zhang and Yaqing (2011) have presented discussions about defects found in 5S implementation based on investigations carried out in workshops of three make-to-order (MTO) electronic assembly companies of China. The study concluded that coordination and support from all employees and managers were essential for successful implementation of 5S.

Ramesh et al. (2014) has presented an application of 5S in technology in a Bio-mass processing unit. 5S lean technology has been utilised for achieving project diagnosing the production process, streamlining the workflow, removing/reducing process waste, cleaning the production environment. The work was a combination of both culture changes and tangible/physical changes on the shop floor. The 5S implementation has resulted in enhancement of efficiency and productivity, while ensuring a pleasant organisational climate. The project has drastically changed the plant and developed the infrastructure for a successful implementation of continuous improvement as well as other best practices and quality initiatives.

GLP was first introduced in New Zealand and Denmark in 1972. GLP was instituted in US following cases of fraud generated by toxicology labs in data submitted to the FDA by pharmaceutical companies. Industrial Biotech Labs (IBT) was the most notable case, where thousands of safety tests for chemical manufacturers were falsely claimed to have been performed or were so poor that police investigators could not piece together what work had been done even though IBT superficially delivered the test results their contracts with the manufacturers specified.

These issues were made public in the hearings at the US Congress, which led to the FDA's publication of Proposed Regulations on GLP in 1976, with establishment of the Final Rule in

June 1979 (21 CFR 58). The Environmental Protection Agency (EPA) had also encountered similar problems in data submitted to it, and issued its own draft GLP regulations in 1979 and 1980, publishing the Final Rules in two separate parts (40 CFR 160 and 40 CFR 792) in 1983.

To avoid different schemes of implementation that could impede international trade in chemicals, OECD Member countries have pursued international harmonisation of test methods and good laboratory practice. In 1979 and 1980, an international group of experts established under the Special Programme on the Control of Chemicals developed the “OECD Principles of Good Laboratory Practice” (GLP), utilising common managerial and scientific practices and experience from various national and international sources. These Principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)]

In 1995 and 1996, a new group of experts was formed to revise and update the principles. The current document is the result of the consensus reached by that group. It cancels and replaces the original Principles adopted in 1981.

**CHAPTER 4**  
**MATERIALS & METHODS**

## **MATERIALS:**

### **VISUAL TOOLS**

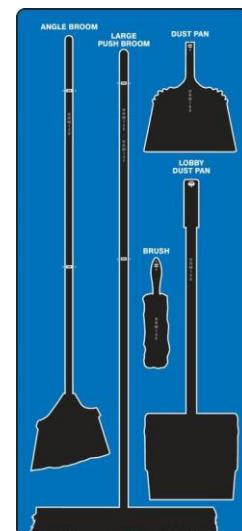
**Labels:** Labels are arguably the most useful tool for organizational strategy. Several areas and items in a space can be labeled. For example, you can place labels on tool drawers to identify contents or label shelves indicating where larger tools are to be stored. The floor can even be labeled to indicate where machinery, carts, trash cans and other equipment should be placed. Labels help workers know where items are stored should they need to move or use them.

These visuals use text, colours and symbols to convey information. They can indicate the



contents of drawers, call out hazards or tell people where to store parts. Many styles and sizes exist and some businesses even choose to make these in-house with a label and sign printer.

**Shadow boards:** Tools can become one of the most disorganized materials in a facility, however, shadow boards can help improve organization and ensure tools are stored properly. Essentially, a shadow board is a backing, usually a bright colour, that is visible when a tool is removed from a pegboard or tool chest.



**Tool foam:** Toolbox foam works similarly, except it fits into a toolbox drawer. The tool's shape is cut out of a top layer of foam, so a bright bottom layer of foam shows through. This method highlights missing tools and tell people exactly where tools should be placed when they are finished using them.



**Floor markings:** Floor tape is self-explanatory, but it can have a dramatic impact on visual workplaces. You can use floor tape to create defined spaces in an otherwise open facility floor or mark off work areas and create specific locations for pallets, raw materials, finished goods, shipping and other static locations.



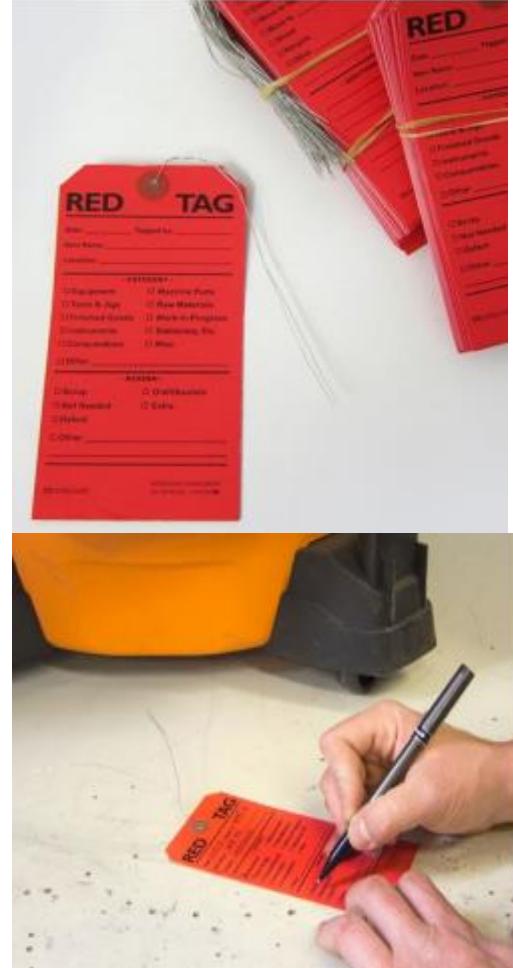
**Line Marking:** Painted or taped lines are often associated with safety (pedestrian paths, forklift and equipment paths, etc.). These techniques can be used for work cells of any kind. They will improve workflow and result in improved productivity. Additionally, misplaced items and equipment are easy to spot. You'll make it easier for employees and visitors to make sense of space.



**Wall signs:** Signs, posters, and banners are other methods that may help sustain your 5S efforts. Large signs can be hung above storage areas to indicate where tools and equipment are stored. You can also use posters to indicate clean-up areas and remind workers of the importance of 5S.

**Red tags:** Sorting, the first step of 5S, is designed to help go through the items in the space and decide what to do with them. 5S red tags are a tool used during this process to identify objects that may need to be removed, recycled or relocated. The idea of using red tags is to place items you may be unsure about in a kind of “holding area” to give you time to evaluate their necessity. You can mark off a red tag holding area with red floor tape and post signs indicating the red tag area. After some time has passed, you can re-evaluate the items by checking their red tag and decide whether they need to be relocated or removed from the facility entirely.

Also, a Red Tag needs to be put on some items which are difficult to decide whether those are necessary or unnecessary during Sort practice, and those items shall be observed for a month. If you did not move or use it for a month, it means these items are “may be necessary” or “unnecessary” for the current workflow. You need to decide on its category by ticking on the options on the tag 1) Necessary, 2) Uncertain or 3) Unnecessary, as illustrated right. These tags are needed to be managed by the person in charge of department.



**Colour coding:** Having color-coding standards in your workplace can help ensure a uniform style for your visual workplace. Colour coding can apply to a variety of areas, including colour coding shadow boards for tools, or following the colour code for floor marking standards. Another tool that can be used is a color-coded work board. These are work boards that are updated on a regular basis provide instructions on everyone's tasks in the workplace. Implementing a color-coded board can help employees keep track of their work tasks and 5S activities.



**Safety signs:** This tool is used for “Set” and “Standardize” activities. This is used to warn visitors and workers to pay attention on hazardous items. Majority of hazardous items that are commonly used have international/national standardized safety signs. Therefore, it is recommended to use common safety signs. If you may not find or have access to common safety signs, you may develop your own safety design.



**Symbols:** This tool is used for “Set” and “Standardize” activities. This is used for making everyone to understand the meaning of something by marks/symbols without or minimum explanation.



**Numbering / Alphabetical Cording:** This is used for “Set” activity. This is to organize files and other items by numbers / It helps users to find necessary things or information quickly and easily. It is



very useful for practice of “Can See, Can Take Out and Can Return” principle. It requires an agreed set of rules, or a central coordinator to maintain system.

## **METHODS**

### **TRAINING BEFORE IMPLEMENTATION:**

#### **Proper timing to conduct “briefing meeting”**

“Briefing meeting” was conducted which was related to “5S Basic Training”. Agendas were mainly “Explanation of 5S principles and effectiveness” and “Discussion for making decision”.

#### **Explanation of basic concepts and effectiveness of 5S activities**

It was explained that “What 5S principles are” and “How 5S is effective for working improvement” with materials provided at “5S Basic Training”. Awareness of importance of 5S activities shall be increased among all the members.

#### **Building consensus**

After explanation, it was also discussed that whether 5S approaches are useful for improving working environment or not. At the discussion, effectiveness and expected outcomes by installing 5S should be clarified concretely. - How 5S can contribute to improve working process/procedure.

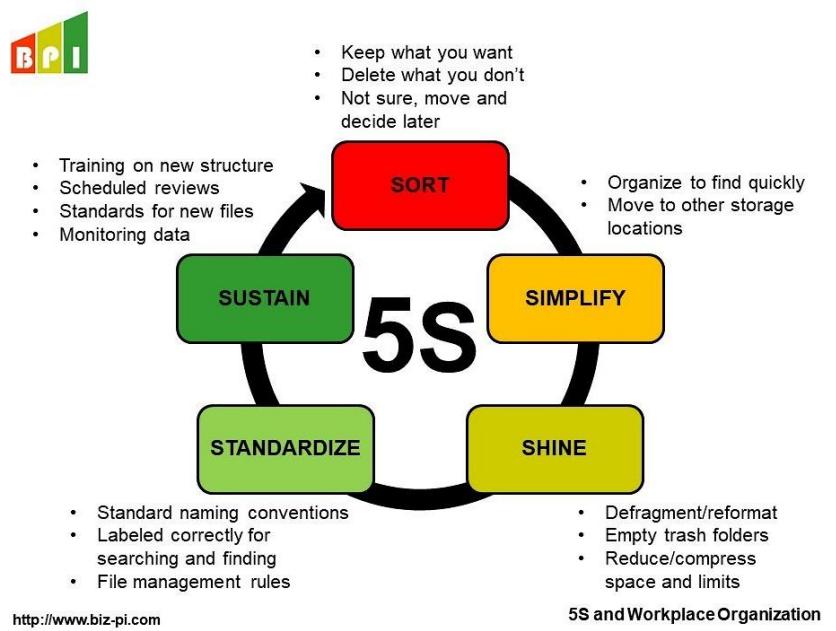
- How 5S can contribute to reduce cost, time burden in working procedures
- How 5S can contribute to prevent dangers, incidents and accidents in working place

5S represents Japanese words that describe the steps of a workplace organization process.

English equivalent words are

shown in parenthesis.

1. Seiri (Sort)
2. Seiton (Straighten, Set)
3. Seiso (Shine, Sweep)
4. Seiketsu (Standardize)
5. Shitsuke (Sustain)



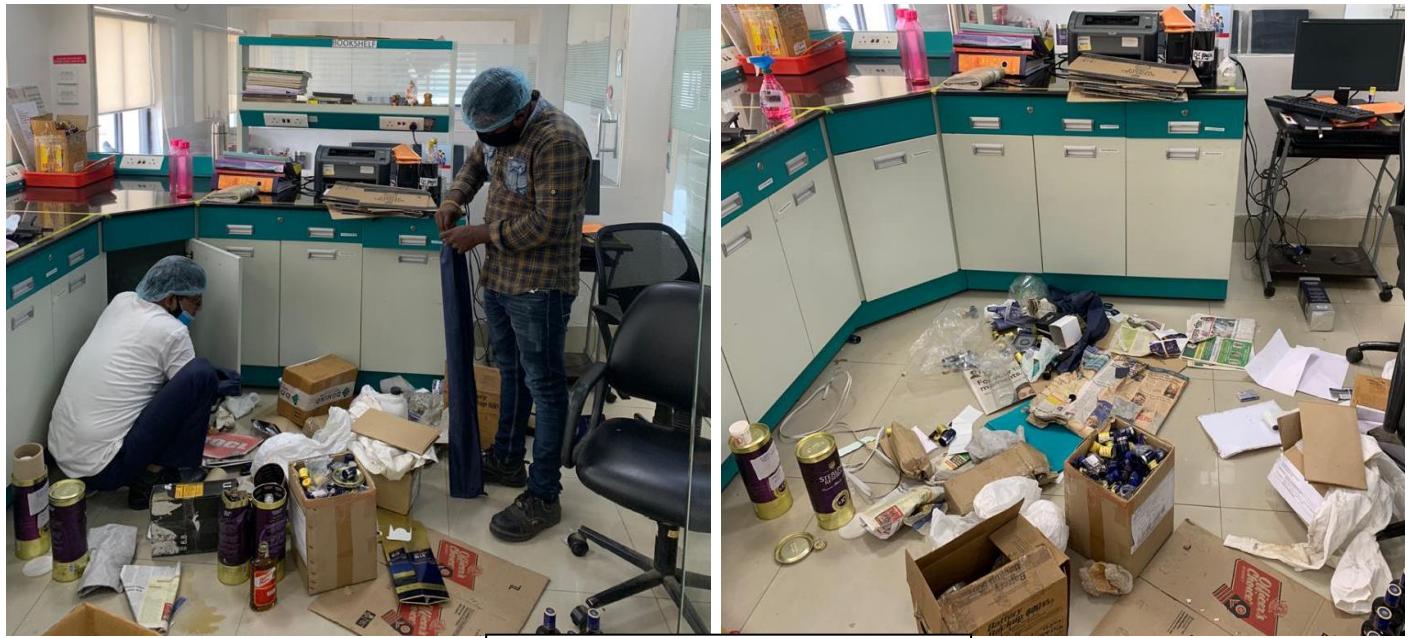
In simple terms, the five S methodology helps a workplace remove items that are no longer needed (sort), organize the items to optimize efficiency and flow (straighten), clean the area in order to more easily identify problems (shine), implement colour coding and labels to stay consistent with other areas (standardize) and develop behaviours that keep the workplace organized over the long term (sustain).

## 1. SORT (SEIRI)

– Distinguishing between necessary and unnecessary things, and getting rid of what you do not need

- Remove items not used in area – outdated materials, broken equipment, redundant equipment, files on the computer, measurements which no longer use.
- Ask staff to tag all items which they don't think are needed – this improves understanding about need and use.
- Classify all equipment and materials by frequency of use to help decide if it should be removed – place '**Red Tag**' on items to be removed.

- Establish a ‘holding area’ for items that are difficult to classify – hold item for allotted period to enable others not on 5S team to review.

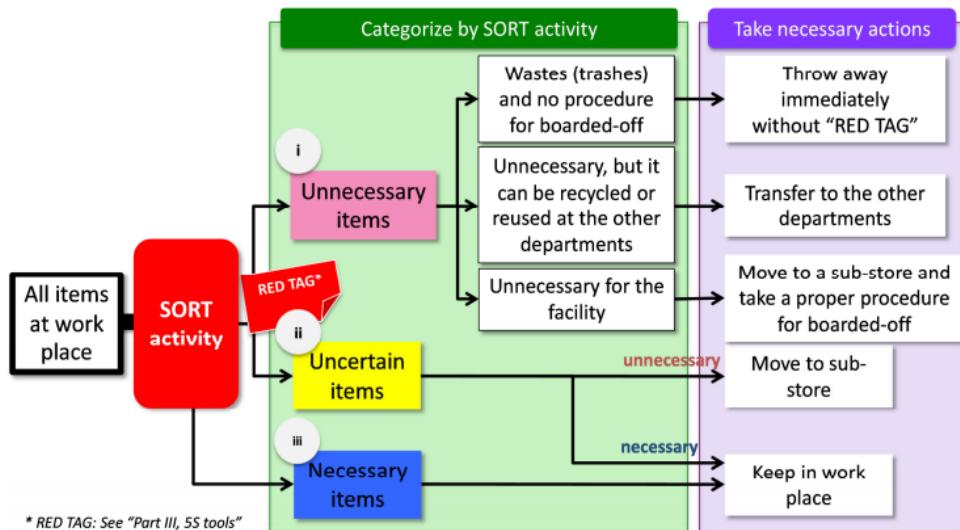


Removal of items not used in area



‘Holding area’ for items that are difficult to classify

Practice of Sort is starting from identification of unnecessary items in the work place. It has to be initiated by disposing all that are no longer needed after identification of unnecessary items through putting Red Tag and colour coding. Through Sort activity, we can create spaces and categorize all items in departments/sections clearly. A simple way of Sorting is to categorize all equipment, machines and furniture into three (3) categories by using colours. These categories are; Unnecessary (not need it), May/May not be necessary (Uncertain), and Necessary (Need it) as depicted.



- Unnecessary (Not need it):** Unnecessary items should be discarded if the item is not repairable. If the item is repairable, repair it and store as it may be needed by other departments/sections. Since the unnecessary items are property of the government, it might be difficult to discard immediately. Official audit procedures are necessary before disposal. Some valuable items might be sold to recycle agents. The items should be segregated for necessary disposal.



ii) **Uncertain items (May be necessary/May not be necessary):** May/May Not

Necessary items mean that the items are not used often (probably only once a month) or it is functioning but not used in current workflow. This kind of items should be stored in sub-store of departments /sections so that it can take out quickly when it is needed.



iii) **Necessary (Need it):** Necessary items should be organized properly based upon current workflow. This will be explained in “setting” activities.

When unnecessary items are collected from various departments/sections, the followings must be recorded and filed for smooth discarding procedures:

- Name of items
- Inventory number
- Where it was
- Where it will be stored

“**Unnecessary item store**” should be established and all unnecessary items properly stored until discarding process is completed. If sizes of unnecessary items are large and not repairable, space for unnecessary items should be created within the industry compound with safe storing measures. Rules for regular disposal have to be established.

## **2. SET IN ORDER / STRAIGHTEN (SEITON)**

– The practice of orderly storage so the right item can be picked efficiently (without waste) at the right time, easy to access for everyone. A place for everything and everything in its place.

- Identify and allocate a place for all the materials needed for your work
- Assign fixed places and fixed quantity
- Make it compact
- Place heavy objects at a height where they are easy to pick from
- Decide how things should be put away, and obey those rules

After Sort activity, remaining items have to be arranged and stored according to frequency of use. All areas including floors, cupboards and table tops have to be organized. Through Set activity, we can access needed items easily and immediately, do stock control of medical supplies and medicines easily, and keep workplace to look organized. Therefore, the changes have to work to be done more efficiently than before.

Practice of Set emphasizes on proper orderliness of things in the work place. Items are placed to facilitate easy access and to optimize workflow. For example;

- Signboards are set at the entrance to access easily for various services locations.
- All locations are named or labelled.
- Every item has to be labelled with an inventory number (discretely) and assigned a location. The assigned location is marked on the item and at the location.
- Visual controls including colour coding are practiced.
- Files and cupboards are indexed.
- X-axis-Y-axis alignment is practiced in the positioning of items.

### **3. SHINE (SEISO)**

– Create a clean worksite without garbage, dirt and dust, so problems can be more easily identified (leaks, spills, excess, damage, etc)

- Identify root causes of dirtiness, and correct process.
- Only one work activity on a workspace at any given time.
- Keep tools and equipment clean and in top condition, ready for use at any time
- Cleanliness should be a daily activity – at least 5 minutes per day
- Use chart with signatures/initials shows that the action or review has taken place.
- Ensure proper lighting – it can be hard to see dirt and dust.

Practice of Shine is the cleaning stage.

- All the items including floors, walls, windows, ceilings and equipment are cleaned.
- Appropriate cleaning tools, methods and materials are identified and practiced. - Waste bins are available at required places.
- Cleaning maps and schedules are developed and displayed for continuous practice of cleaning.
- Waste bins colour coding must follow Infection Prevention Control (IPC) Guidelines and Control Guidelines of MOH. Shine activity also means not only “Cleaning” but also “Maintenance”.

### **4. STANDARDIZE (SEIKETSU)**

– Setting up standards for a neat, clean, workplace

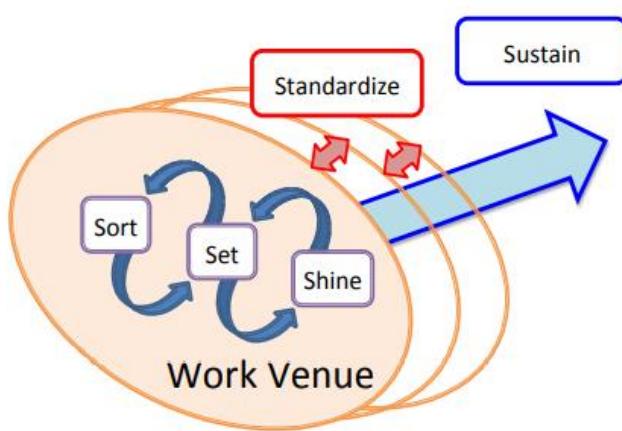
- Standardization of best practices through ‘visual management’.
- Keep each area consistent with one another.
- Standards make it easy to move workers into different areas.
- Create process of how to maintain the standard with defined roles and responsibilities

- Make it easy for everyone to identify the state of normal or abnormal conditions – place photos on the walls, to provide visual reminder.

Thus, the following kinds of activities are implemented in this phase:

- Development of Standard Operational Procedures (SOPs),
- Display marking of safety signs.
- Colour coding for linen system
- Zoning for equipment and instruments.

“Checklists” should be developed for each activity/service area and utilize it for the standardization.



## **5. SUSTAIN (SHITSUKE)**

– Implementing behaviours and habits to maintain the established standards over the long term, and making the workplace organization the key to managing the process for success

- Toughest phase is to Sustain – many fall short of this goal
- Establish and maintain responsibilities – requires leader commitment to follow through
- Every one sticks to the rules and makes it a habit
- Participation of everyone in developing good habits and buy-in
- Regular audits and reviews
- Get to root cause of issues

- Aim for higher 5S levels – continuous improvement.

The other options to include with 5S are Safety, Security and Spirit.

**Safety:** Safety is often said that it is implied within 5S that everything should be done with safety as the number one priority, but to ensure that is the case, Safety is added as an additional S. It is particularly prominent in laboratory settings, and in other contexts where potentially dangerous equipment or substances may be involved, and less prominent in office settings.

- **Spirit:** To ensure that the focus of 5S is to make it easier for the workers, Spirit is added to remind people that it should be fun, and that creativity is key to coming up with new ideas and better ways to implement 5S. Without engaged workers, the 5S approach will not last or be successful.

## **INTERNAL TRAINING**

One of key factors for successful 5S implementation is “everyone’s participation”. Therefore, training of all staff is essential.

### Outline of 5S Basic Training

#### (1) Objectives:

- To make participants understand 5S principles and necessity/importance of improving working environment
- To make participants understand how to practice Sort, Set and Shine activities

#### (2) Participants: Employees

<b><u>TIMETABLE OF INTERNAL 5S BASIC TRAINING</u></b>		
Time(mins)	Topics	Method
5	Pre-course assessment	Paper assessment
5	Objectives of 5S- Approach	Lecture
10	5S Principle	Lecture
15	How to practice Sort, Set and Shine activities	Lecture, Practical session
15	5S tools	Lecture, Practical session
5	Building and maintaining positive attitude	Lecture
20	Field observation	Practical session
10	Developing an action plan	Lecture, Practical session
5	Post-course assessment	Paper assessment



## **GOOD LABORATORY PRACTICES PRINCIPLES:**

A set of rules, operating procedures and the proper practices that ensure the reliability of the data generated by pharmaceutical control laboratories Principles, or parts, of Good Laboratory Practices:

- Organization and personnel
- Quality Assurance Program Responsibilities
- Installations and facilities
- Documentation
- Equipment and instruments
- Materials and reagents
- Reference and assay samples
- Assay methods. Validation
- Self-inspections and audits

**Organization and personnel:** Should have the Knowledge of the GLP principles. • Access to the study plan and appropriate SOP's. • Comply with the instructions of the SOP's. • Record and documented all the data. • Personnel are, therefore, a critical element when implementing GLP and maintaining compliance in a laboratory. It is clear that the person of a test facility has overall responsibility for the implementation of both good science and good organisation, including compliance with GLP.

**Quality Assurance Program Responsibilities of the QA Personnel:** • Designated individuals as members of the QA team directly responsible to the management • QA members not to be involved in the conduct of the study being assured • Access to the updated study plans and SOP's • Documented verification of the compliance of study plan to the GLP principals •

Inspections to determine compliance of the study with GLP principles. Three types of inspection – Study-based inspections – Facility-based inspections – Process-based inspections.

**Installations and facilities:** Suitable size, construction and location • Adequate degree of separation of the different activities • Isolation of test systems and individual projects to protect from biological hazards • Storage rooms for supplies and equipment.

Archive Facilities → Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. → Archive design and archive conditions should protect contents from untimely deterioration.

Waste disposal → Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

**Equipment and instruments & Materials and reagents:** Include: equipment, standard solutions, laboratory materials, Calibration, symbolization, storage system, and at least it should be applying the following requirements:

- All equipment and instruments should be labelled and recorded all required data such as (the manufacturer, year of manufacturing, company name ... etc).
- Putting a schedule for the calibration of laboratory equipment and instruments.
- Equipment and instruments data undergo to a central verification at upper laboratory level.
- Laboratory chemical stores in accordance with the storage system, and they are labelled for protection from fires and accidents.
- Standard solutions keep and stores according to the conditions of functions and calibration program of the equipment and within the controlled temperatures.
- Equipment keeps safety after using and according to the instructions of using and maintenance.

- Standard solutions symbolize with the date of validity.

## pH METER

A **pH meter** is used to determine the acidity or alkalinity of the solution. **pH** is the concentration of hydrogen ions in the solution. A solution containing more H<sup>+</sup> ions remain acidic while the solution containing more OH<sup>-</sup> ions remains alkaline.

### 1.0 FREQUENCY OF CALIBRATION -

When Required

### 2.0 PERSON RESPONSIBLE FOR ACTIVITY -

QC Executive

### 3.0 PRINCIPLE –

pH- Measure the concentration of Hydrogen ion.

### 4.0 OBJECTIVE –

Estimation of pH of Samples being analyse as per specification.



pH Meter

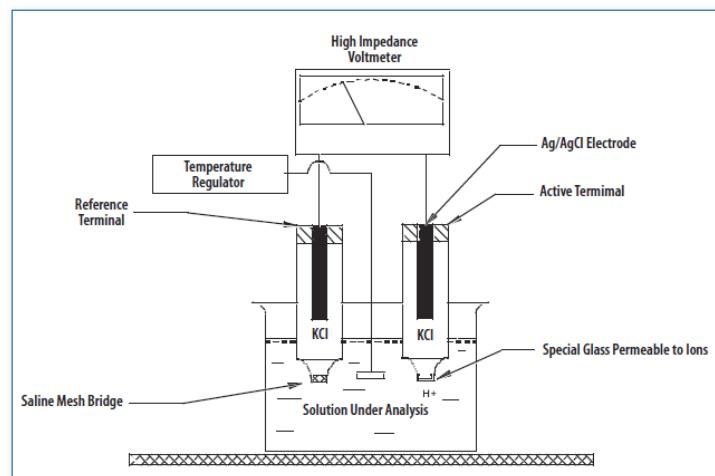
### 5.0 PROCEDURE-

5.1 Switch on the pH meter.

5.2 The pH electrodes wash with water & wipe from tissue paper.

5.3 Again wash the electrodes by sample& wipe from tissue paper.

5.4 Take sample in beaker measure reading of pH.



5.5 Confirm RM / PM / Ingredients passes, fails, reject, reprocess.

5.6 Confirm approval signature Endorsed by concerned authority.

## **CONDUCTIVITY METER**

**Conductivity** is the ability of a material to conduct electric current. The **principle** by which instruments measure **conductivity** is simple—two plates are placed in the sample, a potential is applied across the plates (normally a sine wave voltage), and the current that passes through the solution is measured.

### **1.0 FREQUENCY OF CALIBRATION -**

When Required

### **2.0 PERSON RESPONSIBLE FOR ACTIVITY -**

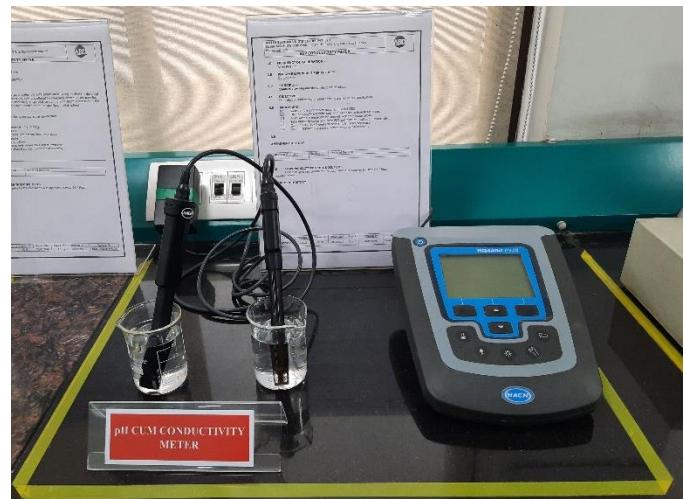
QC Executive

### **3.0 PRINCIPLE –**

Conductivity- Measure the conductance of solution.

### **4.0 OBJECTIVE –**

Estimation of conductivity of Samples being analyze as per specification.



pH cum Conductivity Meter

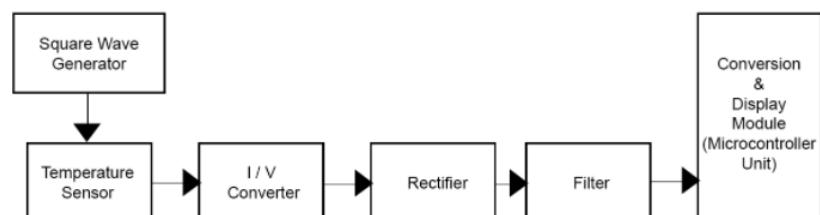
### **5.0 PROCEDURE-**

5.1 Switch on the conductivity meter.

5.2 The Conductivity electrode wash with water & wipe from tissue paper.

5.3 Again wash the electrodes by sample& wipe from tissue paper.

5.4 Take sample in beaker and press ENT and measure reading of Conductivity.



5.5 Confirm RM / PM / Ingredients passes, fails, reject, reprocess.

5.6 Confirm approval signature Endorsed by concerned authority.

## **SPECTROPHOTOMETER**

A **spectrophotometer** is an instrument that measures the amount of photons (the intensity of light) absorbed after it passes through sample solution. With the **spectrophotometer**, the amount of a known chemical substance (concentrations) can also be determined by measuring the intensity of light detected.

### **1.0 FREQUENCY OF CALIBRATION:**

6 Monthly / External Calibration from Hach

### **2.0 PERSON RESPONSIBLE FOR ACTIVITY:**

QC Executive

### **3.0 PRINCIPLE:**

When beam of monochromatic light passes through the transparent medium the intensity of the transmitted light is directly proportional to the concentration and absorbance of the solution.



Spectrophotometer

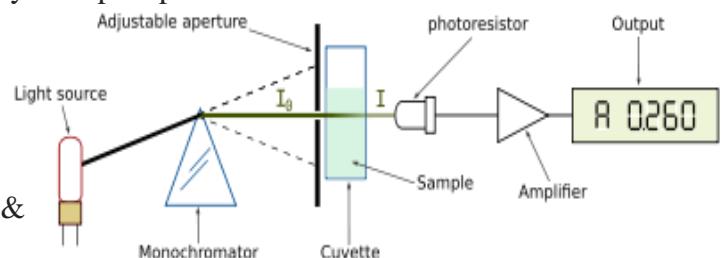
### **4.0 OBJECTIVE:**

Estimation of colour of Samples being analyze as per specification.

### **5.0 PROCEDURE:**

5.1 Switch on the Spectrophotometer.

5.2 Select single wavelength at 450& 520nm.



5.3 Take DM Water in cuvette for adjusting zero.

5.4 Rinse cuvette with sample 2-3 times & take sample in cuvette wipe with tissue paper for exterior portions sides and bottom.

5.5 Ensure no particles / wetness / moisture / humid conditions or fibres / dust remains on the wall of cuvette

5.6 Measure reading of sample.

5.7 Record the reading in format for blend analysis

## **TURBIDITY METER**

**Turbidity** is a measure of the degree to which the water loses its transparency due to the presence of suspended particulates. The more total suspended solids in the water, the murkier it seems and the higher the **turbidity**. **Turbidity** is considered as a good measure of the quality of water.

### **1.0 FREQUENCY OF CALIBRATION -**

6 Monthly / External Calibration form HACH

### **2.0 PERSON RESPONSIBLE FOR ACTIVITY -**

QC Executive

### **3.0 PRINCIPLE –**

As light passes through ‘absolutely pure’ water, the light beams travel along relatively undisturbed paths. However, some distortion occurs as light is scattered by molecules present in the pure fluid. When light passes through a fluid containing suspended solids, the light beam interacts with the particles and the particles absorb the light energy and re-radiates light in all directions.

### **4.0 OBJECTIVE –**

Estimation of turbidity of Samples being analyze as per specification.



### **5.0 PROCEDURE**

5.1 Switch on the Turbidimeter (HACH -2100Q).

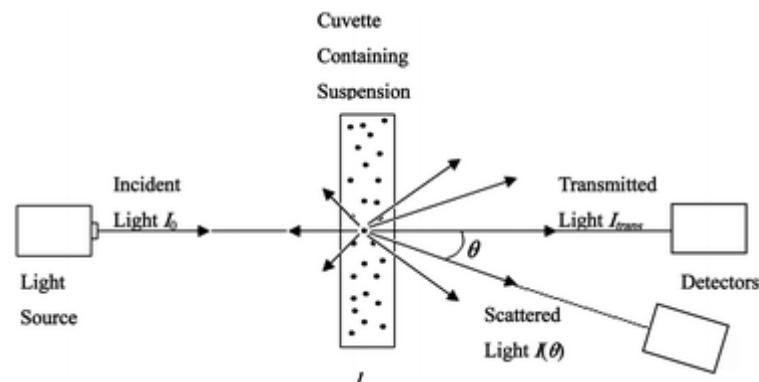
5.2 Set Date & Time. Press Ok.

5.3 Take sample in bottle. Wipe bottle clean from tissue paper.

5.4 Measure reading of sample.

5.5 Record the reading in format.

5.6 Confirm RM / PM / Ingredients passes, fails, reject, reprocess.



5.7 Confirm approval signature Endorsed by concerned authority.

### **ANTON PAAR:**

**Anton Paar** is the world leader in digital density measurement and renowned for the high accuracy of its measuring instruments. The metal tube with the measuring cell inside remains immersed in the distillate during the measurement. This guarantees that the sample temperature stabilizes quickly.



**Anton Paar**

### **HYDROMETER**

A **hydrometer** is an instrument used for measuring the relative density of liquids based on the concept of buoyancy. They are typically calibrated and graduated with one or more scales such as specific gravity.



**Hydrometer**

### **SCUFF RESISTANCE TESTER:**

This equipment is intended to evaluate the Rub Proofness of prints on paper or board. It can also be used to measure / evaluate Colour Transfer from printed / coated surface during rubbing. The application can be extended for measurement of abrasion resistance of some Plastic materials / Aluminium Foils.

Principle:

In this machine, 2 samples of the same substrate are rubbed against each other in the same plane, under a constant pressure of 2 p.s.i and at a fixed speed of 60 RPM. The number of rubs is recorded using a non-contact type digital counter.



**Scuff Resistance Tester**

## **BURSTING STRENGTH TESTER**

Bursting strength tester adopts signal transmission pressure, sample rupture automatically retains maximum fracture strength. The test piece is placed on the rubber mold, and is clamped by the clamping piece, and then the pressure is uniformly applied, so that the test piece and the adhesive film are free to bulge together, until the test piece is broken, the maximum value of the hydraulic pressure is applied, that is, the bursting strength value of the test piece is tested.



**Bursting Strength Tester**

## **VERNIER CALLIPER**

Vernier scale is for both internal and external measurements, used by closing the jaws on to the work surface and taking the readings from the main scale as well as vernier scale. For the precise setting of the movable jaw, an adjustment screw is provided to lock the sliding scale on the fixed scale.



**Vernier Scale**

## **SCREW GAUGE**

A screw gauge works on the principle of screw. This screw principle helps to convert smaller distances into larger ones by measuring the rotation of the screw. It amplifies the smaller dimensions and this converts into larger ones. When we rotate the screw, there's a linear movement of the main scale.



**Screw Gauge**

## MICROMETER

A **micrometer** works on the **principle** of a screw and a nut. It allows you an axial rotation of the barrel-like structure, also known as Thimble, which is used to measure the distance of the object. The axial value can be reduced and can increase the accuracy by decreasing the pitch of the screw thread.



Micrometre

## HEIGHT GAUGE

A Vernier **height gauge** is a measuring device used either for determining the **height** of something or for the repetitive marking of items to be worked on. The pointer is sharpened to allow it to act as a scribe and assist in marking on workpieces.

## ULTRASONIC THICKNESS GAUGES

**Ultrasonic thickness gauges** measure the **thickness** of a part by measuring the time sound travels from the transducer through the material to the back end of a part, and then measures the time of reflection back to the transducer.



Ultrasonic Thickness Gauges

## LUX METER

The **lux meter** measures the brightness specifically with the intensity by which the brightness appears to the human eye. This measurement method is different from the measurement of actual light energy produced by or reflected from an object or light source. **Lux** is a unit of measurement of brightness or illuminance.

**Reference and assay samples:** It includes standard samples, reference samples, assay samples (raw materials like: ENA, caramel, blend, water) all are labelled and identified properly.

- Receipt, handling, sampling and storage
  - Records for date of receipt, expiry date, quantities received and used in studies etc
  - Handling, sampling and storage procedures to ensure validity and stability and avoid contamination or mix-up
  - Identification information on storage containers.
- Characterization
  - Identification of each test and reference item like Code, number, name etc
  - Identification of each batch of the test or reference items like Batch number, purity, composition, concentration etc
  - Cooperation between the sponsor and the test facility like Verification of identity of the test item.
- Known stability of test and reference items
  - Stability of the test item in its container.
  - Samples for analytical purposes for each batch.

**Assay methods. Validation:** Assay validation provides an assurance of reliability during normal use, and is sometime referred to as "the process of providing documented evidence that the method does what it is intended to do. Full Assay Validation will include inter-assay and inter-laboratory assessment of assay repeatability and robustness. All the testing procedures, assay methods and protocols were segregated and kept in proper places.

**SOPs:** A full set of good Standard Operating Procedures (SOPs) is a prerequisite for successful GLP compliance. Setting up the SOP system is often seen as the most important and most time-consuming compliance task. Even without GLP regulations, classical quality assurance

techniques, indeed good management, require standardised, approved, written working procedures.

The successful implementation of SOPs requires:

- Sustained and enthusiastic support from all levels of management, with commitment to establishing SOPs as an essential element in the organisation and culture of the laboratory.
- SOP-based education and training of personnel, so that the procedures are performed in the same way by everyone.
- A sound SOP management system to ensure that current SOPs are available in the right place.

**Documentation:**

- Documents are the Life-blood of the Organization.
- Demonstrate what actually went on at the time,
- Critical for complete reconstruction of the study,
- Authentication that all the required procedures were correctly carried out at the correct time.
- Regulatory requirement.
- Results of original measurements, observations, and activities associated with the study which may be needed to verify and evaluate the study and will provide a picture of what actually happened during the course of an activity.

**Results - Raw Data and Data Collection:** The laboratory should have descriptive documents which are records describing what actually happened during the course of the experimentation. The records are the qualitative and quantitative results of the study. This interpretation, as well as an accurate representation of the data, will be incorporated into the final report of the study. Finally, at study completion, all the documents, both prescriptive and descriptive, are archived so that when necessary full study reconstruction will be possible through examining the archived material.

**Self-inspections and audits:** Self Inspection or Internal Audit is a Quality System to check whether activities followed by all departments are according to the written approved procedures and complying with the GMP and Regulatory Requirements.

- Promote awareness for Quality and GMP within lab.

- Proactive approach to identify and correct the non-conformance.
- Assure the effectiveness and support continuous improvement of compliance to GMP and Quality management system.
- Develop confidence to minimize and possibly to eliminate the scope for major or critical regulatory findings.
- To identify the non-compliance or Gap with respect to Manufacturing Practices of production, Quality Control systems, quality assurance procedures, environmental conditions etc.

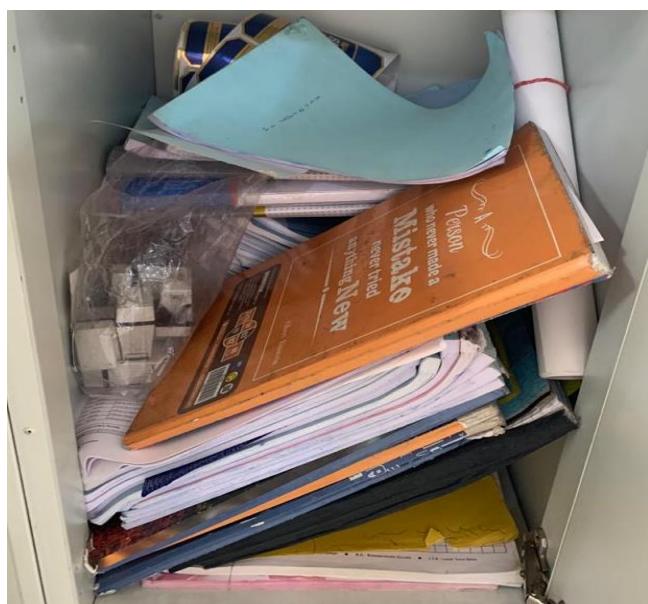
## **CHAPTER 5** **RESULT AND DISCUSSION**

## **S1 – Sort – SEIRI:**

✓ / x

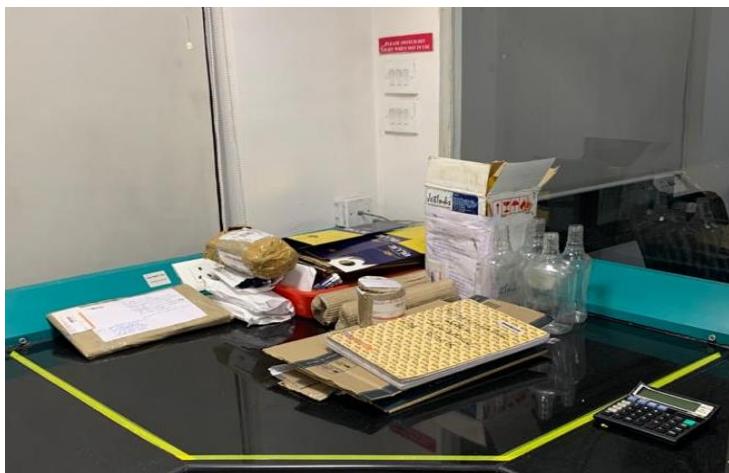
1. No irrelevant reference materials, documents, drawings, etc.	✓
2. No excess pieces of equipment, documents, etc.	✓
3. Storage area is defined to store unneeded items and out-dated documents.	✓
4. Standards for eliminating unnecessary items exist and are being followed.	✓



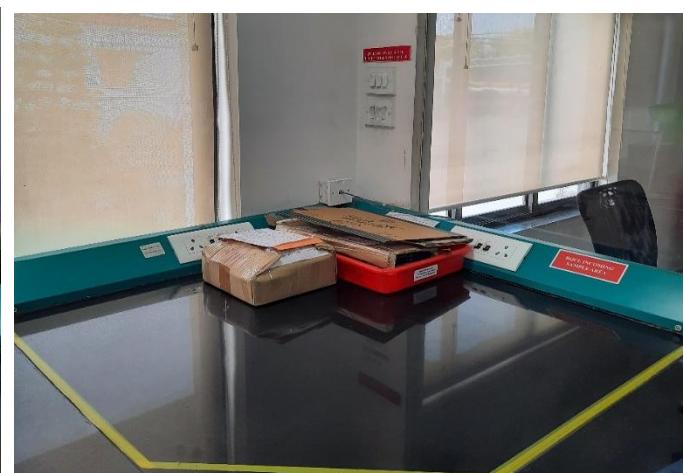


## **S2 – Set in order – SEITON:**

5. Desks and cabinets are free of accumulations of papers and other objects.	✓
6. Shadow impressions are created to keep all the utilities.	✓
7. All tools and equipment are stored in a fixed place.	✓
8. Tools and equipment are well organized for ease of take and return.	✓
9. Labelling of cabinets, shelves and files allows immediate identification.	✓
10. Documents are filed in accordance with the Record Retention Guidelines.	✓
11. Displays are tidy, free of clutter, labelled and up-to-date.	✓
12. Safety equipment easily accessible and in good condition.	✓
13. Locations of materials and products are clear and well organized.	✓
14. Labels exist to indicate locations, containers, boxes, shelves and stored items	✓
15. Dividing lines are clearly identified and clean as per standard.	✓
16. Chemical reagents & glass wares are kept in a fixed place.	✓

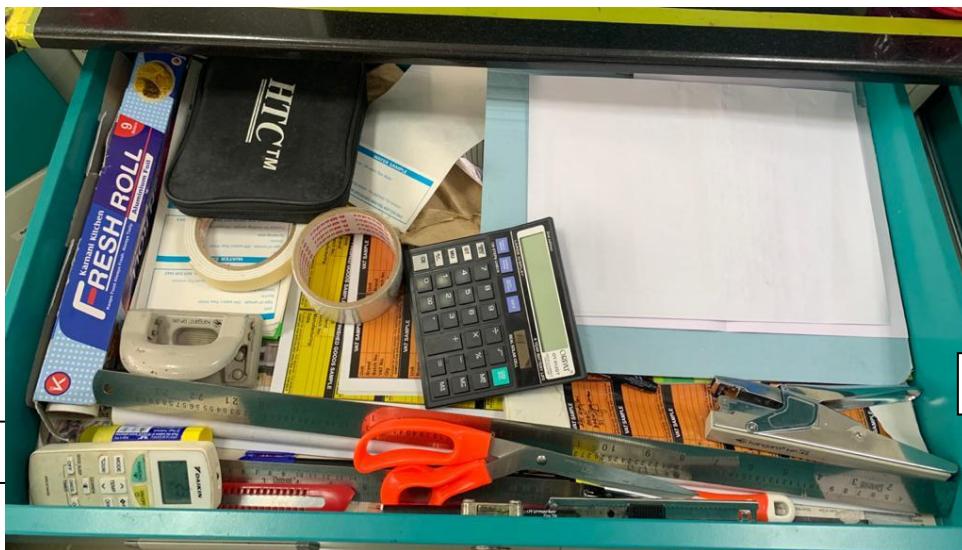


Before



After





After

## Other unnecessary objects

## Before



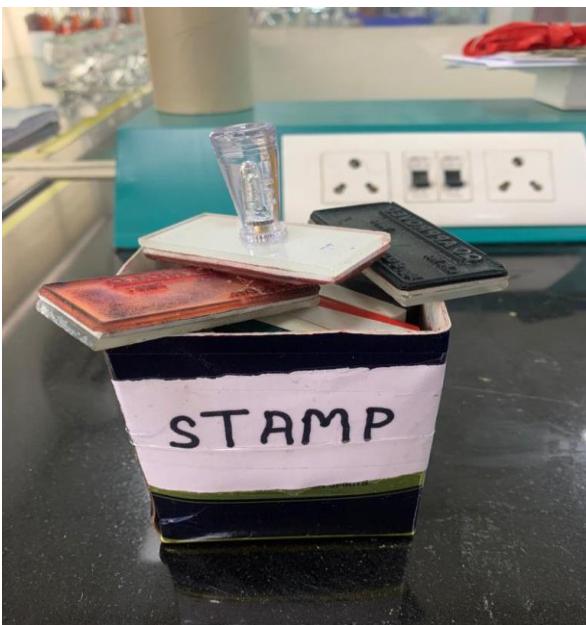
## After



Before



After



Before



After



Before



After



Before

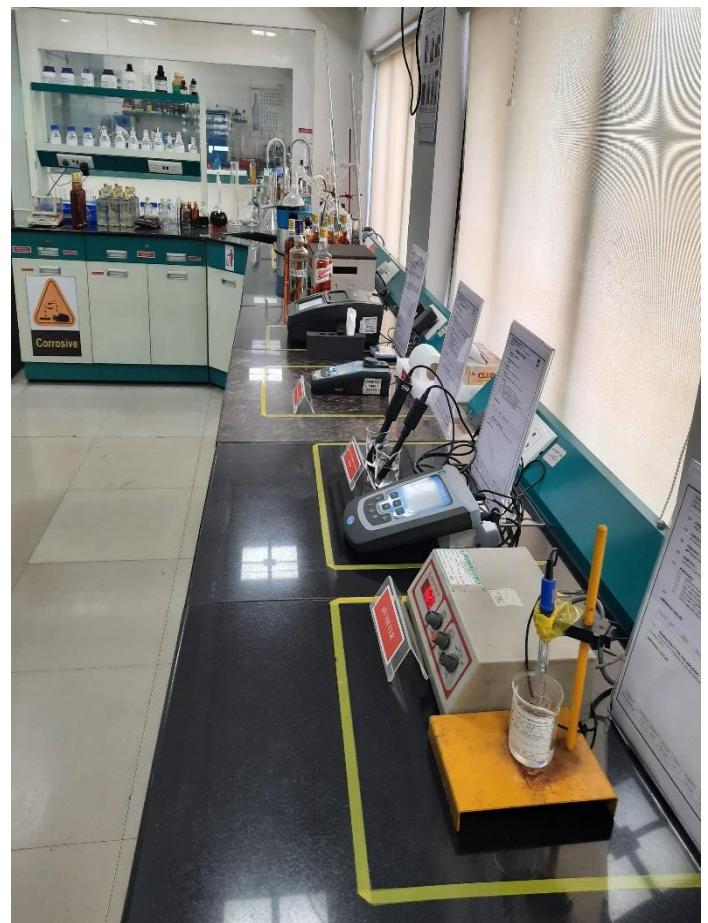


After

**Shadow impressions are created to keep all the utilities**



Before



After



Before



After



Before



After



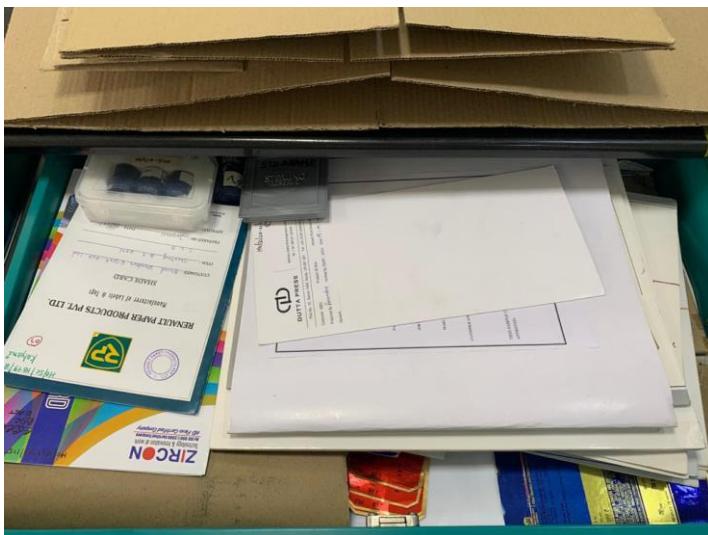
Before



After



All tools and equipment are stored in a fixed place



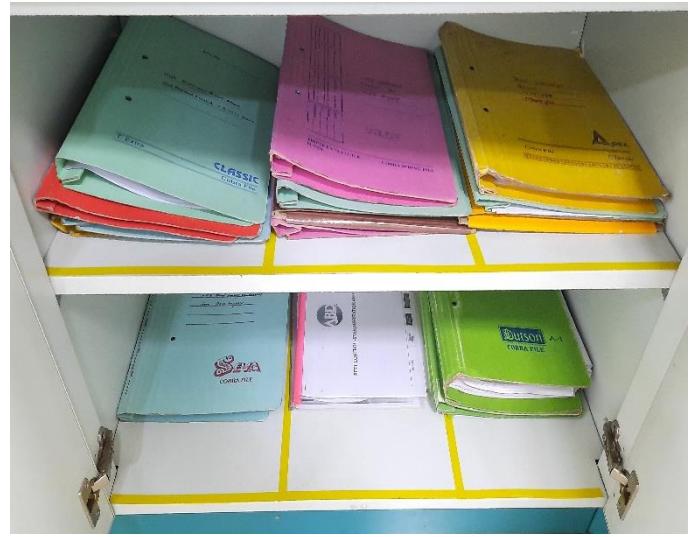
Before



After



Before



After



Documents are filed in accordance with the Record Retention Guidelines





Before



After



Before



After

**Displays are tidy, free of clutter, labeled and up-to-date**



**Labelling of cabinets, shelves and files allows immediate identification**



Before



After

**Safety equipment easily accessible and in good condition**



**Reflective Safety Tape**



Before



After

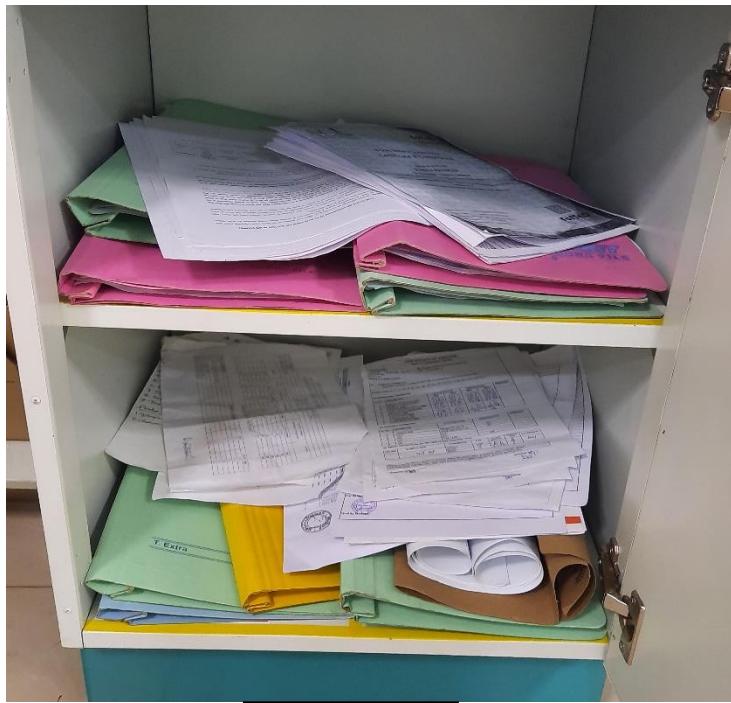


Before

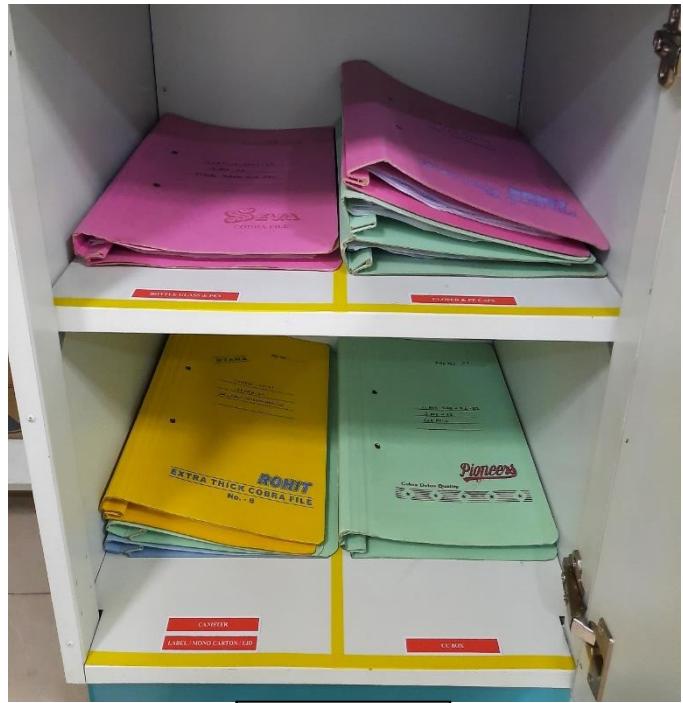


After

**Chemical reagents & glass wares are kept in a fixed place**



Before



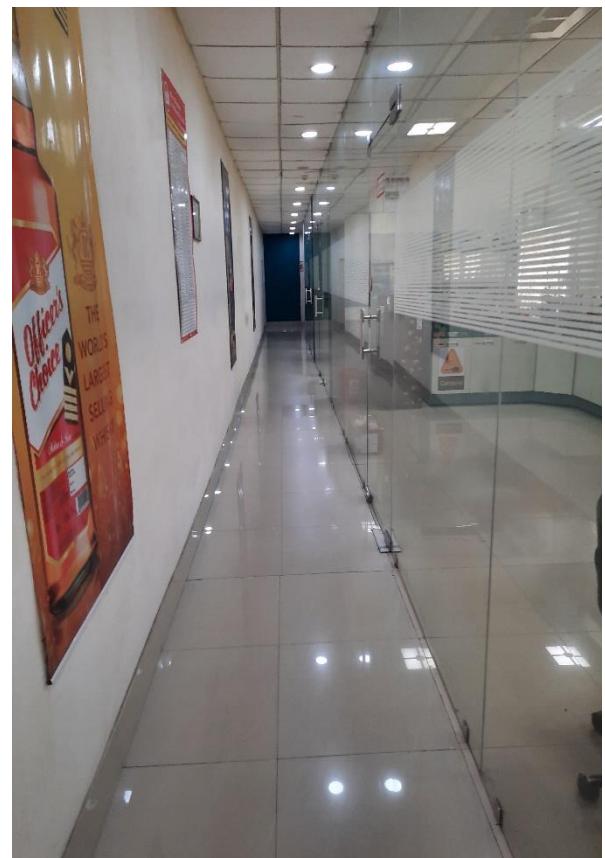
After



Dividing lines are clearly identified, clean and labelled

### **S3 – Shining – SEISO:**

17. The floor is kept clean and no signs of damage.	✓
18. Walls and ceilings are in good condition and free from dirt and dust.	✓
19. Racks, cabinets and shelves are kept clean and in good condition.	✓
20. Equipment and tools are kept clean and in good condition.	✓
21. Desks, tables and work station are kept clean	✓
22. Lighting is enough and the angle and intensity of illumination are appropriate.	✓
23. Good movement of air exists through the room.	✓
24. Trash containers are emptied on a regular basis.	✓
25. Stored items, materials and products are kept clean.	✓
26. Pest control exists and effective.	✓
27. Cleaning tools and materials are easily accessible.	✓
28. Cleaning assignments are defined and are being followed.	✓



**The floor is kept clean and no signs of damage**



**Walls and ceilings are in good condition and free from dirt and dust**



Before



After



Before



After



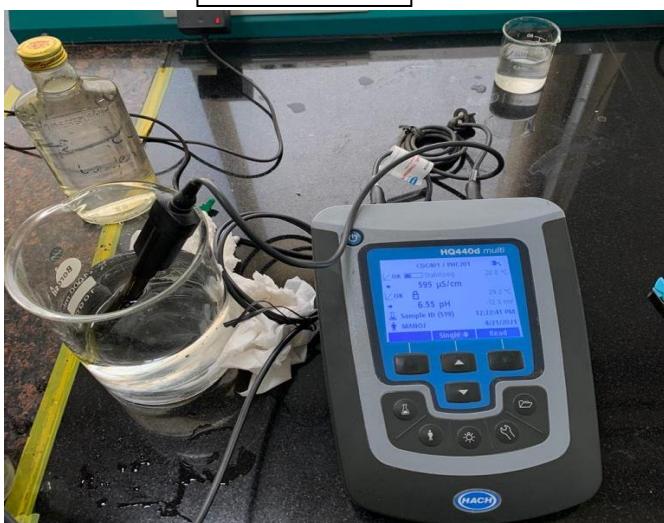
**Racks, cabinets and shelves are kept clean and in good condition**



Before



After



Before



After

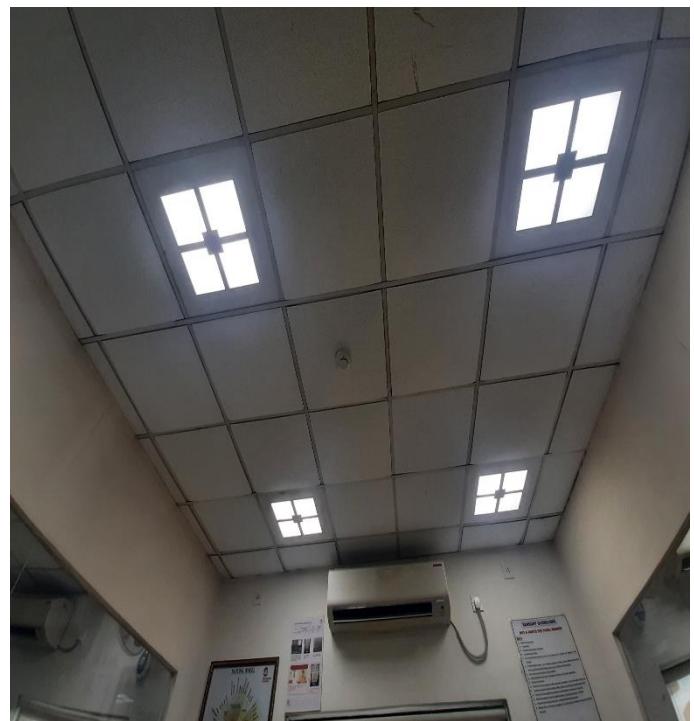


Equipment and tools are kept clean and in good condition

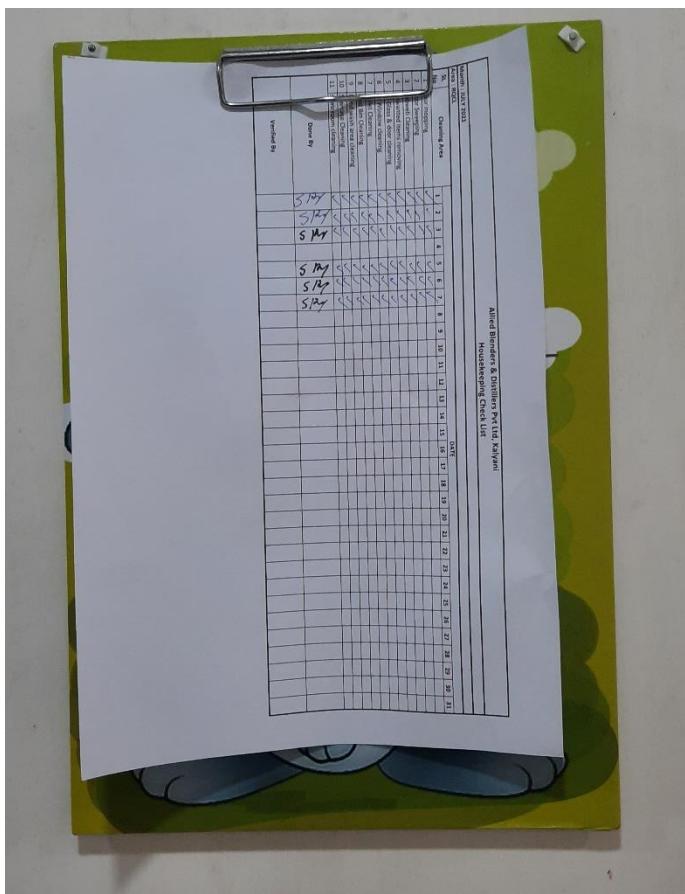




**Desks, tables and work station are kept clean**



**Lighting is enough and the angle and intensity of illumination are appropriate condition**



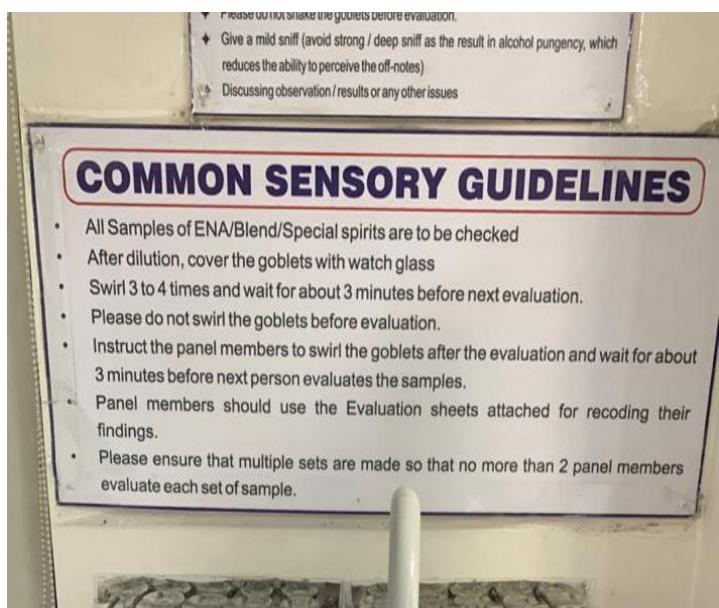
**Cleaning assignments are defined and are being followed**



**Stored items, materials and products are kept clean**

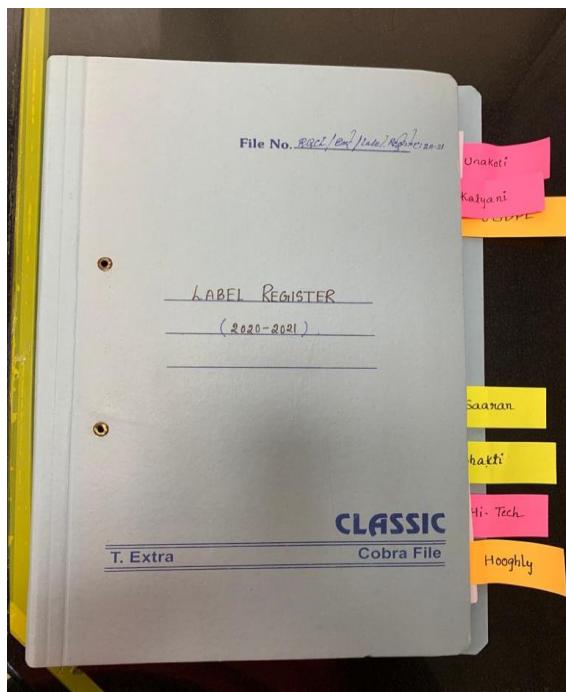
## **S4 – Standardize – SEIKETSU:**

29. Visual controls and display boards are used and regularly updated.	✓
30. Information displays, signs, colour coding and other markings are established.	✓
31. Procedures for maintaining the first three S's are being displayed.	✓
32. 5S checklists, schedules and routines are defined and being used.	✓
33. Everyone knows his responsibilities, when and how.	✓
34. Regular audits are taking place using checklists and measures.	✓



**Visual controls and display boards are used and regularly updated**

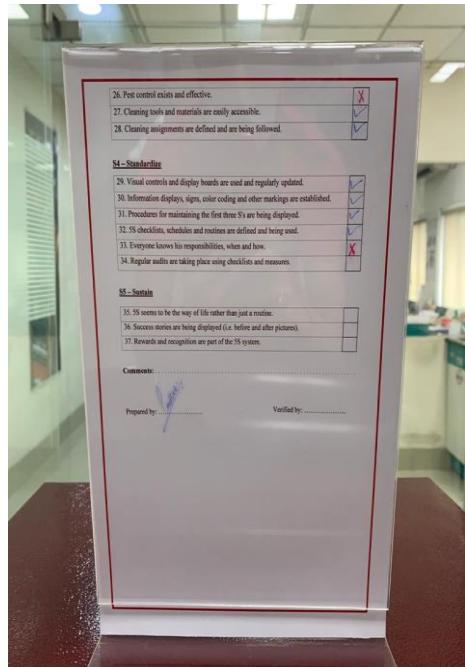
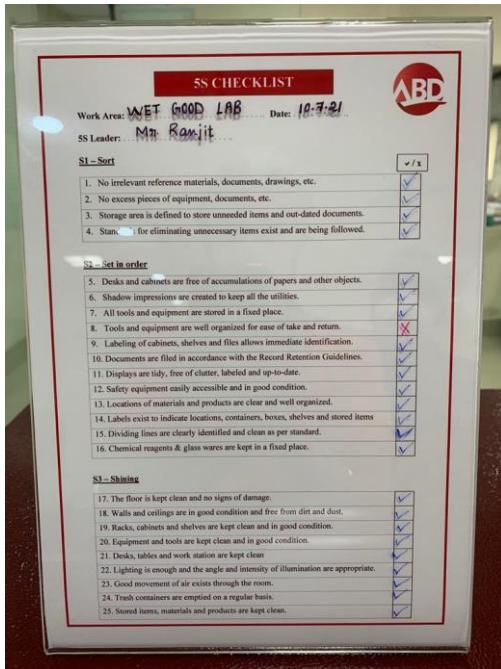




Information displays, signs, colour coding and other markings are

## **S5 – Sustain – SHITSUKE:**

35. 5S seems to be the way of life rather than just a routine.	✓
36. Success stories are being displayed (i.e. before and after pictures).	✓
37. Rewards and recognition are part of the 5S system.	✓



**5S seems to be the way of life rather than just a routine**



**Success stories are being displayed**

## **GLP Clauses:**

Before implementing the GLP, we have conducted one survey to check the level of laboratory practices in quality control lab, with reference to the laboratory manual.

The following is the survey results before GLP implementation.

Clause 1: Organization and Personals / Laboratory		
Questions	Yes	No
Are the tasks, duties, responsibilities and powers (i.e.: job description) identified strictly to the laboratory staff?	✓	
Is the quality policy put within the role and responsibilities of all employees towards quality results and customer satisfaction? Should it have declared in Lab entrances?		✓
Are the ideal and selected scientific practices by lab management apply according to accurate study?	✓	
Does the laboratory management limit principles in quality adjusting through laboratory tests, implementation, monitoring, recording and archiving?	✓	

Clause 2: Quality Assurance Program		
Questions	Yes	No
Has the Laboratory management plan for self-assessment and analysis of the results of effects?	✓	
Are the laboratory Personals trained strictly to apply the requirements of quality assurance in the laboratory and all of laboratory practices?	✓	
Are the laboratory management plays an active role to monitor the incorrect analytical results and then put corrective actions, in addition to its commitment to development and implementing management system and achieving continuous improvement		✓
Is the daily work of Laboratory administration systematic and structured to achieve technical competence in performing practices, tasks and functions assigned to the employees? And are the roles and responsibilities referred in the laboratory manual?		✓

Clause 3: Facilities		
Questions	Yes	No
Are the protection kits for employees available in the laboratory? And are the employees trained to use them?		✓
Is the laboratory equipped with Life protection requirements (ventilation, lighting, grounding ground, fire alarm system, sensors, self-extinguishing) and according to the characteristics of the laboratory and its risk?		✓
Is the laboratory equipped with first aid box and guidance for using in emergency situations when dealing with chemical, physical, mechanical or electrical risk?		✓
Is the laboratory designed with sufficient space in terms of the number of employees and the laboratory experiments?	✓	
Are the laboratory staff trained to use fire distinguishes according to its characteristics and its use?	✓	
Is the maintenance program of ventilation systems and lighting applied according to the degree of laboratory risk? And is any timetable program used for the maintenance and prevention in the laboratory?	✓	
Is the laboratory divided into wet good lab, sensory analysis room and other room?	✓	

Clause 4: Equipment, Standard Solutions, Reagents and Materials		
Questions	Yes	No
Have the instruments and equipment symbolized? And is it recorded all the required data such as (the manufacturer, year of manufacture, company name ... etc)?	✓	
Is there any timetable for calibration laboratory equipment and instruments?		✓
Is the equipment and instrument entering to central program to build a database on a laboratory level?	✓	
And are the chemicals materials symbolized for protection from fires and accidents.	✓	
Are the standard solutions keep and stores according to the conditions of functions and calibration program of the equipment and within the limited temperatures?		✓

Is the equipment keep safety after using and according to the instructions of using and maintenance?	✓	
Are the standard solutions symbolizing with the date of validity?		✓

Clause 5: Testing		
Questions	Yes	No
Is any assessment for testing and analysis procedures realized?	✓	
Are the conditions of laboratory experiments determined accurately?	✓	
Is it takes into account accurate procedures in each of sampling, symbolizing and procedures for taking samples?		✓
Do be sure of the cleanliness of the equipment, instruments, glasses and the concentrations of solutions, its type and using?	✓	
Are the specifications select from time to time for its impact of quality results?	✓	
Are the test methods and alternative test methods available completely?	✓	
Do be sure of the validity of standard solutions and the solutions prepared within specific concentrations for experiences?		✓

Clause 6: Test and References		
Questions	Yes	No
Has the laboratory a clear policy and procedures for testing or calibration? And, are the responsibilities and authorities specified in work management?		✓
In the case of non-conforming action, is it applied to adjust the corrective action, repeating the experience, implementation of measure evaluation and identifying the possible sources in the reasons of nonconformity?	✓	
Are the laboratory management implements preventive action after each corrective action to prevent potential sources of non-conformity occurrence in the future?		✓
Are the laboratory uses methods and procedures for all tests / calibrations within the scope of work (sampling, handling, transportation, storage and destroyed)?		✓

Clause 7: Standard Methods		
Is the laboratory select and prove experimental methods and review them in accordance with the accreditation of good laboratory requirements?	✓	
Does the laboratory management determine the environmental conditions and safety through the implementation of laboratory practices for employees?	✓	
Are the methods (operating procedures) easy to apply, transparent and understandable for all employees in work steps and the achievement of results and goals?	✓	

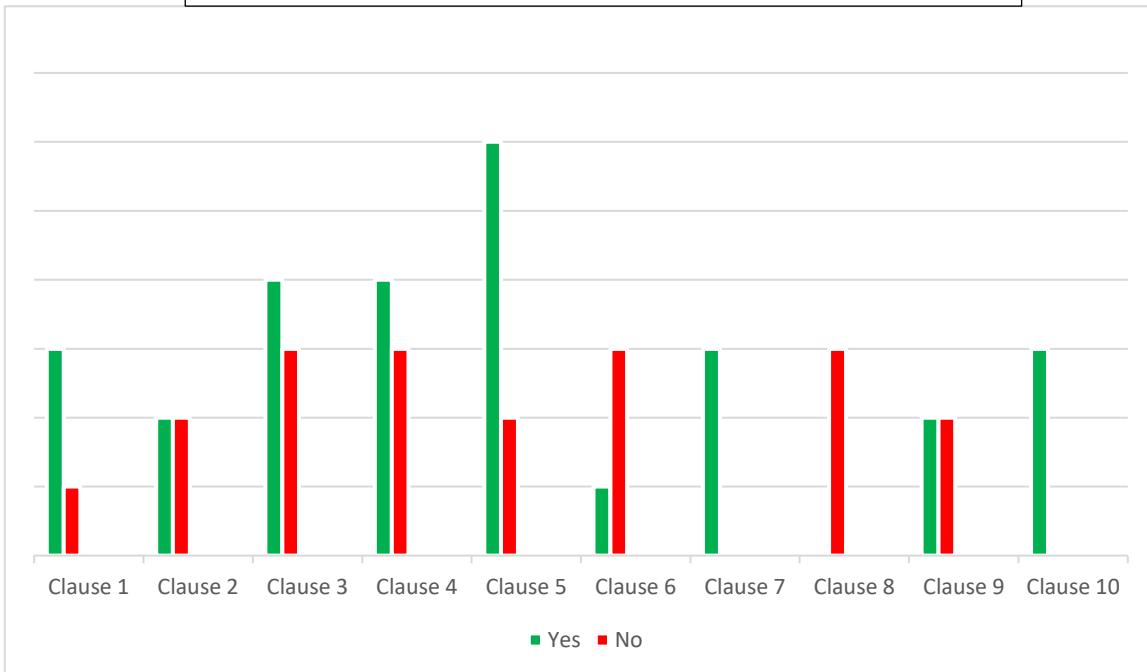
Clause 8: Performance Evaluation		
Has the laboratory Placed an annual plan to evaluate the performance of employees in laboratories?		✓
Does the laboratory management looking for performance evaluation program as a means to raise the efficiency of laboratory employees and supervisors in the good laboratory to give a good opportunity for superiority?		✓
Has the laboratory specific standards in evaluating the performance of the lab activity as well as its employees to develop performance evaluating system?		✓

Clause 9: Results Report		
Has the laboratory suitable procedures to adjust and avoid the error in the results of test, analysis and calibration through recording of data, operating and results?		✓
Does the laboratory management analyse the data and adjust the documents and perform the correct action into un conformity and unacceptable results?	✓	
Has the laboratory design of results report for each of testing and calibration implemented?		✓
Does the laboratory management perform correction of the factors affected in the results?	✓	

Clause 10: Archiving, Recording and Storage of Reports		
Does the laboratory management implement procedures to adjust legal, technical and referential documents and each kind of manuals and reports?	✓	

Does the laboratory management perform periodical review of documents and to mark the important one and taking procedures and solutions for developing and improving?	✓	
Does the laboratory management use coloured seals to characterize different kind of documents and to achieve quality performance?	✓	

### **SURVEY RESULT (BEFORE IMPLEMENTING GLP)**



#### **LABORATORY SAFETY**

#### **GENERAL LABORATORY PROCEDURES**

##### **General Procedures**

1. Labs are conducted in pairs. You will need to be organized and divide tasks to complete the labs in the allocated time.

2. Glassware will be provided on an as needed basis during the lab period. Students should come to the lab prepared with a list of required glassware and an organized work plan.

**Note:** You may need to pre-rinse some glassware prior to use.

3. In order to avoid contaminating supplied chemical reagents, a sufficient quantity of reagents should be transferred to an appropriate receptacle, e.g. small beaker or weigh boat. A reagent bottle should always be returned to its allocated place after use.

**Note:** NEVER RETURN A CHEMICAL TO THE REAGENT BOTTLE.

**Note:** ALWAYS HANDLE PRIMARY STANDARDS AND STOCK SOLUTIONS WITH CARE. CONTAMINATION WILL LEAD TO POOR RESULTS FOR YOU AND OTHERS.

4. At the end of the laboratory period: All glassware should be thoroughly washed (including a final rinse with deionized water) and left on the return cart. All electrical apparatus should be switched off and unplugged. All taps should be turned fully off and all waste should be placed in the appropriate waste container.

A chemical laboratory is a potentially dangerous environment; the hazards of fire, cuts, burns and poisoning being most prevalent. It is a safe practice to assume all chemical reagents are potentially hazardous. While the use of particularly toxic or carcinogenic reagents is generally avoided, some of the reagents in this lab are dangerous. Check the MSDS and consult your instructor for more information. The first line of defence for skin contact is to flush with plenty of water. Two eyewash stations are provided for the immediate flushing of eye splashes. In the event of an accident, contact your instructor immediately. Safety rules will work only if you obey them and encourage others to obey them. Please familiarise yourself with the following regulations.

##### **Personal Safety**

- There must be no smoking or eating in the laboratory.
- Analyst must wear safety glasses at all times. Safety glasses are available. Contact lenses should be removed prior to entering the laboratory. Prescription glasses may be worn, but should be covered with safety glasses.

##### **Analyst are recommended to wear laboratory coats in the laboratory.**

- Many of the chemicals in the laboratory are poisonous whether taken orally or absorbed through the skin. If any chemical is swallowed the supervisor should be summoned immediately. If any chemical comes into contact with the skin, it should be washed off immediately with plenty of water.

• While heating a substance in a test tube, care should be taken to ensure that the mouth of the test tube is not pointing at anyone.

• Concentrated acids and bases; strong oxidising and reducing agents; flammable solvents and toxic chemicals should be treated with respect.

• Always wash your hands prior to exiting the lab and before eating.

##### **Fire**

- In the event of fire, the flames should be extinguished with one of the extinguishers in the laboratory and the supervisor notified immediately.

##### **Spillages and Fumes**

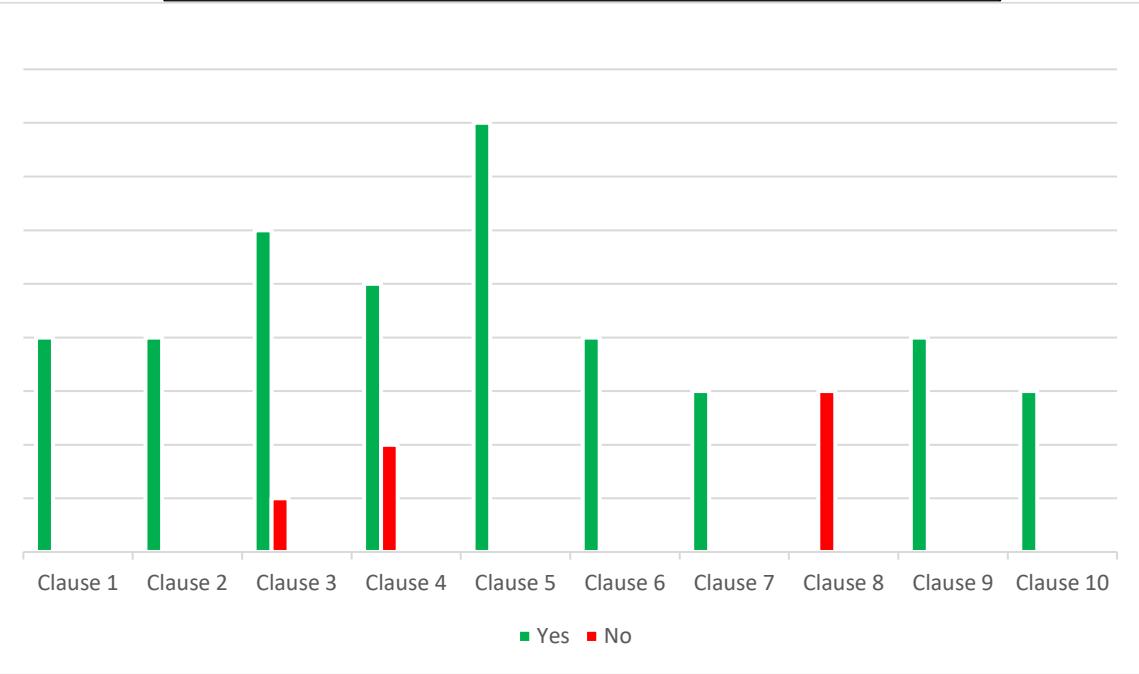
- All breakages and minor spills of chemicals should be reported immediately to the supervisor or technician without delay.

• A receptacle in the laboratory is reserved solely for broken glassware.

• Any experiment involving the evolution of pungent odours or fumes must be carried out in the fume hood.

Above Pictures are taken from lab manual, that lab manual was followed as standard to maintain and implement GLP

### SURVEY RESULT (AFTER IMPLEMENTING GLP)



## **CHAPTER 6** **REFERENCES**

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