

**“Evaluation of Water Quality through Chemical Analysis at  
Hindustan Foods Limited, Baddi”**

Project report submitted in partial fulfillment of the requirement for the

Degree of Master of Science

In

**Biotechnology**

By

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Under the Supervision of

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To



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## DECLARATION

I declare that the work which is proclaimed in this thesis titled “**Evaluation of Water Quality through Chemical Analysis at Hindustan Foods Limited, Baddi**” in fulfillment of the requirement for the awarding of the degree of Masters of Science in Biotechnology submitted in Jaypee University of Information Technology, Waknaghat (Solan) is a legitimate record of my work carried out during my masters period under the supervision of **DR. UDAYABANU MALAIRAMAN**.

The material present in this dissertation has not been provided by me to any other institute or university in award of any other degree.



Signature:

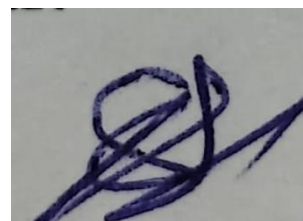
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## **SUPERVISOR'S CERTIFICATE**

This is to certify that the project work done on “Evaluation of Water Quality through **Chemical Analysis at Hindustan Foods Limited, Baddi**” is carried out by **RITIKA CHAUHAN** as the partial fulfillment of the requirement for award of Masters of Science (MSC) degree in Biotechnology at Jaypee University of Information Technology, Waknaghat Solan under my supervision.



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Signature:

Ritika Chauhan (225111015)

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## ABBREVIATIONS

HFL	Hindustan Foods Limited
EU	European Union
ZLD	Zero Liquid Discharge
HSSE	Health, Safety, Security & Environment
$\mu\text{S/cm}$	Microsiemens Per centimeter
WWTP	Wastewater treatment facilities
PPCP	Pharmaceutical and personal care products
RO	Reverse Osmosis
ED	Electrodialysis
pH	Potential of Hydrogen
NAWI	Non Automatic Weighing Tool
M	Molar
KCL	Potassium Chloride
H <sub>2</sub> SO <sub>4</sub>	Sulphuric Acid
KNO <sub>3</sub>	Potassium nitrate
KmNO <sub>4</sub>	Potassium Permanganate
ppm	Parts per million
ml	Milliliters
IP	Indian Pharmacopoeia
SP	Sampling Point
AYUPW	Ayurvedic Block Purified Water
COPW	Cosmetic Block Purified Water

BW	Borewell Water
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°C	Degree Celsius
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FDA	Food and Drug Administration
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EMA	European Medicines Agency
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WHO	World Health Organisation
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TOC	Total Organic Carbon
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## **ABSTRACT**

Water quality is paramount in the pharmaceutical industry due to its extensive use in drug synthesis, formulation, and equipment cleaning. This abstract summarizes the critical need for rigorous chemical analysis of water samples in this context, emphasizing five key aspects: ensuring product safety and quality, adhering to regulatory standards, preventing contamination, optimizing manufacturing processes, and maintaining robust quality assurance systems.

Firstly, the quality of water directly impacts the safety and efficacy of pharmaceutical products. Contaminants such as organic chemicals, heavy metals, and microorganisms can compromise product quality, potentially leading to harmful effects on patients. Chemical analysis identifies and quantifies these contaminants, ensuring that water meets stringent quality standards necessary for pharmaceutical production .

Secondly, regulatory compliance is a major driver for chemical water analysis. Health authorities like the FDA, EMA, and WHO mandate strict water quality guidelines, specifying limits for various pollutants. Regular chemical analysis is essential for compliance with these regulations, thereby avoiding legal penalties and ensuring the safety of pharmaceutical products .

Thirdly, chemical analysis of water helps in the early detection and prevention of contamination. Contaminated water can lead to serious health risks, especially in the production of injectable drugs. Timely chemical analysis allows for quick intervention, preventing contamination and safeguarding public health .

Fourthly, consistent water quality is crucial for stable manufacturing processes. Variations in water composition can lead to unexpected reactions, equipment corrosion, and process inefficiencies. Regular chemical analysis helps maintain the necessary purity levels, facilitating smooth and efficient production operations .

Finally, chemical analysis is integral to the quality assurance and control frameworks within pharmaceutical manufacturing. By routinely testing water samples, companies can document compliance with required standards, which is vital for audits and

inspections. This practice ensures traceability and reinforces the integrity of the production process .

In conclusion, chemical analysis of water samples is indispensable in the pharmaceutical industry. It guarantees product quality, ensures regulatory compliance, prevents contamination, optimizes manufacturing efficiency, and supports robust quality assurance systems, ultimately safeguarding public health and maintaining industry standards .

# **CHAPTER-1**

## **INTRODUCTION**

Our existence is closely linked to water, which is the essence of life itself. Realizing that water is the main source of our nutrition is essential. However, the rapid industrialization and urbanization sweeping through societies have brought forth a tide of environmental challenges, particularly in the realm of water quality safety. With the discharge of industrial wastewater, domestic sewage from urban and rural areas, and the rampant use of pesticides and fertilizers, our precious water sources are under siege. Amidst this backdrop, industries stand at the forefront, recognizing the paramount importance of daily water sampling. Such sampling endeavours are not merely a regulatory obligation but a steadfast commitment to upholding product integrity and ensuring compliance with environmental standards. By vigilantly monitoring water quality, industries safeguard the purity of their processes, mitigate risks, and uphold their responsibility to deliver safe and reliable products to consumers.

In consideration of this, I started a thorough five-month training (January to May 2024) program in water sample analysis, led by the renowned Hindustan Foods Limited, Baddi. The goal of this thesis is to explore various aspects of water sample techniques that are specific to the wide range of water sources that are encountered. Several sampling strategies were investigated by means of careful testing and observation, each of which was customized to the particular features of the water being gathered. Meticulous measures were taken at every stage of the testing procedure to guarantee precision and dependability of outcomes. This thesis aims to provide light on the subtleties of water sampling analysis by providing an understanding of the techniques used and the safety measures required to guarantee reliable and strong results.

## **CHAPTER-2**

### **REVIEW OF LITERATURE**

#### **2.1 Water Analysis**

##### **2.1.1 Introduction**

Water is a free gift from nature that is abundant and vital to the survival of life and the environment. It also plays a significant role in ecosystem function. Owing to various harmful chemicals, industrialization, growing human population, increased fertilizer use, and various manmade activities, water has become heavily contaminated. Natural sources of water contamination include soil erosion, rock weathering, and mining operations. Since many water-borne illnesses impact those who consume contaminated drinking water, it is crucial to regularly monitor the quality of drinking water. (Ramamurthy et.al, 2015).

One of the main resources needed by the pharmaceutical business is water. It can function as an excipient, be utilised to reconstitute items during synthesis, produce the final product, or clean vessels, equipment, primary packaging materials, among other things (Rajeswari,et.al, 2013). Once water for medicinal use has been acquired, it needs to be distributed and kept in storage.

The pharmaceutical sector relies significantly on different degrees of water purity, given its substantial economic importance. (Strade et.al, 2020). The European Union (EU) ranking states that the industries producing pharmaceuticals, chemicals, paper, and agriculture account for the largest portion of the EU economy's gross value, but they also depend the most on a steady supply of water that is both sufficient in quantity and quality (J. Schellekens et. al, 2020).

In addition, the water-related industries must address water scarcity and climate change, as well as environmental sustainability (Willet et.al, 2020)To ensure the sustainability of water resources, it is essential to focus on sustainable industrial water usage. This involves implementing real-time water quality monitoring systems, enhancing water management practices, addressing the water-energy relationship, and adopting zero liquid discharge (ZLD) technologies (Tong et al., 2016). These measures will contribute significantly to maintaining the viability of water resources.

### 2.1.2 Water Sampling

Almost every industry uses water extensively for a variety of reasons. The same procedures as with any other raw material or ingredient should be followed to ensure its quality. The source, treatment, distribution, and storage of water inside the factory should all be covered by a quality assurance programme (Poretti et.al, 1990) so, regular tests for adherence to regulatory or internal requirements should also be included. The selection of criteria, standards, analytical techniques, and sampling strategies, as well as the interpretation of the findings and choices for corrective actions, should all be made with the local environment in mind when establishing a monitoring programme of this kind.

At the time of sampling as shown in figure 2.1, each sample should be carefully labelled, preventing loss or confusion. Every sampling person is included trained on sensual and hygienic practices. Along with comprehensive analysis in compliance with drinking water standards, the samples are even gathered for quality assurance, occupational safety, self-monitoring (HSSE, Safety First), operator and traffic safety requirements (liability prevention & risk management), and other reasons.



**Figure 2.1** *Sampling procedure* (2023, March 28), adopted from WATER control; WATER control AG.

### 2.1.3 Types of Water

Types of water mainly used in the industry includes:



### **2.1.3.1 Purified Water :**

Purified water serves as a crucial resource in various industrial and pharmaceutical applications, as well as in health care facilities. While potable water meets human consumption standards, its suitability for industrial purposes, pharmaceutical manufacturing, and health care settings, particularly for cleaning semi-critical areas and equipment, is inadequate. Therefore, industries and pharmaceutical facilities, especially those involved in health product manufacturing, necessitate appropriate water purification systems tailored to their specific requirements.

A standardized water purification system comprising unit operations is employed to derive purified water from drinking water sources, conforming to the guidelines stipulated by the Brazilian Ministry of Health's directives from 1978 to 1990.

Validation of purified water systems is imperative to ensure compliance with stipulated standards for total organic matter and ionic purity (conductivity  $\leq 1.3 \mu\text{S}/\text{cm}$  at  $25^\circ\text{C}$ ).

Various processes are employed for the production of purified water. Freezing desalination utilizes phase change phenomena, specifically freezing and melting, to eliminate impurities from water, resembling distillation processes. Solvent extraction employs gradients in chemical potential to facilitate pollutant transport, segregating contaminants based on their solubilities in two immiscible liquids, typically water (polar) and an organic solvent (nonpolar). The choice of semipermeable membrane can be tailored based on the target contaminant, rendering membrane processes versatile. Reverse osmosis (RO), ultrafiltration, nanofiltration, and microfiltration are among the membrane processes utilized.

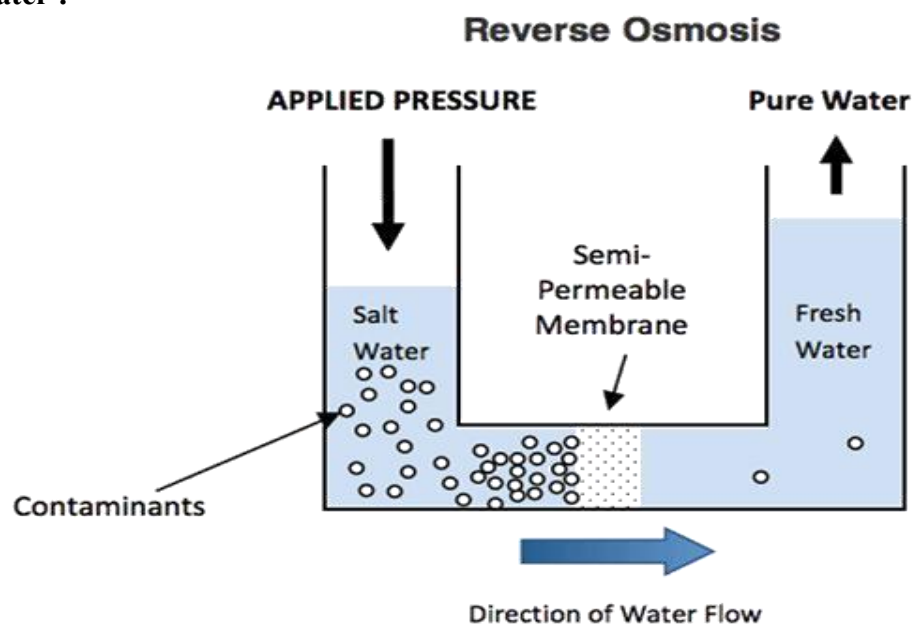
### **2.1.3.2 Raw Water :**

Synthetic organic compounds are extensively utilized worldwide in various products, industrial processes, and daily activities (Söregård et al., 2019). These substances can potentially contaminate water bodies used for drinking water production, posing a threat to the raw water quality (Tröger et al., 2020). Major point sources of such chemicals include wastewater treatment facilities (WWTPs), industrial operations, and healthcare institutions (Söregård et al., 2019). Inadequate removal of pollutants of emerging concern (CECs) during drinking water treatment presents a risk of human exposure to various substances such as pesticides, pharmaceuticals, and personal care products (PPCPs) (Falconer et al., 2006).

While physicochemical investigations can identify the presence or absence of harmful substances and quantify them, they alone are insufficient to assess the true quality of water due to the lack of direct evaluation of biological impacts (Botelho et al., 2013; Singh et al., 2014). Additional testing is thus required to confirm and validate the potential effects of hazardous components. Toxicity testing is essential for evaluating water quality as physicochemical standard analyses cannot distinguish contaminants that may harm biological systems (Tedesco et al., 2012; Singh et al., 2014). It's important to note that toxicity analyses complement rather than replace chemical analyses.

Various methods and bioassays can be employed to assess the toxicity of environmental sources, thereby enhancing the scientific foundation for ecological risk assessment (Serpa et al., 2014). These approaches integrate the biological effects of all pollutants, considering factors such as bioavailability and potential synergistic or antagonistic interactions (Ghosh et al., 2017).

### 2.1.3.3 RO Water :



**Figure 2.2:** Process of Reverse Osmosis, adopted from (Lenntech.com)

Reverse osmosis (RO) is a membrane-based technique designed to extract dissolved solids, organic matter, pyrogens, submicron colloidal matter, colorants, nitrate, and bacteria from water by utilizing semipermeable spiral wound membranes. In this

process, feed water is pressurized and passed across a semipermeable membrane, enabling water molecules to permeate through the membrane's micro-scale apertures, thereby yielding purified water known as permeate. Concurrently, contaminants are concentrated in the reject stream, forming reject water, which is subsequently discharged.

The semipermeable nature of these membranes selectively allows water molecules to traverse while rejecting salt ions. RO membranes are typically composed of materials such as polyamides, various polymers, and cellulose acetate. The choice between hollow-fiber and spiral-wound membrane configurations depends on operational parameters and the composition of the feed water.

RO is a fundamental process in desalination, particularly in membrane-based seawater desalination and wastewater reuse, which are recognized strategies for augmenting water resources and mitigating water scarcity (S. Lee et al., 2010). In brackish water desalination, RO and electrodialysis (ED) are commonly utilized membrane techniques, with RO being the preferred choice for seawater desalination over distillation methods (Mahamed, 2006).

Moreover, municipal wastewater treatment increasingly incorporates RO due to its capability to remove dissolved solids, which are inadequately addressed by conventional treatment methods.

In chemical and environmental engineering, RO serves as a prominent separation process for eliminating organics and organic contaminants from wastewater.

Extensive literature supports the widespread application of RO techniques for solvent separation and concentration in various industrial domains.

#### **2.1.3.4 Soft Water :**

Soft and low-alkalinity fluids are prevalent in water distribution systems and open, recirculating cooling systems. It is widely acknowledged that these systems can lead to elevated levels of metal corrosion (Boulay et al., 2001), potentially resulting in the release of iron corrosion byproducts into potable water (Valcarce et al., 2010). Carbon and lowalloy steels are the predominant materials utilized in water distribution, petroleum,

power generation, chemical, and electrochemical sectors (Farag et al., 2013). However, iron-based alloys are prone to corrosion, particularly in neutral or acidic solutions containing strong anions, which can initiate pitting corrosion (Sayin et al., 2013). Corrosion-related incidents can incur significant financial losses and operational challenges.

## 2.2 Instrumentation

### 2.2.1 pH Meter:



**Figure 2.3** pH Meter. Image source: Department of Quality Control, HFL, Baddi.

A significant portion of everyday items, including food and beverages, medications, cosmetics, and tap water, undergo pH testing, as illustrated in Figure 2.3. Many chemical and biological processes are inherently pH-dependent (M. Filomena et al., 2010).

The concept of pH was first introduced by Danish chemist Søren Peder Lauritz Sørensen in 1909 at the Carlsberg Laboratory. In 1924, he refined this concept into the modern pH scale to standardize definitions and measurements in terms of

electrochemical cells. Initially, the lowercase "p" was written with a subscript "H" to denote pH. The symbol "p" in "pH" represents "power of hydrogen." Alternative theories suggest that "p" may derive from the French word "puissance," meaning "power," or the German word "potenz," considering the Carlsberg Laboratory's predominantly French-speaking staff.

pH measurement finds diverse industrial applications across various sectors of the economy, including wastewater treatment, water conditioning, and process monitoring. pH indicates the acidity or alkalinity of a water solution, determined by the relative concentration of hydroxyl (OH<sup>-</sup>) or hydrogen (H<sup>+</sup>) ions. Acidic solutions contain higher concentrations of hydrogen ions compared to alkaline or basic solutions.

The Henderson–Hasselbalch equation, depicted in Figure 2.4, is a fundamental equation in chemistry utilizing pK<sub>a</sub>, the negative logarithm of the acid dissociation constant, to elucidate pH as a measure of acidity in chemical and biological systems. This equation also facilitates the determination of equilibrium pH in acid-base reactions and the pH of buffer solutions.

## Henderson Hasselbalch Equation

$$\text{pH} = \text{pK}_a + \log \frac{[\textit{conjugate base}]}{[\textit{weak acid}]} \quad (\text{for weak acid})$$

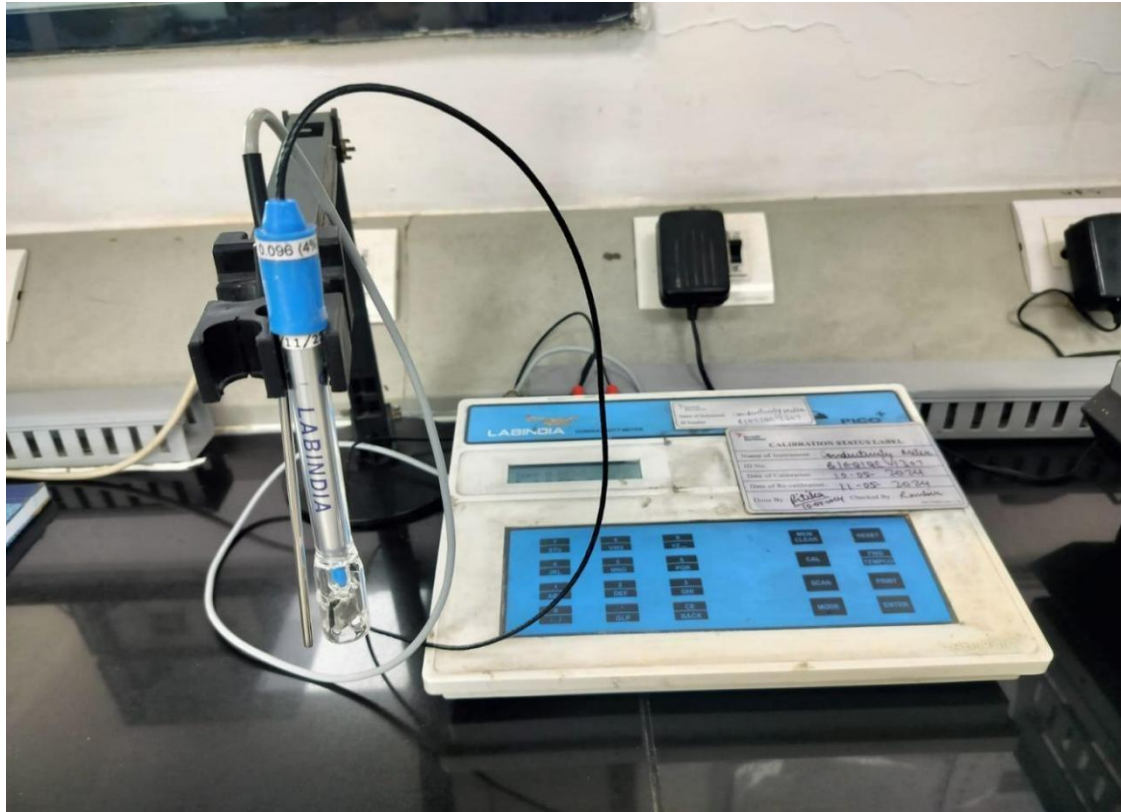
$$\text{pOH} = \text{pK}_b + \log \frac{[\textit{conjugate acid}]}{[\textit{weak base}]} \quad (\text{for weak base})$$

The  
Biology  
Notes



**Figure 2.4** Henderson Hasselbalch Equation, adopted from (Henderson Sapkota, A. 2022, January 21)

### 2.2.2 Conductivity Meter:



**Figure 2.5** Conductivity Meter. Image source: Department of Quality Control, HFL, Baddi.

The conductivity method is a commonly employed technique for evaluating water quality (Gu Yu et al., 2017). Among the crucial metrics for assessing water quality is its conductivity, which indicates the level of dielectric in water. The presence of salt, alkali, or inorganic acids leads to an increase in water conductivity.

Conductivity in aqueous solutions serves not only as an indicator of water quality but also as a measure of the concentration of ionizable compounds present in the water (Lu Peng et al., 2020). Ions are present in water, and when subjected to an external electric field, they undergo migration. Consequently, the specific conductivity of water can be utilized to calculate the water's electrical capacitance and conductivity value, reflecting the increasing number of ion charges (Liu Yuanyuan et al., 2019).

Recent advancements in water purification technologies for contaminated water primarily encompass membrane processes, oxidation techniques, adsorption methods, and biological treatments. The overarching aim is to ensure the quality of drinking water (Guo Zhiming et al., 2020).

The objectives of drinking water treatment include elevating water quality to safe levels, removing harmful constituents, suspended particles, and colloidal materials. Presently, commonly employed methods for drinking water treatment comprise sedimentation, coagulation, clarification, filtration, oxidation, and disinfection. These methods facilitate accurate and timely assessment of current water quality status and dynamic changes, providing comprehensive, scientific, and authentic representations of measured water quality.

Evaluation of ion equivalent conductivity (Figure 2.5) in assessing drinking water quality enables real-time identification of abnormal well conditions, thereby pinpointing contamination sources. Moreover, it offers reference values for studying water quality trends and forecasting future water quality conditions.

### 2.2.3 Analytical Balance



**Figure 2.6** Analytical Balance. Image source: Department of Quality Control, HFL, Baddi.

An analytical balance (depicted in Figure 2.6) is a device designed to measure the gravitational force exerted by an object on its support within Earth's gravitational field, enabling the calculation of the sample's mass (Nater et al., 2009).

Non-automatic weighing instruments encompass analytical electronic balances (NAWI), which necessitate operator intervention throughout the weighing process to assess the suitability of the weighing result.

Calibration of an analytical balance is essential across its entire range. However, calibration may be limited to the portion of the measuring range in use if the balance is only partially utilized.

Precision balances and scales, also referred to as top loader and milligram balances, are employed for weighing medium-to-large sample volumes into vessels or containers and for applications requiring weighing capacities up to the kilogram range.

The operation of an analytical balance is underpinned by the "magnetic force restoration" theory. These electromagnetic balances utilize an electromagnet to ascertain an object's mass. Rather than directly measuring mass, these balances quantify the force acting downward on the balancing pan (Analytical balances. (n.d.). Sartorius).



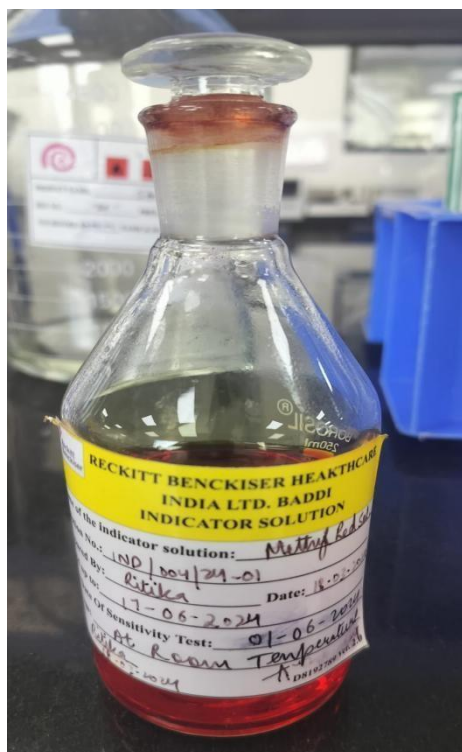
## CHAPTER-3

### MATERIAL AND METHOD

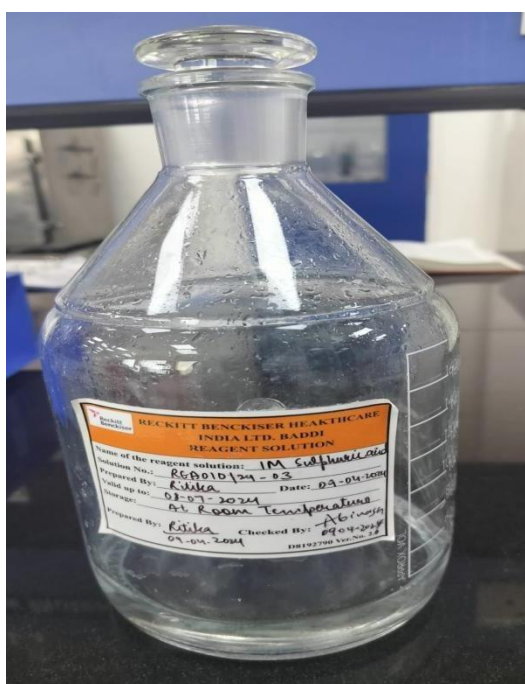
#### 3.1 Material :

The materials utilized in the study encompass a combination of in-house prepared solutions and commercially available substances. In-house preparations include Methyl Red Indicator (Figure 3.1), 1M H<sub>2</sub>SO<sub>4</sub> (Figure 3.2), 0.163% KNO<sub>3</sub> (Figure 3.3), 0.02M KMnO<sub>4</sub> (Figure 3.4), 10% KCl (Figure 3.5), Diphenylamine Sol (Figure 3.6), Glycerine Base (85%) (Figure 3.7), Thioacetamide Solution (Figure 3.8), and Acetate Buffer pH 3.5 (Figure 3.9). These substances were carefully prepared according to established protocols. Additionally, other materials sourced externally include 4.01, 6.86, 9.18 pH Buffer solutions (Thermo Scientific), Bromothymol Blue Indicator (RANKEM), Sulphuric Acid (Merck), and Lead Standard (1000 ppm) (Merck).

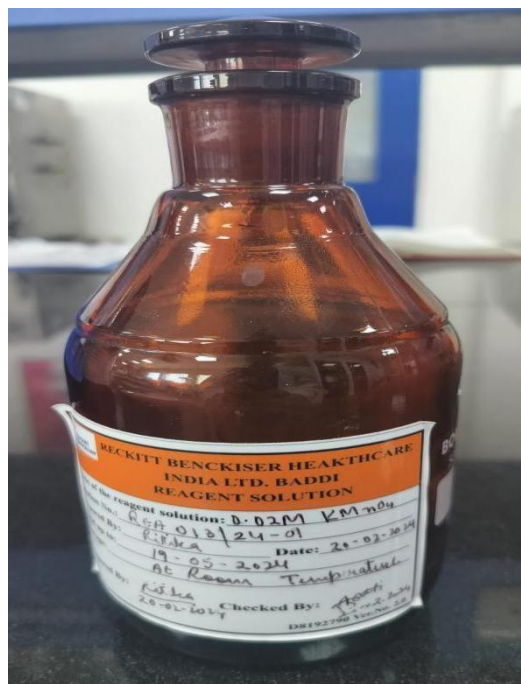
Various glassware items were employed in the experimental procedures, such as 1000 ml Volumetric Flasks, Stoppers, 100 ml Glass Beakers, 1000 ml Reagent Bottles, Nessler's Cylinders, Measuring Cylinders, Evaporating Dishes, Test Tubes, Test Tube Stands, as well as a range of glass pipettes including 0.1 ml, 0.005 ml, 2 ml, 4 ml, 1 ml, and 10 ml capacities. Additionally, a bubbler was used for specific experimental setups.



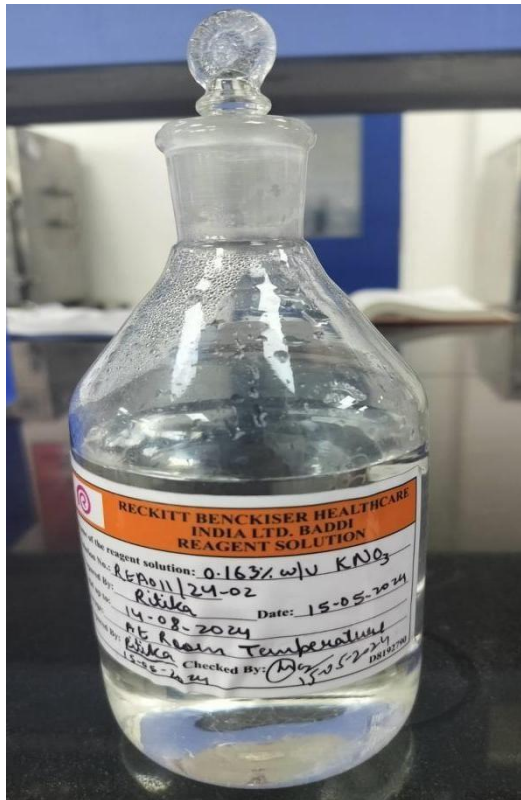
**Fig 3.1** Methyl Red Indicator ( Preparation as per IP)



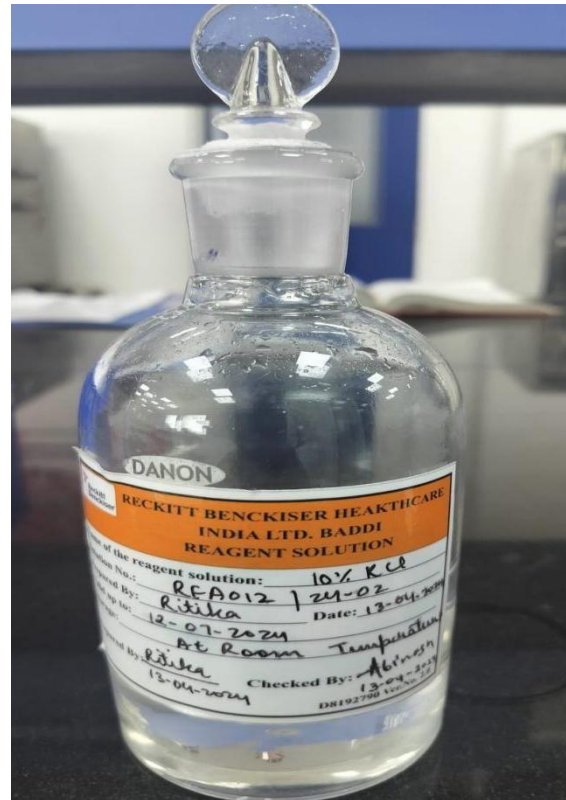
**Fig 3.2** 1M  $H_2SO_4$  ( Prep as per IP)



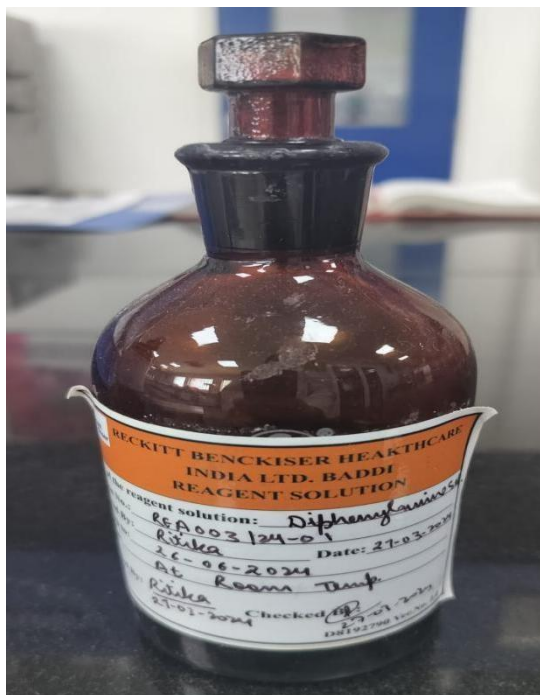
**Fig 3.3** 0.02 M  $KmNO_4$  (Prep as per IP)



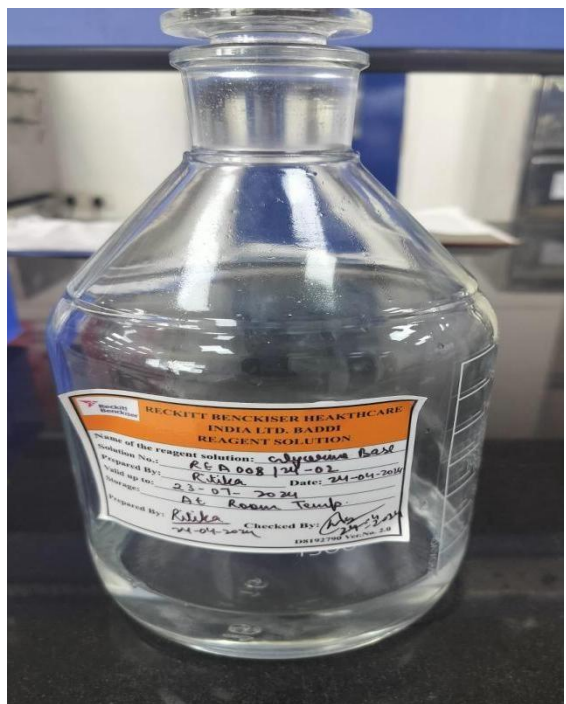
**Fig 3.4** 0.163% KNO<sub>3</sub> (Prep as per IP )



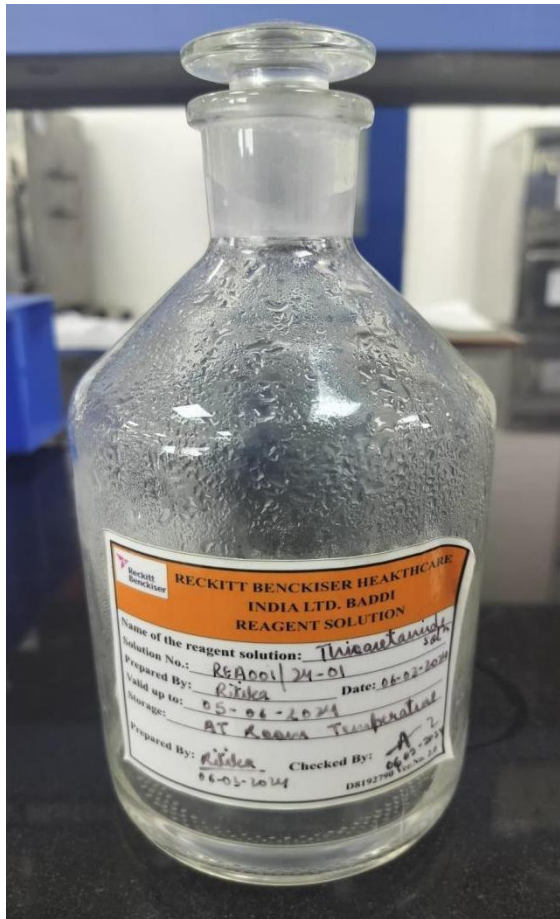
**Fig 3.5** 10% KCL (Prep AS per IP)



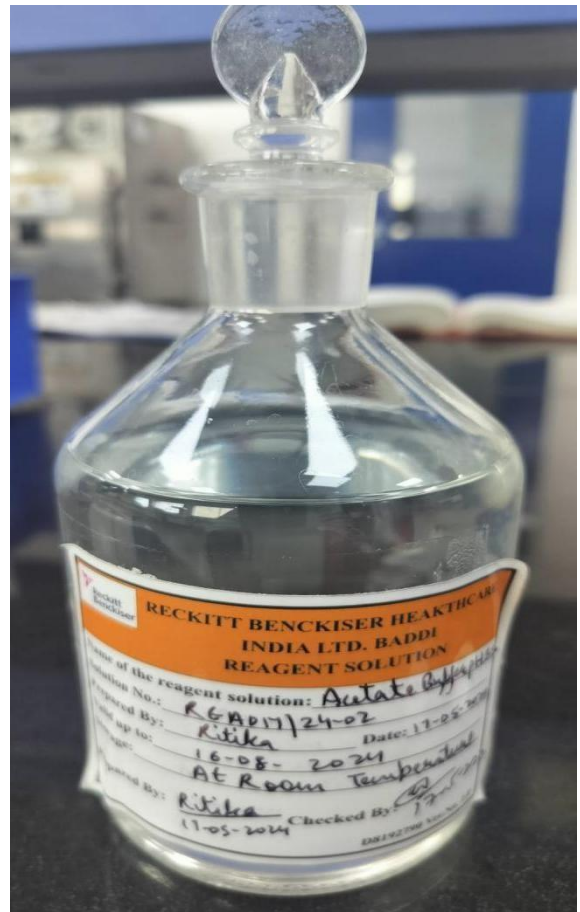
**Fig 3.6** Diphenylamine Sol (Prep as per IP)



**Fig 3.7** Glycerine Base (85%) (Prep as per IP)



**Fig3.8** Thioacetamide Sol (Prep as per IP)



**Fig 3.9** Acetate Buffer ( Prep as per IP)

### 3.2 Methodology:

3.2.1 Sampling of Water from various locations in plant :



**Fig 3.10** Sampled Water from various locations in Plant

DAY	DAILY WATER SAMPLING POINTS
Monday	SP-55, 58, 50, 52
Tuesday	SP-55, 58, 50, 52
Wednesday	SP-55, 58, 50, 52
Thursday	SP-55, 58, 50, 52
Friday	SP-55, 58, 50, 52
Saturday	SP-55, 58, 50, 52

Table 3.1 : Daily Sampling Points as per Schedule

WEEK	MONTHLY SAMPLING POINTS					
DAY	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6
1 <sup>st</sup> WEEK	AYUPW-01 AYUPW-02	CWH-01	MLQ-01	COPW-02 SP-17	SP-18	AYUPW-03 AYUPW-04
2 <sup>nd</sup> WEEK	COPW-03 SP-20	AYUPW-06 SP-21	SP-01,SP-02 SP-03	BW-01, BW-02	SP-23, SP-24, SP-25	AYUPW-08
3 <sup>rd</sup> WEEK	COPW-06 SP-26, SP27, SP-28	AYUPW-10 SP-08, SP-09, SP-10	COPW-07 AYUPW-11 SP-29	SP-13 SP-14	AYUPW-12 SP-30	AYUPW-13 SP-32 SP-33
4 <sup>th</sup> WEEK	AYUPW-15 SP-35 SP-36	AYUPW-16 SP-37	AYUPW-17 SP-38 SP-39	AYUPW-18 SP-40 SP-41	AYUPW-19 SP-42 SP-43	SP-44 SP-45

Table 3.2: Sampling Schedule on Weekly basis for Water

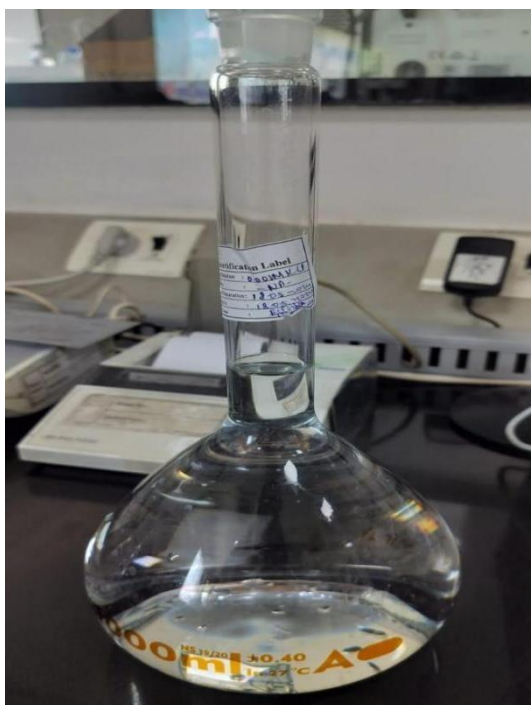
### 3.2.2 Tests Performed On Sampled Water

**3.2.2.1 Description :** All samples should complies with the the description limit , a clear, colourless and Odourless liquid.

#### 3.2.2.2 Conductivity Measurement :

Take the reading of conductivity of water on a calibrated conductivity meter.

Calibration of conductivity meter is done using 0.001M KCl - Value of cell Constant = 0.096, Conductivity value = 147  $\mu$ S/cm



**Fig3.11** 0.001M KCl (Prep as per IP)



**Fig3.12** Value of cell constant and Conductivity of KCl

### 3.2.2.3 pH :

Took 100ml of sample in a cleaned glass beaker, and measure the pH at 25<sup>0</sup>C.

### 3.2.2.4 Oxidisable Substances:

After the addition of 10 ml of 1 molar sulfuric acid and 0.1 milliliters of 0.02 molar potassium permanganate to a 100-ml sample, boiling the mixture for 5 minutes resulted in a faint pink coloration of the solution, as illustrated in Figure 3.13.



**Fig 3.13** Procedure for oxidisable substances test

### 3.2.2.5 Acidity/Alkalinity :

0.05 ml of methyl red solution was introduced into a borosilicate glass flask containing 10 ml of freshly boiled and cooled sample; however, the resulting solution did not exhibit a red coloration. Subsequently, 0.1 ml of bromothymol blue solution was added to another 10 ml of the sample, yet the resultant solution did not display a blue hue.

### 3.2.2.6 Nitrate:

**Prep. of Nitrate Standard:** The standard is prepared by diluting 1ml of a 0.163%  $\text{KNO}_3$  solution to 10 ml using water (100 ppm). Use water to dilute 1 ml of the nitrate standard solution to a total volume of 50 ml (resulting in a concentration of 2 ppm). Then, fill test tubes with 0.5 ml of this 2 ppm nitrate standard solution and add 4.5 ml of nitrate-free water.

**Preparation of sample:** Transfer 5ml of sample in a test tube. And to all the test tubes added 0.4ml 10%  $\text{KCl}$  , 0.1ml Diphenylamine solution and 5ml of Sulphuric acid.

Then incubated all test tubes at  $50^\circ\text{C}$  for 15 minutes.



### 3.2.2.7 Heavy Metal:

**Prep. of Thioacetamide Reagent:** Heated 20 ml (85% glycerine base) and 4 ml (thioacetamide solution) in a water bath for 20 seconds, then cooled and use right away.

**Prep. of Lead Standard solution (1ppm):** 10 ppm of of lead standard was from from 1000ppm lead standard by diluting 10ml of 1000ppm Pb in 100ml water. Then diluted 10ml of this 10ppm solution again to 100ml to produce 1ppm sol.

10 ml of 1ppm lead solution and 2 ml of sample were put into a 50 ml Nessler cylinder.

**Test prep:** 150 ml of the sample were evaporated down to 15 ml using a water bath in a glass evaporating dish. Then, 12 ml of this concentrated solution were transferred into a Nessler cylinder. Thioacetamide reagent and 2 ml of pH 3.5 acetate buffer were added to each Nessler cylinder.



**Fig 3.14** Procedure for Heavy Metal test

## CHAPTER-4 RESULTS AND DISCUSSION

### 4.1 RESULTS:

**4.1.1 Conductivity:** The acceptance criteria of conductivity of purified water is NMT 1.3  $\mu\text{S}/\text{cm}$ .



**Fig 4.1** Conductivity results for purified water

**4.1.2 pH:** The pH of purified water should rely between the acceptance criteria of 5.0-7.0



**Fig4.2** pH Results for purified water

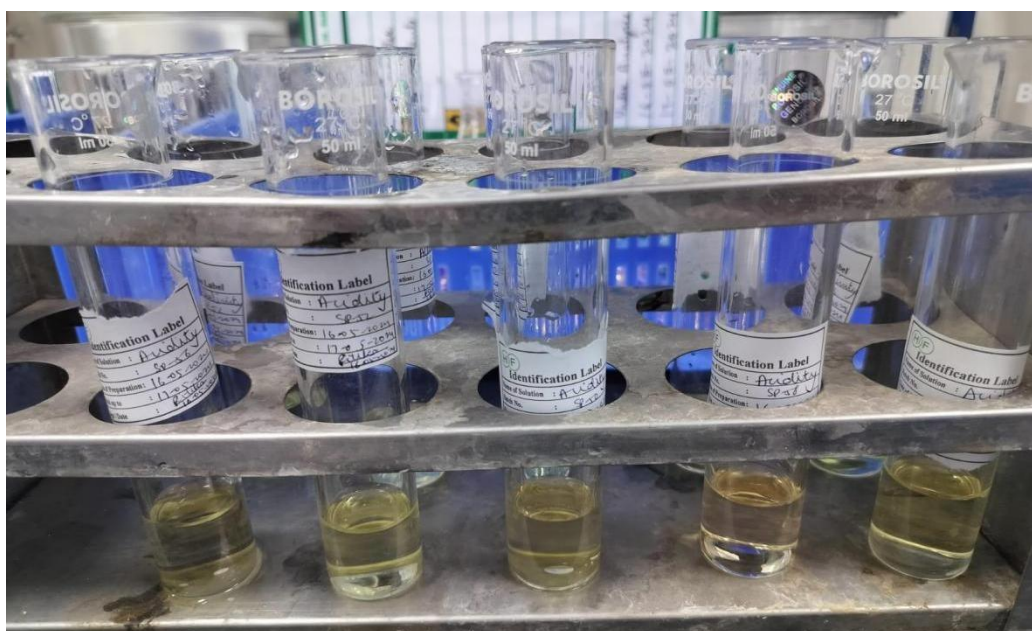
**4.1.3 Oxidisable Substances:** Pink colour did not disappear after 5 mins of boiling.



**Fig 4.3** Oxidisable substances Results

#### **4.1.4 Acidity/Alkalinity:**

The sample didn't coloured red when methyl red was added and blue colour didn't appear when bromothymol blue was added in sample.

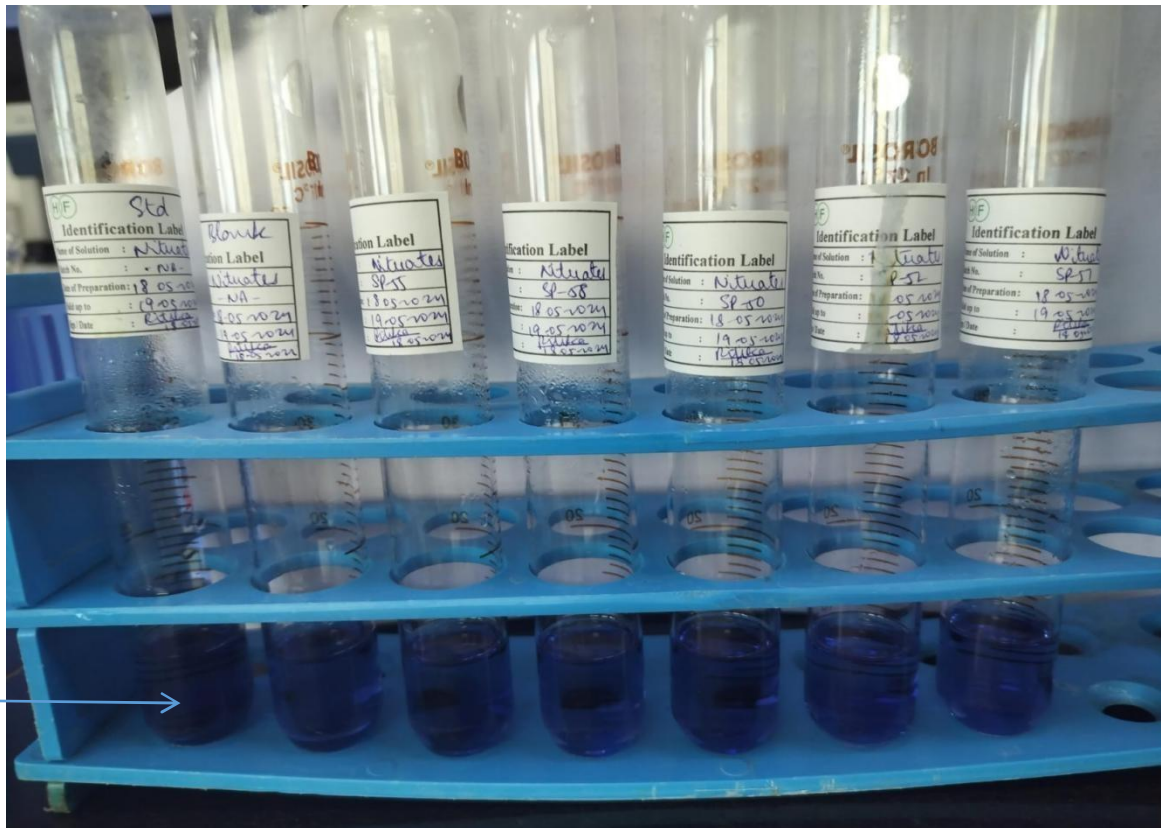


**Fig 4.4** Acidity Test Results



**Fig 4.5 Alkalinity Test Results**

**4.1.5 Nitrates:** Compared to the standard solution, the sample solution's blue colour production is less intense.



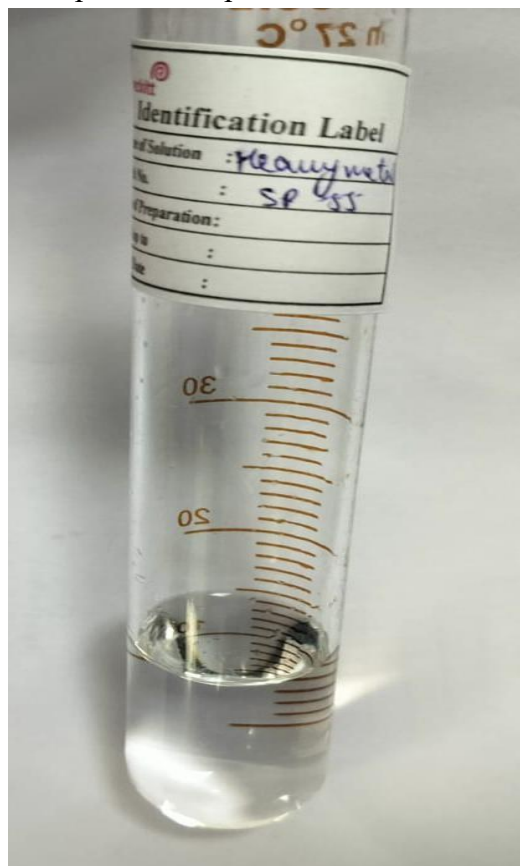
**Fig 4.6 Results of Nitrates test**

**4.1.6 Heavy Metal:**

Brown colour produced is much less intense in samples as compared to standard.



**Fig 4.7 Lead Standard Solution**  
(showing slight Brown colour)



**Fig 4.8 Sample Solution**  
(less intense brown colour)

## **4.2 DISCUSSION:**

The purity and cleanliness of the water used in its procedures are extremely important to the pharmaceutical business. Water is an essential ingredient in the production of pharmaceuticals, used in many steps including synthesis, formulation, and even as a cleaning agent for tools and packaging. Given this widespread application, chemical analysis of water samples becomes a crucial procedure for a number of important reasons:

### **1. Ensuring Safety and Quality of the Product**

The water used in pharmaceutical manufacturing has a direct impact on the final product's quality. Both the effectiveness and safety of medications can be jeopardised by contaminants such as organic chemicals, heavy metals, or microbiological organisms. Chemical analysis aids in the identification and measurement of these contaminants, guaranteeing that water satisfies the strict quality requirements needed for the manufacturing of pharmaceuticals.

### **2. Adherence to Regulations**

Health agencies like the FDA, EMA, and WHO have regulations that pharmaceutical businesses have to follow. Strict guidelines for water quality are outlined in these rules, along with particular thresholds for different pollutants. Frequent chemical analysis guarantees adherence to these requirements, protecting the products from fines and guaranteeing their safety for consumer usage.

### **3. Guarding Against Contamination**

If water quality is not adequately controlled, it may become contaminated. Chemical analysis facilitates the timely intervention and prevention of contamination problems by aiding in the early detection of potential contaminants. This is especially crucial for parenteral or injectable product processing, as even little amounts of pollutants can have serious negative effects on health.

### **4. Improving Manufacturing Procedures**

For production processes to be stable and consistent, water quality must be consistent. Changes in the composition of water can cause unanticipated reactions during manufacturing, equipment corrosion, and inefficiencies in processes. Water is kept at the appropriate purity levels through chemical analysis, which facilitates efficient and seamless production processes.

### **7. Control and Quality Assurance**

A crucial component of pharmaceutical manufacturing's quality assurance and control procedures is chemical analysis. Businesses can record and confirm that every production batch satisfies the necessary criteria by testing water samples on a regular basis. For traceability, audits, and inspections, this documentation is essential.

#### Analysis of Common Parameters

In the pharmaceutical sector, the chemical analysis of water usually consists of:

Conductivity and pH are markers of ionic contaminants and general water quality.

Organic pollutants are measured using total organic carbon, or TOC.

Finding bacterial and fungal pollutants is known as microbial contamination. Particular

Ions and Heavy Metals: Iron, lead, mercury, sulphate, chloride, Pesticides and residual

solvents: Making sure there are no dangerous leftovers.

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