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Biochemical Evaluation and Stability Assessment of Eye Drops Manufactured at Mengo Hospital: A Quality Control Study

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Abstract:- This comprehensive study undertook a thorough evaluation of the biochemical composition and stability of eye drops manufactured at Mengo Hospital. A range of analytical tests were conducted to assess the eye drops' pH, osmolarity, viscosity, protein content, and susceptibility to microbial contamination. Additionally, stability testing was performed under various storage conditions to simulate real-world scenarios.

The results of the study revealed that the eye drops manufactured at Mengo Hospital largely conformed to regulatory standards for pH and osmolarity. However, significant variations were observed in viscosity and protein content, indicating inconsistencies in the manufacturing process. Furthermore, stability testing under accelerated conditions demonstrated degradation of the eye drops, highlighting concerns regarding their shelf life and potency.

Notably, microbial contamination was detected in some samples, raising concerns about the risk of eye infections and the need for improved sterilization protocols. A comparative analysis with commercial eye drops revealed similarities in biochemical composition but distinct differences in stability profiles. This suggests that while the Mengo Hospital eye drops may possess similar characteristics to commercial products, their stability and longevity may be compromised.

The findings of this study have significant implications for quality improvement initiatives at Mengo Hospital. Recommendations include optimizing the manufacturing process to minimize variations in viscosity and protein content, implementing enhanced sterilization protocols to prevent microbial contamination, and conducting regular stability testing to ensure the eye drops' potency and shelf life. By addressing these areas, Mengo Hospital can enhance the quality and safety of its eye drops, ultimately benefiting patients and maintaining trust in its products.

I. INTRODUCTION

A. Presentation of Subject or Issue

According to Kaur et al., 2019, millions of patients globally rely on eye drops for the treatment of various eye conditions. These are essential in managing eye health and cannot be overemphasized.

The use of eye drops is both convenient and efficient in administering drugs directly into the eyes (Singh et al., 2020). By this direct approach, ocular diseases have been optimally treated by using these therapeutic agents which are very important tools in ophthalmology.

Eye drops should be made with utmost care due to their quality and safety. Eye infections, vision loss, even blindness can result from defective eye drop products (WHO, 2018). Hence it is vital to ensure that these items are excellent in terms of quality and safe to avert such negative outcomes during the medication administration process.

B. Scope of the Study

This study carries out a comprehensive evaluation of the biochemical composition and stability of eye drops manufactured at Mengo Hospital, a renowned Ugandan healthcare institution. Mengo Hospital is well-known for its provision of eye healthcare services and has been making eye drops for patients; however, these products' quality and stability need rigorous assessment.

The purpose of this study is to deeply examine the biochemical composition and stability of the products being produced by Mengo Hospital's eye drops which are being confined to this facility only. The consequences of this research can go beyond the confines of Mengo Hospital. The overall pharmaceutical industry and health sector will benefit greatly from the findings as they provide precious information on the quality and safety of eye drops (Mugisha et al., 2017).

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Healthcare encompasses many sectors that together work towards promoting quality in medicine production with an emphasis on safe drugs. This is a relevant study among others that focuses on eye drop manufacturing at Mengo Hospital because these products are used globally to help deal with various ocular diseases. High-quality product manufacture is one aim of assessing them in terms of their chemical constitution as well as their firmness to meet international standards.

The outcomes of this study will be very important to the pharmaceutical industry and the wider healthcare system in Uganda and other parts of Africa. The outputs will help in informing quality improvement efforts at Mengo Hospital as well as policy-making for developing policies and guidelines aimed at ensuring the correct distribution and use of pharmaceuticals. In addition, these study findings will offer significant experience to healthcare professionals, researchers, and policymakers thus helping them improve healthcare services and eventually enhance patient outcomes.

C. Background Information

It is evident that Mengo Hospital is dedicated to providing critical eye medicines in the form of eye drops for patients. In this view, the safety and efficacy of these products are ensured only after rigorous testing and confirmation (Okello et al., 2015). Consequently, it guarantees that patients get high-quality products that meet worldwide standards.

In its quest to offer excellent eye health services, Mengo Hospital manufactures eye drops for use by patients. It is important to know however that assuring the quality of pharmaceuticals remains a never-ending process and needs constant monitoring as well as evaluation (NDA, 2020). Under this approach, Mengo Hospital can detect loopholes in its practices and work towards achieving the highest level of quality.

By checking the stability and quality of their eye drops, Mengo Hospital shows commitment to patient safety. For trust and confidence in the hospital's services and products, commitment to quality becomes vital. The ongoing assurance mechanisms will enable Mengo Hospital to make certain that its eye drops remain safe and active when used by patients.

D. Context of Subject

- *Cultural Context*

Uganda is a country where traditional medicine has not lost its meaning and remains a strong practice. Many people prefer to use customary remedies to treat their health problems. This includes the use of traditional eye drops, which may not have undergone rigorous testing for quality and safety. Traditional eye drops are still tabulated by some patients being, therefore, further studies on the safety and efficacy of these are essential.

The employment of untested traditional eye drops brings great dangers to patient health, as these remedies can carry dangerous substances or impurities. Additionally, the unregulated and unmonitored environment in which traditional medicine is practiced, further heightens the risk, necessitating the need for the issue to be handled through education, research, and policy initiatives (Kiggundu et al., 2018). By examining the quality and safety of traditional eye drops, we can better understand the implications for patient care and work towards ensuring that all patients receive safe and effective treatments.

- *Political Context*

The Ugandan government has made tremendous strides towards better healthcare for its citizens, which the government sees as a critical aspect of the overall well-being of the citizens. The main strategy in this direction has been to adopt policies that focus on the regulation of pharmaceutical products, making sure that the quality and safety of the medications are strictly adhered to (MoH, 2019).

So as to be compliant with the regulatory measures, the government makes it clear that pharmaceutical products like eye drops should be safe for patient use and should be effective in treating various health conditions. Uganda's government sets out clear guidelines that show the national dedication to safeguarding the health of citizens and building a relationship based on trust between the healthcare system and the public. This, subsequently, leads to improved health conditions and a better quality of life for the citizens of Uganda.

- *International Context*

The global healthcare community reconnected in its common purpose to ensure the quality and safety of pharmaceutical products, declaring them the essential tools in both preventing and treating diseases. Rising concern for quality and safety is from the World Health Organization (WHO) and other international organizations, which stress the importance of rigorous testing, regulation, and oversight of pharmaceutical products (WHO, 2019).

Thus, different countries of the Earth have launched initiatives to guarantee that medicine products like eye drops will be of superior quality and safe. This includes amelioration of the regulatory frameworks, the expansion of testing and inspection protocols, and the promotion of international collaboration to deal with the global challenge of substandard and falsified pharmaceutical products. Through collaboration, the global community can guarantee that patients throughout the world have the right to be treated and their health be secured.

- *Economic Context*

Uganda's pharmaceutical industry is a key player in the country's economy as it is one of the sectors that contributes greatly to the growth and development of the country. The pharmaceutical industry which is important to the economy is directly affecting the economic performance of the country, and its growth is in line with the overall economic

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situation of Uganda (UBOS, 2020). Thus, the provision of quality medication is not only important for the health of the public but also for the preservation of economic growth.

Up by quality pharmacy, the industry could be one of the stable sectors of the economy getting better and creating more opportunities for investment, innovation, and job opportunities. On the other hand, the impact of substandard or falsified pharmaceutical products can be very far-reaching, because, they can result in the loss of public trust, the damage of the industry's reputation, and the economic decline. Hence, securing the quality of pharmaceutical products is a critical factor in Uganda's economic development strategy, and ongoing efforts are necessary to protect and promote this vital sector.

E. Purpose of the Study

This study's main goal is to check the biochemical makeup and durability of eye drops made at Mengo Hospital. We want to take a close look at the physical, chemical, and biological features of these drops to make sure they meet the standards set for medicines.

Looking at the chemical makeup and durability matters a lot when it comes to making sure the eye drops are safe and work well. By studying their biochemical properties, we can spot any unwanted stuff, impurities, or breakdown products that might affect how good the eye drops are.

Also, testing how well the eye drops hold up over time is key to making sure they stay effective and safe while they're on the shelf. This means putting the drops through different tests, like changing the temperature, humidity, and light, to see how they hold up and if they break down.

The study's second goal is to find ways to make the eye drop manufacturing process better. This means taking a good look at every step, from getting the raw materials to packaging the final product, to spot any weak points or things that could be done more.

By spotting areas to improve, researchers can suggest ways to make the manufacturing process better making sure the eye drops meet global standards. This might mean putting new quality checks in place, upgrading tools or buildings, or giving staff more training.

The global standards mentioned in this study are the ones set by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, 2019). These standards give rules to develop, make, and test drug products making sure they are high-quality, safe, and work well.

When Mengo Hospital follows these global standards in making its products, it can make sure its eye drops are high-quality and safe. This helps keep people's trust in what they make.

In the end, what this study finds will help make the eye drops from Mengo Hospital better. It will make sure they are top-quality, safe, and work well. This will be good for public health, as people will be able to get treatments that work and are safe for their eye problems.

II. THE RESEARCH FOCUS

A. Research Statement

Biochemical Evaluation and Stability Assessment of Eye Drops Manufactured at Mengo Hospital. The biochemical evaluation and stability assessment of eye drops made at Mengo Hospital plays a key role to ensure these pharmaceutical products are safe and high-quality. The study looks at the eye drops' biochemical traits such as pH, osmolarity, and sterility, and checks how stable they remain over time. This research matters because it fills an important gap in quality control for eye drops produced at Mengo Hospital, a major eye care provider in Uganda. The results will affect patient safety, treatment success, and the hospital's standing. By examining the biochemical properties and stability of the eye drops, the study will offer useful insights about the products' quality and spot areas to improve in the manufacturing process. This will help make sure patients get safe and effective treatments leading to better health and improved life quality.

B. Background:

Eye drops play a crucial role in eye care. Doctors use them to diagnose, treat, and manage many eye problems (Kaur et al. (2019).). They deliver medicines straight to the eye, which makes treatment more effective and reduces side effects in the rest of the body.

How well eye drops work and how safe they are depends a lot on their quality. Poor quality eye drops can be less effective, cause bad reactions, or even lead to lasting vision loss. This shows why it's so important to make sure eye drops are made with strict quality checks.

Strict quality control plays a key role in making eye drops. It helps to make sure they're safe and work well (WHO (2018). When companies focus on quality control, they can make products that meet global rules. This protects people's health and keeps eye care trustworthy.

C. Research Question:

What is the biochemical evaluation and stability assessment of eye drops manufactured at Mengo Hospital?

D. Objectives:

- To evaluate the biochemical properties of eye drops manufactured at Mengo Hospital.
- To assess the stability of eye drops manufactured at Mengo Hospital.
- To determine the quality control measures in place at Mengo Hospital for eye drop manufacturing.

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E. Description:

This study aims to carry out a thorough check of the biochemical traits of eye drops made at Mengo Hospital. Its main goal is to examine the physical, chemical, and biological features of the eye drops to make sure they meet the needed standards for quality and safety.

The study will also look into how stable the eye drops are over a set time. This involves testing the eye drops in different settings, like temperature, humidity, and light exposure, to figure out their stability and breakdown patterns. By looking at the stability of the eye drops, the study hopes to ensure they stay effective and safe throughout their shelf life.

At its core, the study aims to make sure the eye drops made at Mengo Hospital are up to standard in terms of quality and safety. By checking their biochemical features and how well they hold up over time, the study wants to give useful insights into how good these eye drops are and spot ways to make the manufacturing process better. In the end, this means patients will get safe and effective treatments, which leads to better health results and a boost in their quality of life.

F. Theoretical Framework:

This study has its foundation in quality control principles for making pharmaceutical products. This approach stresses how crucial it is to make sure eye drops and other medicines are safe, work well, and meet high standards.

Quality control principles state that drugs need to meet certain benchmarks and rules to ensure they're safe and effective for patients to use (Singh et al. 2020). This study uses this approach to examine the chemical makeup and shelf life of eye drops made at Mengo Hospital.

This study uses quality control principles to make sure the eye drops are up to scratch in terms of quality and safety. The study's theory base lays the groundwork for how it's carried out and analyzed. It guides the check of the eye drops' biochemical traits and how well they hold up over time. This is to ensure they hit the mark for keeping patients safe and making the treatment work well.

G. Importance of this Research:

The importance of this research stems from its capacity to fill a key gap in quality control protocols for eye drops made at Mengo Hospital, a top eye care provider in Uganda. The hospital plays a vital role in offering eye care to many people, so it's crucial to make sure the eye drops used for treatment meet high-quality standards.

The research aims to assess the biochemical features and stability of eye drops to ensure they meet required quality and safety benchmarks. By spotting any flaws in quality control methods, the study can help improve the manufacturing process, which should lead to better health results for patients.

This study's results will affect eye healthcare in Uganda in making sure patients get safe and effective treatments. By focusing on quality control, Mengo Hospital can keep its good name as a trusted eye healthcare provider, and help make public health better in Uganda.

H. Definition of Terms:

- **Biochemical Evaluation**: The process of analyzing the biochemical properties of eye drops, including pH, osmolarity, and sterility.
- **Stability Assessment**: The process of evaluating the stability of eye drops over a specified period.
- **Quality Control**: The process of ensuring that eye drops meet the required standards for quality and safety.

III. REVIEW OF OTHER WORK DONE

Studies have shown that eye drops have a complex makeup needing strict control of ingredients pH, and osmolarity (Smith et al. (2018). This complexity means we need tough quality checks to make sure they stay stable and work well.

A study in the Journal of Pharmaceutical Sciences looked at how pH affects eye drop stability showing why exact pH control matters so much (Kim et al. (2019).

A look at eye drop formulas found more use of multi-dose packaging, which brings new challenges for stability and keeping them clean (Martin et al. (2020).

Scientists have explored using new additives, like cyclodextrins or liposomes, to improve eye drop stability and delivery (Patel et al. (2022).

A thorough examination of eye drop creation and durability has highlighted the necessity to keep researching and innovating to tackle new problems and boost product standards (Smith et al. (2022)

A. Other Research Done

Research has looked at how temperature affects eye drop stability showing it has a big impact on how well the formula holds up (Johnson et al. (2020). Light has also been found to break down active ingredients, which hurts product quality (Lee et al. (2019).

A paper in the European Journal of Pharmaceutics and Biopharmaceutics checked out how light makes eye drops break down stressing that we need packaging to protect them (Chen et al. (2020).

Scientists have tried using different preservatives, like natural antioxidants, to make eye drops last longer and cut down on toxicity risks (Brown et al. (2020).

Research on how temperature changes impact the stability of eye drops has resulted in calls for stricter controls on storage and transport (Thompson et al. (2018).

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B. Other Findings & Conclusions

Experts have pinpointed contamination risks as a key issue in keeping eye drops stable. If bacteria grow, it could lead to companies having to recall their products (Davis et al. (2017). Rules set by regulators require strict quality checks to lessen these risks.

Taylor et al. (2018) stress how crucial it is to control osmolarity in eye drops. When osmolarity differs from what's normal in the body, it can irritate the eyes and make them feel uncomfortable.

Studies have looked into how packaging materials affect eye drop stability. Some research points out that substances that leak or can be extracted from packaging might harm product quality (White et al. (2022).

Lee et al. (2020) shed light on how regulatory compliance plays a key role in developing eye drops. Companies that make these products must meet tough quality and safety rules.

C. Other Methodologies

Scientists use different methods to check how well eye drops hold up over time. These include quick tests and long-term studies (Patel et al. (2022). These methods help companies make sure their products are good quality and last as long as they should.

Scientists use a special machine called HPLC to look at eye drops. It helps them find any unwanted stuff or things that shouldn't be there (Garcia et al. (2021).

Quick tests help predict how eye drops will do over a long time. This lets companies spot any problems on when they're making new products (Hall et al. (2021).

Long-term studies look at how eye drops do when they're stored . This gives important info for product labels and to figure out how long the drops will last (Kim et al. (2021).

D. Strengths & Weaknesses

People have argued about putting preservatives in eye drops. Some research shows they work well to stop germs from growing (Brown et al. (2020). But other studies worry these additives might harm or bother eyes.

Adding stuff like salt or glycerin to eye drops helps them last longer and feel better on the eye (Hernandez et al. (2019).

Scientists have talked about the good and bad sides of using surfactants in eye drops. These chemicals can affect how well the drops work and how long they last (Brooks et al. (2019).

Scientists have looked into using combination products, like eye drops that contain several active ingredients. This research has brought up unique challenges in stability and compatibility (Brown et al. (2022).

IV. RESEARCH METHODS

A. Research Goals and Objectives:

This study's main aim is to check the eye drops made at Mengo Hospital. The research will look at three key things: what's in the drops how well they last, and if they have any germs. By looking at these, we want to make sure the eye drops from Mengo Hospital are safe to use and work well.

The first thing we want to do is to see what's inside the eye drops. This means finding out what active parts are in there, what keeps them fresh, and what else is mixed in. This way, we can tell if the drops have the right amounts of each part and if they match what the medicine books say they should.

The second objective has an impact on checking how stable the eye drops are when stored in different ways. This means looking at how heat, moisture, and light affect the eye drops' chemical makeup and strength. By running stability tests, the study will find out if the eye drops stay effective and safe for as long as they're supposed to.

The third objective is to analyze whether the eye drops contain germs. This involves testing to see if any bacteria, fungi, or other tiny organisms that could make the eye drops unsafe or less effective. By finding any germs, the study will make sure the eye drops are clean and okay to use in sensitive places like the eyes.

The fourth and last goal is to compare how Mengo Hospital eye drops and commercial eye drops work and how stable they are. This comparison will help figure out if the eye drops made at Mengo Hospital are as good as the ones you can buy in stores. By reaching these goals, the study will give useful insights into the quality of eye drops made at Mengo Hospital and help come up with ways to make them better.

B. Research Hypotheses

- Mengo Hospital eye drops' biochemical makeup will meet regulatory standards.
- Storage conditions will have an impact on the stability of Mengo Hospital eye drops.
- Microbial contamination will stay within acceptable limits.
- The biochemical and stability profiles of Mengo Hospital eye drops will match those of commercial eye drops.

C. Research Strategy and Techniques

The study's research strategy will use a numbers-based approach running lab tests and analysis methods to check the quality of eye drops made at Mengo Hospital. This method will let us gather numerical data, which we'll then analyze and interpret to draw useful conclusions.

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The first step in our research plan is to collect eye drop samples from Mengo Hospital. We'll get a typical sample of eye drops from the hospital's pharmacy or where they make them. We'll put the samples in clean containers and take them to the lab to analyze.

The second step has to do with analyzing the eye drop samples. This includes measuring different biochemical factors like pH, osmolarity, viscosity, and how much protein is in them. These tests help figure out if the eye drops have the right biochemical makeup and meet the standards they need to.

The third step is about testing stability. This involves doing quick stability studies and finding out how long the eye drops last on the shelf. This helps assess how the eye drops act when stored in different ways and if they stay effective and safe to use for as long as they're supposed to.

The fourth step has an impact on microbial contamination testing. It aims to check for sterility and to find endotoxins. This helps make sure the eye drops don't have harmful microbes and are safe to use in delicate areas like the eyes.

Besides these tests, the study also wants to compare the biochemical and stability profiles of Mengo Hospital eye drops with store-bought ones. This comparison helps figure out if the eye drops made at Mengo Hospital are as good as the ones you can buy in stores.

To get results you can trust, the study will use different ways to analyze things. These include spectrophotometry, chromatography, and tests for microbes. These methods give exact measurable data. The team will then use special computer programs to look at all this information.

By using this wide-ranging research plan and running various lab tests and analysis methods, the study aims to give a thorough check of the eye drops quality made at Mengo Hospital. What we learn will help shape ways to make things better and make sure the eye drops meet the needed standards to be safe and work well.

D. Data Sources

- Eye drop samples from Mengo Hospital.
- Commercial eye drops (for comparison).
- Regulatory standards and guidelines.

E. Method of Data Collection:

- Laboratory tests and analysis.
- Literature review.

F. Method of Data Analysis:

- Descriptive statistics (mean, standard deviation).
- Inferential statistics (t-tests, ANOVA).
- Comparison with regulatory standards.

G. Verification and Ethical Considerations:

Checking lab results plays a key role in making sure the ingredients for eye drops are accurate and precise. This means putting in place strict quality checks, like regular equipment tune-ups confirming test methods work, and skill tests. When we check if the lab results are right, we can make sure the ingredients meet the needed specs and are safe to use in our products.

Keeping things private and unnamed matters a lot when making eye drops especially when dealing with patient info or sensitive data. This means setting up strong data safeguards, like storing records letting certain staff access them, and following data privacy rules. By keeping things private and unnamed, we can keep patients' trust and make sure sensitive info stays safe.

Getting the right approvals and permissions plays a key role in making eye drops when we bring in new products or ingredients. This means following the rules, like getting licenses and permits checking safety, and sticking to Good Manufacturing Practices (GMP). When we get these approvals and permissions, we make sure our products meet the standards and are safe for patients to use. This also includes getting ethical approvals for any research or clinical trials we do to develop new products.

H. Challenges Encountered:

While researching and making eye drops, we ran into some big problems. We didn't have enough good tools and resources. Our lab gear was old or not up to par, we were short on money, and we couldn't get our hands on special tools or expert help. These issues slowed down our work and made it hard to keep the quality steady and make sure all our products were the same.

We also had trouble getting store-bought eye drops to compare ours to. We needed these to check if our products were as good as what's already out there and met industry rules. But it was tough to get these eye drops because they were hard to find, cost a lot, and had rules about who could buy them. This made it tricky to see how Mengo Hospital eye drops stacked up and if they were good enough.

Getting lab results that were spot-on and trustworthy was also a big hurdle. This needed expert know-how cutting-edge tools, and strict quality checks. But with not much money or gear, it was tough to keep up the high standards needed for precise and dependable lab results. This had an impact on how good Mengo Hospital's eye drops were and made it hard to make sure they were safe and did the job for patients.

V. RESULTS OF RESEARCH ANALYSIS

A. Results:

The results of the biochemical evaluation and stability assessment of eye drops manufactured at Mengo Hospital are presented below:

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Table 1: Biochemical Composition

pH	Osmolarity (mOsm/L)	Viscosity (mPa.s)
6.9	295	12
7.1	305	14
6.8	290	10
7.0	300	11
6.9	298	13
7.2	310	15
6.9	296	12
7.0	302	11
6.8	291	10
7.1	306	14
6.9	297	12
7.0	301	13
6.9	294	11
7.1	307	15
6.8	292	10
7.0	303	12
6.9	295	13
7.1	308	14
6.9	293	11
7.0	304	12
6.8	290	10
7.1	309	15
6.9	296	12
7.0	302	13
6.9	291	11
7.1	307	14
6.8	292	10
7.0	303	12
6.9	294	11
7.1	306	13

The eye drops had a pH between 6.8 and 7.2 falling within the okay range of 6.5 to 7.5. Their osmolarity was between 290 and 310 mOsm/L, which fits into the acceptable span of 275 to 325 mOsm/L. The drops' viscosity measured from 10 to 15 mPa.s staying inside the permissible bounds of 5 to 20 mPa.s.

B. Stability Assessment:

➢ *Raw Data for the Stability of the Eye Drops Under Different Storage Conditions:*

- **Note:** The potency measurements show how well the eye drops hold up when stored in various ways.

➢ *Room Temperature (25°C ± 2°C)*

- Sample 1: 99.5% potency after 1 month, 98.2% after 3 months, 95.5% after 6 months
- Sample 2: 99.2% potency after 1 month, 97.5% after 3 months, 94.8% after 6 months
- Sample 3: 99.8% potency after 1 month, 98.5% after 3 months, 96.2% after 6 months
- Sample 4: 99.1% potency after 1 month, 97.2% after 3 months, 94.5% after 6 months

Table 2: Table of Results Showing Potency of Eye Drops under Room Temperature (25°C ± 2°C)

Sample #	1 Month	3 Months	6 Months
1	99.5%	98.2%	95.5%
2	99.2%	97.5%	94.8%
3	99.8%	98.5%	96.2%
4	99.1%	97.2%	94.5%

➢ *Refrigerator (4°C ± 2°C)*

- Sample 5: 99.9% potency after 1 month, 99.2% after 6 months, 98.5% after 12 months
- Sample 6: 99.6% potency after 1 month, 98.8% after 6 months, 97.9% after 12 months
- Sample 7: 100% potency after 1 month, 99.5% after 6 months, 98.8% after 12 months
- Sample 8: 99.4% potency after 1 month, 98.5% after 6 months, 97.5% after 12 months

Table 3: Table of results showing Potency of Eye Drops under Refrigerator (4°C ± 2°C)

Sample #	1 Month	3 Months	12 Months
5	99.9%	98.2%	98.5%
6	99.6%	98.8%	97.9%
7	100%	99.5%	98.8%
8	99.4%	98.5%	97.5%

➢ *Humidity (60% ± 10%)*

- Sample 9: 98.5% potency after 1 month, 96.2% after 3 months, 93.5% after 6 months
- Sample 10: 98.2% potency after 1 month, 95.5% after 3 months, 92.8% after 6 months
- Sample 11: 99.1% potency after 1 month, 97.3% after 3 months, 94.9% after 6 months
- Sample 12: 98.0% potency after 1 month, 95.0% after 3 months, 92.2% after 6 months

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Table 4: Table of Results Showing Potency of Eye Drops under Humidity (60% ± 10%)

Sample #	1 Month	3 Months	6 Months
9	98.5%	96.2%	93.5%
10	98.2%	95.5%	92.8%
11	99.1%	97.3%	94.9%
12	98.0%	95.0%	92.2%

➢ *Light Exposure*

- Sample 13: 97.5% potency after 1 month, 94.8% after 3 months, 91.2% after 6 months
- Sample 14: 97.2% potency after 1 month, 94.2% after 3 months, 90.5% after 6 months
- Sample 15: 98.5% potency after 1 month, 96.1% after 3 months, 93.3% after 6 months
- Sample 16: 97.0% potency after 1 month, 93.5% after 3 months, 90.0% after 6 months

Table 5: Table of Results Showing Potency of Eye Drops under Humidity (60% ± 10%)

Sample #	1 Month	3 Months	6 Months
13	97.5%	94.8%	91.2%
14	97.2%	94.2%	90.5%
15	98.5%	96.1%	93.3%
16	97.0%	93.5%	90.0%

This research tested how well the eye drops held up under different storage conditions. it looked at how temperature, humidity, and light affected the drops. The study showed that the eye drops stayed good for up to 6 months when kept at room temperature (25°C ± 2°C). When stored in the fridge (4°C ± 2°C), they lasted even longer - up to 12 months.

C. Microbial Contamination

The way to test the sterility of eye drops involved putting a small sample on a special plate. To do this, the person doing the test used a clean loop to move 0.1 mL of the drops onto the plate. This plate was made just for growing tiny organisms. It had food for these organisms, like tryptone, yeast extract, and glucose. By using the same amount each time, the test results were reliable across all the samples they checked.

The tools for the inoculation process included a laminar flow hood to keep a germ-free space, a Bunsen burner to clean the inoculation loop, and a vortex mixer to mix the eye drops well before taking samples. The agar plates stayed in an incubator at 35°C ± 2°C for 14 days, which helped microbes grow best. We checked the plates every day to see if any microbes were growing looking for things like colonies or cloudiness.

The tool used to inoculate samples was a standard microbial growth medium created to test the sterility of drug products. This medium contained tryptone, yeast extract, glucose, and agar offering a nutrient-rich setting for microbes to grow. The maker certified that the medium was free from microbe contamination, and it was used as the maker instructed. Using this standard medium made the sterility test results trustworthy and easy to compare with industry and Pharmacopeial standards.

Table 6: Table of Results for 30 Samples of Microbial Contamination Testing, with Results in Colony-Forming Units Per Milliliter (CFU/mL)

Sample #	1 month (CFU/mL)	3 month (CFU/mL)	6 month (CFU/mL)	12 month (CFU/mL)
1	0	0	0	0
2	0	0	0	0
3	0	0	0	<1
4	0	<1	0	0
5	0	0	0	0
6	0	0	<1	0
7	0	0	0	0
8	0	0	0	0
9	0	<1	0	0
10	0	0	0	0
11	0	0	0	<1
12	0	0	0	0
13	0	0	0	0
14	0	0	<1	0
15	0	0		0
16	0	0	0	0

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17	0	0	0	0
18	0	0	0	0
19	0	0	0	<1
20	0	<1	0	0
21	0	0	0	0
22	0	0	0	0
23	0	0	0	0
24	0	0	0	0
25	0	0	<1	0
26	0	0	0	0
27	0	<1	0	0
28	0	0	0	0
29	0	0	0	0
30	0	0	0	<1

Testing for microbial contamination revealed the eye drops remained sterile and free of microbes at 1 month, 6 months, and 12 months.

D. Comparison with Commercial Eye Drops

The process to compare the biochemical and stability profiles of Mengo Hospital eye drops with commercial eye drops used several tools and equipment. A pH meter measured the acidity/basicity of the eye drops, with a range of 6.5-7.5 seen as acceptable. An osmometer measured the solute concentration, with a range of 290-310 mOsm/L considered okay. A viscometer measured the thickness/flowability of the eye drops, with a range of 13-16 mPa.s deemed suitable.

We checked the eye drops by looking at them to see if they were clear or cloudy. We wrote down "Clear" or "Turbid" as the result. To test for germs, a special growth medium was. The outcome was noted as "Pass" or "Fail." We also did a test for harmful substances called endotoxins. This test used a color-changing method. The acceptable limit was set at less than 0.5 EU/mL.

The testing took place in a controlled lab setting. All equipment had proper calibration and validation based on industry norms. For each sample, researchers ran tests three times and averaged the results. This approach aimed to ensure accuracy and reliability. We then compared the data to industry benchmarks and commercial eye drops. This comparison helped confirm that Mengo Hospital eye drops met the same quality standards.

Table 7: Table of Results Showing the Comparison of the Biochemical and Stability Profiles of Mengo Hospital Eye Drops with Commercial Eye Drops

Sample #	Test Parameter	Mengo Hospital eye drop results	Commercial eye drop results
1	pH	6.8	6.9
	Osmolarity (mOsm/L)	295	300
2	Viscosity (mPa.s)	14	15
	Clarity (Clear or Turbid)	Clear	Clear
3	Sterility (Pass or Fail)	Pass	Pass
	Endotoxin (EU/mL)	<0.5	<0.5
4	pH	6.9	7.0
	Osmolarity (mOsm/L)	305	310
5	Viscosity (mPa.s)	15	16
	Clarity (Clear or Turbid)	Clear	Clear
6	Sterility (Pass or Fail)	Pass	Pass
	Endotoxin (EU/mL)	<0.5	<0.5
7	pH	6.8	6.9
	Osmolarity (mOsm/L)	290	295
8	Viscosity (mPa.s)	13	14
	Clarity (Clear or Turbid)	Clear	Clear
9	Sterility (Pass or Fail)	Pass	Pass
	Endotoxin (EU/mL)	<0.5	<0.5
10	pH	6.9	7.0
	Osmolarity (mOsm/L)	300	305
11	Viscosity (mPa.s)	14	15
	Clarity(Clear or Turbid)	Clear	Clear
12	Sterility (Pass or Fail)	Pass	Pass

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	Endotoxin (EU/mL)	<0.5	<0.5
13	pH	6.8	6.9
	Osmolarity (mOsm/L)	295	300
14	Viscosity (mPa.s)	15	16
	Clarity (Clear or Turbid)	Clear	Clear
15	Sterility (Pass or Fail)	Pass	Pass
	Endotoxin (EU/mL)	<0.5	<0.5

We compared the biochemical and stability profiles of eye drops from Mengo Hospital with those available on local market. Their findings indicated that the eye drops produced at Mengo Hospital matched the quality standards of commercial eye drops.

E. Interpretation of Results:

The eye drops made at Mengo Hospital passed biochemical tests and stability checks showing they meet quality and safety standards. These drops have the right chemical makeup, with pH, osmolarity, and thickness levels all falling within safe limits.

Tests also prove that the eye drops stay stable in different storage settings, without big changes in their chemical properties. This means the products can be kept and moved around without losing their quality or how well they work.

What's more, tests show the eye drops don't have any harmful microbes meeting the same quality benchmarks as store-bought eye drops. This means that Mengo Hospital's manufacturing process follows good practices ensuring they make safe high-quality eye drops for patients to use.

F. Explanation of Results:

The results of this study show how important quality control is when making eye drops. By doing a complete biochemical test and checking stability, we can make sure eye drops meet the needed quality and safety standards. This matters a lot to keep the product good and make sure it works well for patients.

What the study found points out that Mengo Hospital's Eye drop Production unit has good quality control. Their eye drops met all the required standards. This shows the hospital works hard to make high-quality products that doctors and patients can rely on.

What's more, the study highlights how crucial it is to compare the quality of Mengo Hospital eye drops with those sold. This comparison helps ensure that the hospital's products are up to the same high standards as those you can buy in stores. This way of doing things helps keep the production of eye drops consistent and top-notch, which in the end is good for patient care.

G. Questions about Alternative Approaches:

- What other ways can we check the chemical makeup and shelf life of eye drops?
- How can we change the study to look at different eye treatments, like ointments or gels?
- What are the weak points of this study, and how can we fix them in future research?

H. Strength and Weaknesses of Statistical Analysis:

This study relied on two types of stats: descriptive and inferential. For the descriptive part, researchers looked at means and standard deviations. When it came to inferential stats, they used t-tests and ANOVA. This approach has its pros and cons. On the plus side, it gives a thorough look at what's in eye drops and how stable they are. The downside? It might not be the best way to figure out how well these drops work for specific eye problems.

VI. CONCLUSION

The eye drops made at Mengo Hospital passed tests to check their chemical makeup and how long they last. These tests show the drops meet the standards needed to be safe and work well.

Tests prove the eye drops have the right chemical mix. Their pH, osmolarity, and thickness fall within pharmacopeial standards.

Checks on how long the drops last found they stay good for up to 6 months at room temperature. When kept cold, they last up to a year.

The drops also passed tests to make sure they're clean and free of germs.

The chemical makeup and shelf life of Mengo Hospital's eye drops match those of eye drops you can buy in stores. They meet the same high standards.

These findings show why it's crucial to have strong quality checks when making eye drops.

The research shows how well the methods for checking biochemical makeup and stability work.

Other ways to check the makeup and stability of eye drops could include using tools like spectroscopes or chromatographs.

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The study has its limits, like not having many samples and testing in certain storage conditions. Future research could look into these areas more.

In the end, the findings prove that the eye drops from Mengo Hospital meet the needed quality and safety standards. They might be a good choice instead of store-bought eye drops.

RECOMMENDATIONS

A. Future Research:

- Evaluate the efficacy of Mengo Hospital eye drops in treating specific eye conditions.
- Compare the quality of Mengo Hospital eye drops with other local manufacturers.
- Investigate the use of alternative preservatives in eye drops.
- Develop a more comprehensive stability testing protocol.
- Explore the use of eye drops in other medical applications.

B. Implementation:

- Establish a quality control unit at Mengo Hospital to monitor eye drop production.
- Develop a training program for production staff on good manufacturing practices.
- Implement a labeling and packaging system for eye drops.
- Establish a system for customer feedback and complaints.
- Develop a marketing strategy to promote Mengo Hospital eye drops.

C. Consideration:

- Regularly review and update the eye drop formulation to ensure it remains effective.
- Consider outsourcing certain production steps to specialized companies.
- Develop a contingency plan for raw material shortages or supply chain disruptions.
- Establish partnerships with other healthcare institutions to share best practices.
- Consider expanding production to meet demand from other healthcare facilities.

D. Best Practices:

- Adhere to good manufacturing practices (GMP) and international quality standards.
- Continuously monitor and evaluate the quality of eye drops.
- Implement a system for tracking and tracing eye drop batches.
- Ensure proper storage and handling of eye drops.
- Provide clear instructions for use and handling to customers.

By considering these recommendations, future research and implementation can build upon the findings of this thesis project and improve the quality and effectiveness of eye drops.

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