## IMPLEMENTATION OF A CLEANER PRODUCTION APPROACH: A CASE STUDY OF SANITIZATION ALTERNATIVES IN WATER

PROCESS SYSTEM

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#### ABSTRACT

The need to reduce pollution and waste from sensitive industrial products, specifically the water used in the pharmaceutical industry, became a vital field of research. The use of chemical sanitization in water treatment processes is a significant source of pollution and can have harmful effects on drug products. This problem is compounded by the increasing demand for pure water and the need to protect pharmaceutical products from pollution in the inlet of the water process. The aim of this study is to assess the efficiency of sanitization based on the results of Microbial Count (MC) within the limits of the operational time. Samples were collected from the production and subjected to thermal or chemical sanitization. The sanitization samples were examined for their microbial counts. After 82 days of operation, thermal sanitization at 65 °C vielded non-conformity results of 110 cfu/ml, whereas thermal sanitization at 85 °C yielded conformity results of 34 cfu/ml. Chemical sanitization at 0.5 % and 5 % concentrations of H<sub>2</sub>O<sub>2</sub> have been studied. A non-conformity microbial count results in 124 cfu/ml after 45 days at a 0.5 percent concentration of H<sub>2</sub>O<sub>2</sub>. After the 75-day operational period, the concentration of 5 percent H<sub>2</sub>O<sub>2</sub> has conformity results of 97 cfu/ml. The study results in the optimum condition for the sanitization of water processes in pharmaceutical industries. The study explained that the thermal sanitization method at 85 °C is the optimum condition and is used in sensitive pharmaceutical and semiconductor industries.

Keywords: Cleaner Production; Biocontamination; Sanitization.

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#### **INTRODUCTION**

In the pharmaceutical industry, an efficient and sustainable method for sanitizing water is essential for protecting drugs from biocontamination (Pal *et al.*, 2022). Water is used in many stages of drug production, including as a raw material, solvent, and cleaning agent. Therefore, the water used in pharmaceutical processes must be of high quality, free from impurities and microorganisms that can compromise the quality and safety of the drugs (Nunez, 2005).

The water industry is a significant contributor to the global economy, providing essential services such as drinking water supply, wastewater treatment, and irrigation. However, it is also a significant source of pollution and waste, with various chemical and biological contaminants entering water sources and ecosystems (Brusseau and Artiola, 2019). One of the primary causes of water pollution in the industry is using chemical sanitizers, which can harm the environment and human health. In response to this problem, alternative sanitization methods, such as thermal and physical methods, have been developed and implemented in some water treatment facilities (Abdelbasier, and Farrag, 2019).

The most used method for water sanitization in the pharmaceutical industry is using various filtration techniques such as reverse osmosis, ultrafiltration, and microfiltration. These techniques remove suspended particles and microorganisms from the water. To further ensure the absence of microorganisms, water is treated with various disinfectants such as ozone, chlorine, or ultraviolet radiation (Dolar *et al.*, 2012). However, the use of disinfectants can introduce other impurities into the water, which can be harmful to drug products (Johnson, *et.al.*, 2000). Therefore, it is important to ensure that the disinfectant is effectively removed from the water before it is used in drug production. In addition to filtration and disinfection, maintaining an appropriate water

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system design is critical for preventing biocontamination in addition to filtration and disinfection. The design should include features such as properly sized piping, appropriate flow rates, and adequate drainage to prevent the growth and accumulation of microorganisms (Brusseau and Artiola, 2019).

The efficient and sustainable method for sanitizing water in the pharmaceutical industry involves a combination of filtration, disinfection, and appropriate system design. The process must be carefully monitored and validated to ensure the absence of microorganisms and the integrity of the drug products (Chaturvedi, and Manan, 2021).

The case study is based on an analysis of primary and secondary data, including interviews with key stakeholders, site visits, and a review of relevant literature (Brusseau and Artiola, 2019). The analysis will provide a comprehensive understanding of the benefits and challenges of implementing cleaner production practices in the water industry and identify the factors that contribute to their success or failure. It will also contribute to the development of guidelines and recommendations for the adoption and implementation of cleaner production approaches in the water industry and other industries facing similar challenges (Grönberg and Hjorth, 2018).

The implementation of cleaner production approaches is vital for sustainable water management in the pharmaceutical industry (Ortiz-Solà *et al.*, 2021). Pharmaceutical manufacturing processes use large amounts of water and generate significant amounts of wastewater and other forms of waste, which can have harmful effects on the environment and human health. In addition, the use of chemical substances in the production of pharmaceuticals can contribute to water pollution and other environmental impacts (Fallon *et al.*, 2011).

Cleaner production approaches in this context might include the use of alternative

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technologies, such as membrane filtration or UV disinfection, to reduce the use of chemicals in water treatment processes (Siahrostami *et al.*, 2020). Other approaches might include the optimization of water use through the reuse and recycling of wastewater, or the implementation of green chemistry practices to reduce the use of hazardous chemicals in pharmaceutical manufacturing processes (Lee and Huang, 2019).

Pacchioni *et al.*, (2018) reported that the implementation of cleaner production approaches in the production of water in the pharmaceutical industry can also have economic benefits, such as reduced costs for water treatment and disposal, improved efficiency and productivity, and enhanced reputation and marketability. Furthermore, the implementation of cleaner production approaches can help companies meet sustainability goals and improve their overall environmental performance. The application of cleaner production strategies is an essential component of sustainable water management in the pharmaceutical industry. In particular, the sanitization of water is a critical process that can significantly impact the environment, public health, and the overall sustainability of pharmaceutical manufacturing (Cooper *et al.*, 2018).

Ultimately, the scientific problem addressed in the research article is how to reduce pollution and waste from industrial activities in a sustainable manner, with a focus on the water industry and the use of cleaner production approaches. This research aims to investigate the application of cleaner production practices in the water industry, specifically focusing on the use of alternative sanitization methods in water process systems. The study adopts a case study approach, examining the implementation of thermal and chemical sanitization alternatives in a water treatment plant.

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One of the objectives of the case study is to identify the benefits and challenges of each approach, as well as the factors that influenced their adoption and implementation. The findings of this study will be of interest to water industry professionals, policymakers, and researchers interested in sustainable water management and the adoption of cleaner production approaches.

#### MATERIAL AND METHODS

In a lab setting, under circumstances that closely resemble the harsh environments from which they were extracted, it is usually the best way to cultivate microorganisms that can endure harsh conditions. Because of this, thermophilic bacteria might be able to survive in the harsh environment of hot pharmaceutical water systems, and if they can, they can only be recovered and grown under similar thermal conditions in a laboratory setting. The method and materials used in decomposing a pharmaceutical water sample's microbial count can vary depending on the specific requirements of the analysis (Pang *et al.*, 2020). However, here is a general overview of the process:

#### Materials:

- Sterile water sample
- Sterile glassware and pipettes
- Nutrient agar plates or other appropriate growth media
- Incubator
- Sterile loop or swab
- Microscope
- Staining reagents (e.g., Gram stain)

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#### Method:

- The water sample was collected as a representative water sample using sterile techniques to minimize the risk of contamination. The sample should be taken from the point of use, such as a tap or outlet (de Mei, 2020).
- The water sample was transferred to sterile glassware and prepare serial dilutions of the sample were to facilitate microbial enumeration.
- Nutrient agar was inoculated in plates with the diluted sample using a sterile loop or swab. The agar plates should be selected based on the target microorganisms and growth requirements (Wahlen *et al.*, 2016).
- The plates were put at an appropriate temperature and duration according to the growth requirements of the microorganisms being targeted.
- After incubation, the colonies were counted on the plates, and calculate the number of microorganisms in the original water sample.
- Microscopy and staining techniques were used to identify the types of microorganisms present in the water sample.
- The results had been recorded and reported, including the total microbial count and the types of microorganisms identified.

#### Thermal sanitization methods (Wahlen et al., 2016)

Preparation of the water to be sanitized, Before thermal sanitization, the water to be sanitized should be pre-filtered and pre-treated to remove any suspended solids or impurities that could interfere with the sanitization process.

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The water is heated to a specific temperature and held at that temperature for a specified time to ensure complete sanitization. In this case, the temperature used is 65°C. The time required for thermal sanitization will depend on the target microorganisms and the water volume being sanitized.

Monitoring the temperature, It is important to monitor the water temperature throughout the sanitization process to ensure that it remains at the required temperature. This can be done using temperature sensors or other monitoring devices (Singh, 2009).

Cooling the purified water, After the sanitization process is complete, the water is cooled to an appropriate temperature before use. This can be done using a heat exchanger or other cooling device.

Testing the water sample, It is important to test the water after thermal sanitization to confirm that the sanitization process was successful (Singh, 2009).

#### **Chemical sanitization methods:**

Chemical sanitization is another common method for sanitizing water used in pharmaceutical applications. One commonly used chemical sanitizing agent is hydrogen peroxide. Here is a brief overview of the method of chemical sanitization using hydrogen peroxide at concentrations between 0.5 and 5 percent for water used in pharmaceutical applications (Wahlen *et al.*, 2016):

Preparation of the hydrogen peroxide solution: The hydrogen peroxide solution is typically prepared) by diluting a stock solution 45-50 % conc.  $H_2O_2$  to the desired concentration ( 0.5 % and 5 % ). The concentration used will depend on the target microorganisms and the water volume being sanitized.

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The hydrogen peroxide solution was added to the water to be sanitized. The amount of solution added will depend on the volume of water being sanitized and the desired concentration. the solution was allowed to contact the water: The hydrogen peroxide solution is allowed to meet the water for a specified time to ensure complete sanitization. The time required will depend on the target microorganisms and the concentration of hydrogen peroxide used. After the sanitization process is complete, any residual hydrogen peroxide in the water had been neutralized to avoid any impact on the quality of the pharmaceutical products. This had been done by adding a chemical-neutralizing agent to the water (Singh, 2009). It is important to test the water after chemical sanitization to confirm that the sanitization process was successful. This can be done using microbial enumeration techniques, such as those described in a previous answer.

#### **RESULTS AND DISCUSSION**

To apply cleaner production strategies in the sanitization of water, several key steps can be followed, conduct a comprehensive assessment of current water sanitization practices: This includes a review of the chemicals and processes currently used for water sanitization, as well as an analysis of the environmental impact of these practices (Rajeswari *et al.*, 2013).

Identify opportunities for improvement: Based on the assessment, potential opportunities for improvement should be identified (Sharma, 2004). This could include the substitution of chemical sanitizers with alternative methods, such as thermal or UV disinfection, or the use of more sustainable chemicals.

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Implement improvements and monitor progress: The next step is to implement the plan and monitor the results. Regular monitoring and reporting can help to track progress toward sustainability goals and identify areas for further improvement.

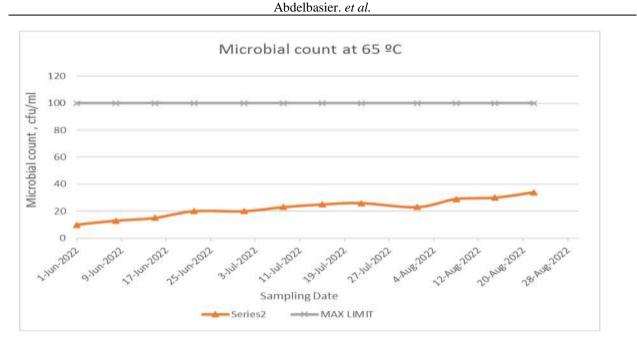
Continually review and update the approach: It is important to continuously review and update the approach to water sanitization, as new technologies and practices become available. This can help to ensure that the most effective and sustainable methods are being used.

#### 1. Thermal sanitization.

#### 1.1 <u>Thermal sanitization at a temperature of 65 °C.</u>

Thermal sanitization is a method for eliminating microorganisms in water by subjecting it to high temperatures. In the pharmaceutical industry, thermal sanitization is a common method for sanitizing water used in drug production, particularly in situations where chemical sanitization may not be suitable (Košutić *et al.*, 2007). The method of thermal sanitization at 65°C for water used in pharmaceutical applications is presented in Fig. (1).

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As shown in fig.(1) the results were out of the specs at the sample dated 22.08.2022 of value 110 cfu/ml. the period of validity of the purified water was extended to 82 days only. The sanitization of the second round was needed after 82 days. thermal sanitization at 65°C is an effective method for sanitizing water used in pharmaceutical applications. The process involves heating the water to a specific temperature and holding it at that temperature for a specified time to ensure complete sanitization (Abdelbasier, and Farrag, 2019). The water is then cooled and tested to confirm that the sanitization process was successful. Careful monitoring and documentation of the process are important for ensuring regulatory compliance and quality assurance.

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#### 1.2 Thermal sanitization of temperature 85 °C.

Another factor that can affect the difference in microbial count between 65°C and 85°C thermal sanitization is the diversity of microbial species present (Košutić *et al.*, 2007). Some microorganisms may be more resistant to heat than others, and these may survive the 65°C thermal sanitization process. On the other hand, the 85°C thermal sanitization process may be able to eliminate more resistant microorganisms, resulting in a more homogeneous microbial population.

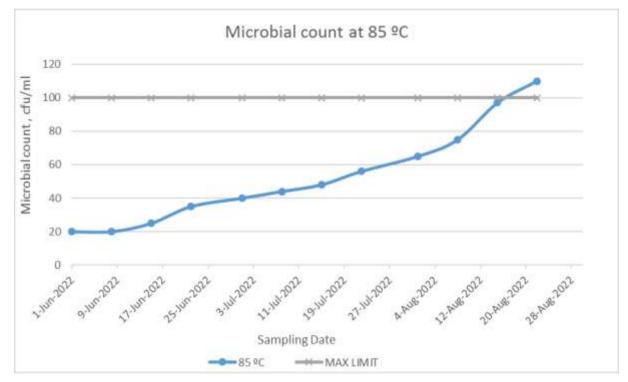


Fig. (2): Microbial count at thermal sanitization at temp. 85 °C within 82 days.

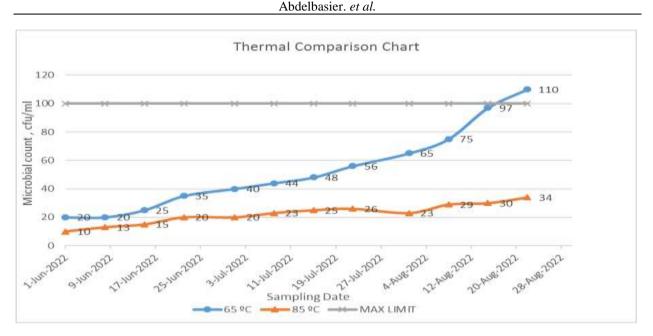
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As seen in fig. (2), the results of the sample taken on August 22, 2022, with a value of 34 cfu/ml, are within the specifications limit (100 cfu/ml). The allowed 82-day expiration date for the purified water was not extended. The second round's sanitization could take longer than 82 days.

#### 1.3 Comparison of thermal sanitization of temps ( 65 °C, 85 °C).

The difference between the microbial count after 82 days of thermal sanitization at  $65^{\circ}$ C and  $85^{\circ}$ C in water for pharmaceutical use is primarily related to the effectiveness of microbial reduction, the diversity of microbial species, the heat stability of microbial toxins, and equipment suitability. Generally, higher temperatures are more effective in reducing microbial populations, but they may also have additional challenges that need to be considered, such as equipment suitability and chemical degradation (Panchal *et al.*, 2014). The choice of the appropriate temperature for thermal sanitization should be based on a thorough evaluation of these factors and other process-specific considerations.

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Fig. (3): Comparison chart, microbial count at thermal sanitization at temp. 65 °C, 85 °C within 82 days.

A comparison in fig. (3) of the two parameters of thermal sanitization at 65 °C and 85 °C was done. The longer operational time is the best method for thermal sanitization. After 82 days, the parameter 85 °C was observed at the value of 34 cfu/ml. Heat Stability of Microbial Toxins is observed in the study of Panchal et al., 2014 where some microorganisms produce toxins that can be harmful to humans even if the microorganisms themselves are destroyed by heat.

#### 2. Chemical sanitization.

Chemical sanitization using hydrogen peroxide at concentrations between 0.5 and 5 percent is an effective method for sanitizing water used in pharmaceutical applications. The process involves adding the hydrogen peroxide solution to the water, allowing it to contact the water for

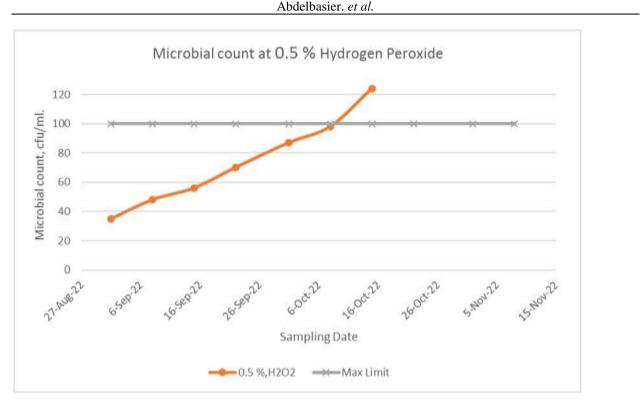
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a specified time, and neutralizing the solution. The water is then tested to confirm that the sanitization process was successful, and the entire process is documented for regulatory compliance and quality assurance purposes (Brusseau and Artiola, 2019).

#### 2.1 <u>Chemical Sanitization of Conc.H2O2 0.5 %.</u>

The treatment of purified water with 0.5% hydrogen peroxide for 45 days can lead to the destruction of microorganisms through the oxidation of their cell membranes and genetic material. The reduction in microbial load is the primary goal of chemical disinfection, but the formation of toxic by-products and the potential for resistance development should also be considered (Brusseau and Artiola, 2019). The specific effects on microorganisms depend on several factors, including the concentration of hydrogen peroxide used, the duration of exposure, and the type of microorganisms present in the water. The appropriate concentration and duration of exposure should be selected based on a thorough evaluation of these factors and other process-specific considerations.

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Fig. (4): Microbial count of chemical sanitization at H<sub>2</sub>O<sub>2</sub> Conc. 0.5% within 82 days.

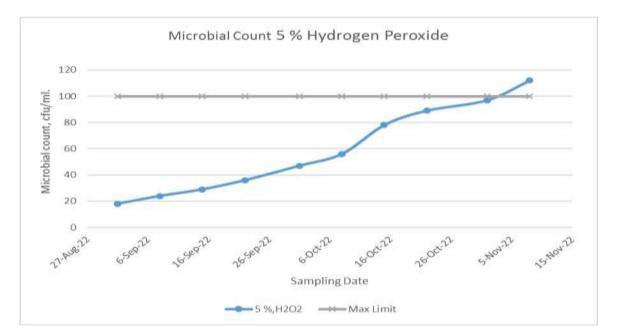
As shown in fig.(4) the results were out of the specs at the sample dated 15.08.2022 of value 124 cfu/ml. the period of validity of the purified water was extended to 45 days only. The sanitization of the second round was assumed to be less than 45 days.

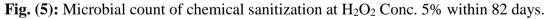
#### 2.2 <u>Chemical Sanitization of 5 % concentrations H<sub>2</sub>O<sub>2</sub>.</u>

Destruction of Cell Membranes: Hydrogen peroxide is an oxidizing agent that can destroy the cell membranes of microorganisms. It can react with cellular components like proteins and lipids, leading to their degradation and loss of function. As a result, the microorganisms lose their structural integrity, and their ability to survive is compromised (Panchal *et al.*, 2014).

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Damage to Genetic Material: Hydrogen peroxide can also cause damage to the genetic material of microorganisms. It can react with the DNA and RNA molecules, leading to their fragmentation and degradation (Grönberg and Hjorth, 2018). The genetic material is essential for the survival and reproduction of microorganisms, and damage to it can prevent their ability to replicate and cause infection. The primary goal of chemical disinfection is to reduce the microbial load in the water. When treated with 5% hydrogen peroxide, the microorganisms in the water are killed, leading to a reduction in their population. The high concentration of hydrogen peroxide used in this case leads to a more rapid and efficient reduction in microbial load compared to lower concentrations.





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The study explains that the using of  $H_2O_2$  of concentration 5 % is more effective but it's not a more friendly environment solution rather than using conc. of 0.5%. the 5 % concentration achieves a microbial count of 112 cfu/ml. after 75 operational days.

#### 2.3 <u>Comparison of Chemical Sanitization of 0.5 %, 5 %. The concentration of H2O2.</u>

Chemical sterilization is a process of eliminating all viable microorganisms from a surface or solution using chemical agents. Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) is a commonly used chemical agent in the pharmaceutical industry for the sterilization of water systems, equipment, and surfaces. The concentration of H<sub>2</sub>O<sub>2</sub> used in the sterilization process can have a significant impact on the effectiveness of the process. In this context, the difference in the microbial count after 82 days of chemical sterilization with 0.5% and 5% H2O2 in pharmaceutical water is discussed as follows:

The primary goal of chemical sterilization is to reduce or eliminate the microbial population. The concentration of  $H_2O_2$  used in the process is directly related to the effectiveness of microbial reduction (Siahrostami et al., 2020). Higher concentrations of  $H_2O_2$  are more effective in reducing the microbial population, as they can more readily penetrate the microorganisms, causing cell damage and destruction (Fallon et al., 2011). Therefore, the microbial count after 82 days of chemical sterilization with 5%  $H_2O_2$  is expected to be better than those obtained with 0.5%  $H_2O_2$ .

Chemical sterilization using  $H_2O_2$  can leave residual chemicals on the surface or in the solution. The concentration of  $H_2O_2$  used in the process can influence the level of residual chemicals left behind. Higher concentrations of  $H_2O_2$  can leave more residual chemicals, which can potentially affect the quality of the product. Therefore, the use of lower concentrations of

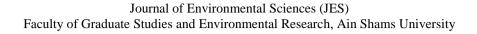
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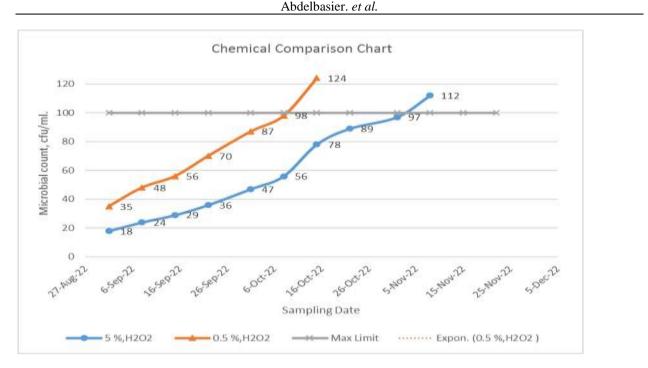
H<sub>2</sub>O<sub>2</sub>, such as 0.5%, is preferred when residual effects are a concern (Lee and Huang, 2019).

The use of chemical agents in sterilization processes can have environmental impacts if not properly disposed of. The concentration of  $H_2O_2$  used in the process can affect the amount of chemical waste generated. Higher concentrations of  $H_2O_2$  can generate more chemical waste, which can have a greater environmental impact. Therefore, the use of lower concentrations of  $H_2O_2$ , such as 0.5%, is preferred when environmental impact is a concern.

Chemical sterilization using  $H_2O_2$  can affect the compatibility of materials used in the pharmaceutical industry. The concentration of  $H_2O_2$  used in the process can affect the level of material compatibility. Higher concentrations of  $H_2O_2$  can cause material degradation, which can potentially affect the quality of the product. Therefore, the use of lower concentrations of  $H_2O_2$ , such as 0.5%, is preferred when material compatibility is a concern (Pacchioni *et al.*, 2018).

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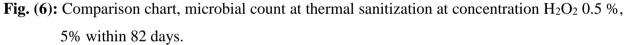


Fig. (6) illustrates that the microbial count obtained was not conformed with the allowable limit of 100 cfu/ml in both concentrations (0.5 and 5 %) after the study's 82 operational days. The parameter of 0.5 % of the concentration of  $H_2O_2$  achieved a value of 124 after 45 operational days means (45/82\*100) = 54 % of the total operational time of the study. In contrast (67/82\*100) = 81 % of the total operational time of this work was achieved by the parameter of concentration 5 % of H2O2 at the value of 79 cfu/ml.

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# **3.** Comparison between the method gives the optimum results of both thermal and chemical sanitization.

Thermal sanitization and chemical sanitization are both common methods used for sanitizing water in the pharmaceutical industry. However, there are several reasons

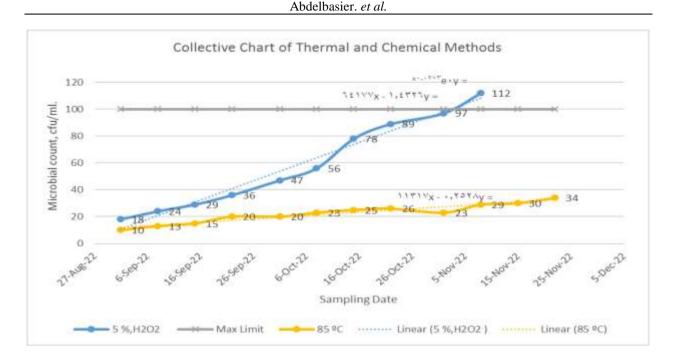
why thermal sanitization may be preferable to chemical sanitization (Pang et al., 2020).

Thermal sanitization is an effective method for removing microorganisms in purified water. The high temperatures used in the process can kill a wide range of bacteria, viruses, and other microorganisms. In contrast, some microorganisms may be resistant to certain chemical sanitizers, which can compromise the effectiveness of the sanitization process (Eissa, *et al.*,2015). No residual chemicals: Unlike chemical sanitizers, thermal sanitization does not leave behind any residual chemicals that could potentially contaminate pharmaceutical products or affect their quality. This is particularly important for water used in sensitive drug formulations, where even low levels of contaminants can be detrimental to the product (Jo *et al.*, 2018).

Thermal sanitization is generally considered to be a safer method of sanitization than chemical sanitization. Chemical sanitizers can be hazardous to handle and require careful storage, handling, and disposal to avoid risks to workers and the environment. In contrast, thermal sanitization simply involves heating the water to a specific temperature and does not require any potentially hazardous chemicals (de Mei, 2020).Thermal sanitization can be a more cost-effective method of sanitization than chemical sanitization in some cases. The cost of chemicals, equipment, and labor required for chemical sanitization can be higher than the cost of the energy required for thermal sanitization (Khan and Nordberg, 2019).

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**Fig. (7):** Collective chart for the optimum sanitization methods of thermal at 85 °C and the chemical of 5 % concentration of H<sub>2</sub>O<sub>2</sub>.

Thermal sanitization and chemical sanitization are two common methods used in the pharmaceutical industry to reduce or eliminate microbial contamination (Wahlen *et al.*, 2016). In fig.(7) both methods can be effective in reducing microbial populations, but the reasons for the good microbial count after 82 days were obtained from the implementation of thermal sanitization at 85°C in the water for pharmaceutical use. The trendline of thermal sanitization at 85 C was expressed in the equation of y = 0.2528x - 11317 eq (1). While the equation of y = 1.4326x - 64177 eq (2) was calculated to interpolate the data from the microbial count at chemical sanitization of 5% concentration of H<sub>2</sub>O<sub>2</sub>.

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Eissa *et al.*, (2015) reported that thermal sanitization works by exposing microorganisms to high temperatures, which can cause denaturation and destruction of proteins, nucleic acids, and other cellular components. In contrast, chemical sanitization uses chemical agents, such as hydrogen peroxide, to destroy microorganisms by oxidizing cellular components (Singh, 2009). While both methods can be effective, the mode of action of thermal sanitization is more comprehensive, as it can eliminate microorganisms throughout their entire structure, whereas chemical sanitization targets specific cellular components.

Thermal sanitization does not leave residual chemical agents on surfaces or equipment, making it an ideal method for use in pharmaceutical manufacturing, where product purity is critical. In contrast, chemical sanitization can leave residual chemical agents on surfaces, which can potentially contaminate the products being manufactured (Singh, 2009).

Thermal sanitization can penetrate deeper into the microorganisms, as heat can penetrate through the entire structure of the cell. On the other hand, chemical sanitization may have limitations in its penetration ability, as it may not be able to reach all areas of a surface or equipment. Also, thermal sanitization is generally a more cost-effective option than chemical sanitization, as it does not require the purchase of chemicals and can be performed using existing equipment (Johnson, *et.al.*, 2000)

Chemical sanitization requires the use of chemicals, which can have environmental impacts if not properly disposed of. In contrast, thermal sanitization does not use any chemicals, making it a more environmentally friendly option (Košutić *et a*l., 2007).

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#### CONCLUSION

The application of cleaner production strategies in the sanitization of water in the pharmaceutical industry involves a comprehensive assessment of current practices, the identification of opportunities for improvement, the development of an implementation plan, the monitoring of progress, and the continual review and update of the approach. Thermal sanitization may be preferred over chemical sanitization for water used in pharmaceutical applications due to its effectiveness, lack of residual chemicals, safety, and cost-effectiveness. Therefore, the effectiveness of thermal sanitization in reducing the risk of microbial toxins may also vary between 65°C and 85°C. The heat stability of these toxins can vary, and some may be more resistant to heat than others. Higher concentrations of  $H_2O_2$  are more effective in reducing the microbial population but can leave more residual chemicals, generate more chemical waste, and affect material compatibility. the optimum microbial count obtained from the implementation of thermal sanitization at 85°C in water for pharmaceutical use, rather than the results obtained from chemical sanitization of hydrogen peroxide if concentration 5%. Finally, Thermal sanitization provides a more comprehensive and cost-effective method of reducing microbial populations while avoiding the environmental concerns and potential product contamination associated with chemical sanitization.

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### تنفيذ نمج الانتاج الانظفم: حراسة حالة لرحائل التحقيم في نظام عملية المياء

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#### المستخلص

أصبحت الحاجة إلى الحد من التلوث والنفايات من المنتجات الصناعية الحساسة ، وخاصة المياه المستخدمة في صناعة الأدوية ، مجالًا حيويًا للبحث. يعد استخدام التعقيم الكيميائي في عمليات معالجة المياه مصدرًا مهمًا للتلوث ويمكن أن يكون له آثار ضارة على المنتجات الدوائية. تتفاقم هذه المشكلة بسبب الطلب المتزايد على المياه النقية والحاجة إلى حماية المنتجات الصيدلانية من التلوث في مدخل عملية المياه. درس هذا العمل كفاءة التعقيم بناءً على نتائج العد الميكروبي في حدود الوقت التشغيلي. تم جمع العينات من الإنتاج وإخضاعها للتعقيم الحراري أو الكيميائي. تم فحص عينات التعقيم لمعرفة عددها الميكروبي. بعد ٨٢ يومًا من التشغيل ، أسفر التعقيم الحراري عند ٦٥ درجة مئوية عن نتائج عدم مطابقة تبلغ ١٠ قدم مكعب / مل ، بينما أدى التعقيم الحراري عند ٥٥ درجة مئوية إلى نتائج مطابقة تبلغ ٢٤ قدم مكعب / مل. تمت دراسة مل بعد ٥٤ يومًا بتركيزات ٥,٥ . و ٥٪ من فوق اكسيد الهيدروجين. ينتج عن العد الميكروبي غير المطابق ٢٤ قدم مكعب/ مل بعد ٢٥ يومًا بتركيز ٥,٥ بالمائة من فوق اكسيد الهيدروجين. ينتج عن العد الميكروبي غير المطابق ٢٤ قدم مكعب/ مل بعد ٢٥ يومًا بتركيز ٥,٥ بالمائة من فوق اكسيد الهيدروجين. ينتج عن الميكروبي غير المطابق ٢٤ قدم مكعب/ بالمائة من فوق اكسيد الهيدروجين نتائج مطابقة تبلغ ٢٤ يومًا ، يكون لتركيز ٥ الم بعد ٢٥ يومًا بتركيز ٥,٥ بالمائة من فوق اكسيد الهيدروجين. ينتج عن العد الميكروبي غير المطابق ١٢ مل بعد ١٢ يومًا بتركيز ٥,٥ بالمائة من فوق اكسيد الهيدروجين. ينتج عن العد الميكروبي في المطابق التكيريز ٥ المائة من فوق اكسيد الهيدروجين نتائج مطابقة تبلغ ٩٢

الكلمات الرئيسية: إنتاج أنظ ؛ التلوث الحيوى تطهير .

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