ISSN No:- 2278 - 6252

International Journal of Advanced Research in Engineering and Applied Sciences

Volume No. 13
Issue No. 1
Jan- Apr - 2024



ENRICHED PUBLICATIONS PVT. LTD

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International Journal of Advanced Research in Engineering and Applied Sciences

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International Journal of Advanced Research in Engineering and Applied Sciences (IJAREAS) is a Monthly Peer Reviewed online International research journal aiming at promoting and publishing original high quality research in all disciplines of engineering and applied sciences. All research articles submitted to IJAREAS should be original in nature, never previously published in any journal or presented in a conference or undergoing such process across the globe. All the submissions will be peer-reviewed by the panel of experts associated with particular field. Submitted papers should meet the internationally accepted criteria and manuscripts should follow the style of the journal for the purpose of both reviewing and editing.

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ISSN No:- 2278 - 6252

International Journal of Advanced Research in Engineering and Applied Sciences

(Volume No. 13, Issue No. 1 January - April 2024)

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Oral Thin Film Technology- Current Challenges And Future Scope

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ABSTRACT

Over the past few years, Oral Thin Films (OTFs) have intrigued scientists and researchers in the domain of pharmaceutical formulations and are being looked upon as a novel approach to designing efficient drug delivery systems. OTFs are currently speculated to be an alternative to the conventional solid and liquid oral dosage forms. Oral Thin Films are dissolving films or oral drug strips to administer drugs via their adsorption in the mouth, ensuring that the drug directly enters systemic circulation. The thin films enable the drug to bypass the first pass metabolism, have quick action, are more convenient for pediatric and geriatric patients where problems of swallowing or nausea are generally encountered, are easy to transport and package and have many such advantages over traditional dosage forms. However, the commercialization of these OTFs has been limited majorly to the American, Japanese and European Union markets only for a restricted number drugs. There is extensive research going on to enable different types of drugs to be formulated into these strips and to overcome certain challenges confronted during manufacture, scale up and the cost effectiveness of the OTFs. The presented review focuses primarily on the different manufacturing processes adopted for making the OTFs like Solvent Extraction, Hot Melt Extrusion, Semi-Solid Casting, Solid Dispersion Extrusion and innovative ones like Flexographic PrintingTechnologies and the technical and economic difficulties that manufacturers encounter during their large scale production. It also describes the current trends in the OTFs market and its future scope worldwide and in India and analyses the feasibility of this innovative approach in terms of the current knowledge and technological resources available.

Keywords: Oral Thin Films (OTFs), drug delivery, extrusion, first pass metabolism.

1. INTRODUCTION

A pharmaceutical formulation is a system that comprises of the active drug, combined with other pharmaceutical ingredients to produce a complete and biocompatible medical product. Tablets, capsules, sprays, creams and syrups are all widely known and accepted pharmaceutical formulations. A drug delivery system has a significant impact on the therapeutic efficacy of the drug. Oral formulations are the most preferred form of drug delivery systems as they are convenient, cost effective and easy to administer. However the oral route may be problematic for pediatric and geriatric and choking where problems of swallowing are prevalent. As a result of this, Oral Thin Films (OTFs), also known as orodispersible film by the European Medicines Agency have attracted significant research and acceptance recently. The idea of OTFs was first presented in the 1970s [1] to overcome swallowing difficulties that the traditional dosage forms like capsules and tablets exhibited. Fast dissolving oral films were first introduced in the market as breath fresheners and personal care products such as dental strips and soap strips. The first of the kind of orally dissolving film was developed by the major pharmaceutical

company Pfizer, who named it as Listerine® pocket packsTM and was used for mouth freshening[2]. However, the United States and European markets have rapidly evolved them as efficient drug delivery platforms. An OTF is essentially a dissolving film or drug strip to administer drugs by adsorbing them in the mouth either buccally or sublingually. The films are essentially made using hydrophilic polymers that dissolve rapidly on the tongue or in the buccal cavity. Thus the drug is delivered directly to the systemic circulation thereby bypassing the first pass metabolism, where a major loss of drug generally occurs in the case of conventional dosage forms. Ease of administration, patient compliance and cost effectiveness in the development of formulations are some of the major advantages of these thin films. Various manufacturing processes are currently being employed while many new ones are being developed for the production of Oral thin Films. However the widespread consumer acceptance of any novel technology depends mainly on its cost effectiveness. The presented review paper focuses primarily on the different manufacturing processes adopted for making the OTFs like Solvent Extraction, Hot Melt Extrusion, Semi-Solid Casting, Solid Dispersion Extrusion and non-conventional ones like Flexographic Printing Technologies along with the technical and economic difficulties that manufacturers encounter during their large scale production. It also describes the current trends in the OTF market and its future scope worldwide as well as in India and analyses the feasibility of this innovative approach in terms of the current knowledge and technological resources available.

2. ADVANTAGES AND DISADVANTAGES

2.1 ADVANTAGES OF ORAL THIN FILMS

Oral Thin Films have the advantages [1, 2] listed below, which have made them potential alternatives to conventional dosage forms:

2.1.1 Advantages over Traditional Dosage Forms

- i. OTFs have enhance the bioavailability of the drug which leads to quicker action
- ii. Drugs bypass the first pass action unlike in the case of conventional dosage forms and hence the amount of drug required to be loaded is reduced.
- iii. Thin Films have greater stability especially compared to liquid dosage forms that require various additives in order to extend their shelf life.
- iv. They do not require special packaging as the drug is loaded into an abuse resistant matrix.
- v. OTFs are less friable as compared to tablets [3, 4]
- vi. Research has proven that, OTFs have lesser side-effects
- vii. The higher surface area available in the oral cavity leads to faster disintegration and dissolution of the strip [5]
- viii. Easily portable

2.1.2 Clinical Advantages

- i. The administration is easy as it employs the oral route
- ii. The patients do not risk choking or suffocation, especially in the case of pediatric and geriatric patients[6]
- iii. The OTFs are a better alternative for patients with nausea
- iv. OTFs are not required to be swallowed with water

2.1.3 Market Advantages:

- i. This novel drug delivery 'system presents pharmaceutical companies with patents on the verge of expiration to extend their revenue cycles.
- ii. OTFs dissuade the misuse, tampering and abuse associated with some prescription drugs as the Film is loaded with a certain amount of drug [7]:
- iii. The Thin Films market is currently in its embryonic stages and limited only to certain over the counter drugs available in the American, Japanese and EU Markets. Thus, researches and companies have a wide scope in formulating drugs that haven't been previously formulated into OTFs and developing newer and cheaper technologies.
- iv. In India, according to Indian Demographics for 2017 roughly 13.39% of the population are senior citizens while 45.7% are children. Thus, Indian investors have a wide consumer range and whereas this technology is only inchoate in our country.

2.2 DISADVANTAGES OF ORALTHIN FILMS

- i. A major manufacturing difficulty that confronts manufactures is the drying time required for the OTFs. Since thermo labile drugs prohibit the use of hot air ovens and high temperatures, it takes a day for the films to dry at room temperature thereby reducing the production rate.[7]
- ii. The films are highly hygroscopic and tend to lose stability in environments having high RH
- iii. It is difficult to achieve uniformity of dosage
- iv. Drugs that are unstable at the buccal pH or irritate the mouth mucosa cannot be formulated into thin films.
- v. The co-administration of multiple drugs remains to be a challenge as the dissolution time is affected.

3. COMPOSITION OF ORAL THIN FILMS

OTFs contain the following key ingredients [5]:

i. Drug or Active Pharmaceutical Ingredients (API)

Needless to explain, the drug is the core ingredient of these polymeric films and generally comprises of 5-30% (w/w) of the films.

Examples: antiallergic, antiemetic, antimigrant etc

ii. Film Forming Agents

Biocompatible and water soluble polymers are the backbone of the OTFs and carry the drug. Various natural and synthetic drugs are available for this purpose.

Multiple polymers can also be combined to achieve desired properties. The polymers must be non-toxic, no-irritant and devoid of any impurities.

Examples: HPMC E3, E5 and E15; K-3 Methyl Cellulose; A-3,A-6 and A-15 Pullulan; pectin, gelatine, Chitosan, cellulose, starch

iii. Plasticizers

Plasticizers improve the strength and flexibility of the polymeric matrix. They decrease the brittleness. Plasticizers are chosen based on the polymers involved and the method used for formulation.

Examples: Glycerol, Dibutyl phthalate, PE glycol

iv. Surfactants

Surfactants are essentially the solubility enhancers that also improve the wetting properties of the film to ensure rapid dissolution and drug release. Examples: Sodium Lauryl sulphate, Tween, Benzalkonium Chloride.

v. Sweetening and Flavouring Agents

Sweetening and flavouring agents are necessary for taste and odour masking of the drug and to increase the appeal of the film. This is an important factor for paediatric patients. Natural of artificial sweeteners and flavours can be incorporated.

Examples: Saccharin, Aspartame

vi. Saliva Stimulating Agents

The OTFs disintegrate on coming in contact with the liquid in the oral cavity which is essentially saliva. Saliva Stimulating Agents produce saliva that helps in quick disintegration and dissolution of the films.

Examples: Citric acid, Lactic Acid, Ascorbic acid

vii. Colorants

Colouring Agents are used to increase the appeal of the film. Pigments are used as colouring agents. Titanium dioxide is most widely used colorant in ODFs and various other pharmaceutical preparations. Apart from titanium dioxide, a full range of colours are available including FD and C, natural and custom pantone-matched colours.

The following table summarizes the general composition of a typical OTF [1]:

Ingredients	Amount (w/w)%
Drug	5-30
Polymer	45
Plasticisers	0-20
Surfactants	As Required
Sweetening and Flavouring	2.6
Agents	3-6
Saliva Stimulating Agents	2-6
Colorants	As Required

4. TYPES OF ORAL THIN FILMS

OTFs are classified into 3 types [1]:

- i. Flash Release
- ii. Mucoadhesive Melt Away Wafers
- iii. Mucoadhesive Sustained Release Wafers

The following table presents the properties that differentiate the aforementioned types of OTFs:

Properties	Flash Release	MucoadhesiveMelt Away Wafers	Mucoadhesive Sustained Release Wafers
Area (cm ²)	2-8	2-7	2-4
Thickness	20-70	50-500	50-250
Structure	Single Layer	Single or Multilayer	Multilayer system
Excipients	Soluble hydrophilic polymers	Soluble HydrophilicPolymers	Low/non-soluble polymers
Drug Phase	Solid Solution	Solid Solution or Suspended Drug Particles	Suspension and/or solid solution
Application	Tongue	Gingival or buccal region	Gingival or other suitable region in the oral cavity
Dissolution	60 s	In few minutes forming Gel	Maximum 8-10 h
Site of Action	Systemic or Local	Systemic or Local	Systemic or Local

5. METHODS OF MANUFACTURE

5.1 CONVENTIONAL METHODS FOR THIN FILM MANUFACTURE

5.1.1 Solvent Casting: In this process Active Pharmaceutical Ingredient (API) is either suspended or dissolved in the selected plasticizer. The other ingredients are dissolved in volatile solvent. The resulting material is known as Film Dope.

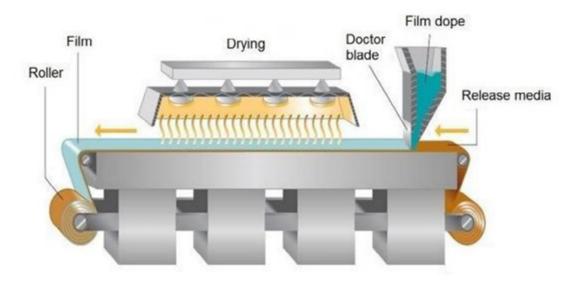


Figure 1: Commercial manufacturing of ODFs using solvent casting [1]

Using conventional solvent-cast film deposition method, the film dope is spread onto a continuous spread media like paper plasticizer. The solution is then dried to remove the solvents. Drying is performed in an oven or a convection chamber. The dried material is then die-cut in small pieces and packed in atmospherically resistant pouches.

This method is best for heat sensitive because the temperatures required for removing the solvent is low. The properties of API like compatibility, temperature sensitivity and polymorphic nature play an important role in selection of solvent. Various precautions need to be taken while producing ODFs like:

a. Effect of moisture: the strength is affected

b. Temperatures need to be maintained to ensure proper viscosity and temperature sensitivity.

Casting of the film, uniform thickness of the film and proper drying are important steps and need to be monitored properly. [2, 3] Also mixing step might lead to introduction of air into the mixture, hence proper de-aeration is required to ensure effective strength. [4]

5.1.2 Hot Melt extrusion: Major areas of production using HME are sustained-release tablets, transdermal and transmucosal systems. Using knowledge of polymers, formulators can extrude mixtures of plasticizers, drugs, polymers into various shapes and final forms for variation in drug release mechanism. In this process, the dry particles are heated by the action of extruder screw until they are molten and homogenized.

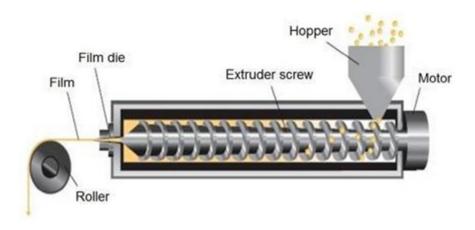


Figure 2: Manufacture of ODFs by Hot Melt Extrusion

The molten materials then passed through an extrusion die to get desired shape and size. The hot molten mass is passed over a roller to monitor the thickness and strength of the film. The extruded film is then cooled, cut and packed. Main advantages of this process include:

- a) There is no need of using solvent or water
- b) The operating parameters can be properly monitored.
- c) Minimum waste
- d) Fewer steps

However in HME, the substances are subjected to very high temperatures, which might lead to thermal degradation and loss of volatile substances. [2, 5, 6]

- **5.1.3 Rolling method:** The drug is rolled along with the solvents in a carrier. The film is dried on the rollers and then cut and packed. The solvents used are generally water and volatile solvents. [7]
- **5.1.4 Semisolid casting:** In this method, polymer is prepared which is water-insoluble. A separate solution of insoluble polymer is prepared in ammonia and sodium hydroxide. The two solutions are mixed together properly along with suitable amount of plasticizers to form a gel like solution. This gel like solution is passed over heat controlled drums to form thin films or ribbons. 1:4 is the ratio maintained between the amounts of acid insoluble polymer to the film forming polymer. Various acid insoluble polymers are cellulose acetate phthalate and cellulose acetate butyrate. [8]
- **5.1.5 Solid-dispersion extrusion:** As the name suggests, the process involves the dispersion of one or

more APIs in solid state in an inert carrier using methods like HME. The immiscible components are extruded with the drug, which are further converted into solid dispersions. The dispersions are shaped into films using dies. [9]

5.2 NON-CONVENTIONAL METHODS FOR THIN FILM MANUFACTURE

The 3D printing technologies have gained tremendous impetus over the past few years and are emerging as platforms for manufacturing pharmaceutical products. These technologies have been adopted for production of OTFs and have the following advantages over the conventional methods of production:

- i. Accuracy in drug loading, especially for potent drugs that are prescribed in small dosages
- ii. Compatibility with different types of APIs including poorly water soluble, peptides and proteins.
- iii. Homogeneity of the OTF which is challenging to achieve in the conventional methods
- iv. Minimal wastage and efficient recycle leads to cost cutting.

Two of the major printing techniques, currently being looked upon by many manufacturers and researchers have been described below:

5.2.1 INKJET PRINTING

Inkjet Printing is a computer printing technology that creates digital images fed to the computer into 3D items by propelling drops of ink onto desired surfaces. [8]

Considering its applications in the pharmaceutical industry, Inkjet Printing can be divided into two main categories

- i. Continuous Inkjet Printing (CIP)
- ii. Drop on Demand Printing (DoD)

In CIP technique, there is consistent ejection of ink from a nozzle. Before reaching the nozzle, the ink stream is broken down into droplets by applying suitable acoustic waves. The drops are then deflected to reach their suitable position by subjecting them to an electric field. The degree of deflection depends on the amount of electric field to which the drop is subjected and thus the necessary pattern is generated. [9] The solvent used is volatile and vaporizes almost instantly after the drop falls, leaving behind our desired compositions In DoD Printing, the drops are generated in multiple nozzles when voltages are applied, due to the change in shape of a piezo-electric material in the ink chamber that generated a pressure

wave in the ink. [2]d.

The major drawbacks of Inkjet printing are the high cost of equipment and maintenance and requirement of extremely skilled labour to handle these machines. Hence for industrial use, Flexographic Printing Technologies are better candidates.

5.2.2 FLEXOGRAPHIC PRINTING

This is a unique orienting technique that works on the principle of contact printing. [10] It consists of a Fountain roller that transfers the ink, containing the active ingredient in solution or suspension that transfers the ink further to an Anilox Roller. This roller accurately measures the amount of ink required for uniform thickness to the plate cylinder which holds the polymeric strip. Pressure is applied to print the ink onto the polymer. This process is advantageous as the film on which the drug is printed is already manufactured and dried. Thus the loss of activity of API due to heat drying is avoided. The production efficiency is high, considering an average of 530 oral films per minute. The drawbacks of this process are the manufacture of a large print roller and high risk of contamination.

These techniques, though highly innovative are confronted by certain challenges like the optimization and improvement of soft wares for a wide range of drugs and excipients, clinical survey to assess the efficacy, stability and safety in terms of long and short term side effects on the patients. [2] Also it must be ensured, that the usage of these techniques does not, in any way, alter the physicochemical or therapeutic properties of the API. It can be anticipated that a faster way to broaden areas of application of these techniques and to commercialize them is to combine them with conventional processes and then optimize, which will lead to a great increase in the OTF market.

Other than these there are a few patented technologies to manufacture OTFs. These include Xgel, Soluleaves, Wafertab, Foamburst and MiCap.

6. ECONOMIC ASPECTS

Due to the ease of application and high effectiveness, there is no surprise that the thin film drugs have recorded a high market acceptance. The technology has gained attention from both established and start-up pharmaceutical firms. The sale has been picked up significantly in economies such as U.S. and the countries in Europe. The drug products market in oral thin film formulations was predicted to be valued at \$500 million in 2007 and could reach \$2 billion by 2010. Further according to a research report, the

global thin film drug manufacturing market is expected to be worth US\$15,984.3 mn by the end of 2024 from US\$7,337.8 mn in 2015, thus estimating an increase of 117% over 10 years. However, in 2015 there existed around 10 prescription products only and around 29 such thin film products under clinical trials. Thus, it can be anticipated that the manufacturing market is going to increase considerably in the coming years.

In the overall market of the thin films, oral thin films will remain the most promising due to the maximum advantages it has over others. The oral thin film segment is likely to surge at a significant CAGR of 18.3% between 2016 and 2024. Currently North America is emerging as the largest manufacturer of the OTFs with a share of 85.3%. Among the key players in the manufacturing are Pfizer, Inc., Novartis AG, Wolters Kluwer, Solvay, Allergan plc. Sumitomo Dainippon Pharma Co., Ltd., IntelGenx Corp. Some of the startups such as FFT Medicals and Cynapsus Therapeutics are also emerging. Around 38% of the products are based on the MonoSol's PharmFilm technology or Applied Pharma Research / Labtec's RapidFilm technology.

However, Asia Pacific is expected to grow at the fast rate during the forecast period with major contribution of countries such as India, Japan and China. In view of this, Indian Investors are looking OTF as an excellent opportunity for business. New companies such as Aavishkar Oral strips Pvt. Ltd, Hyderabad; NU Therapeutics, Hyderabad; and ZYM Laboratories, Nagpur have been extensively concentrating on this technology. Bigger manufacturers like Cipla, Mankind and Dr. Reddy's laboratory are also working for the development of this technology.

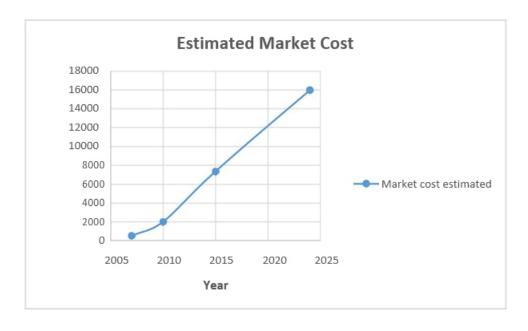


Figure 3: Estimated market cost of Oral Thin Films

Apart from drugs, hormones as well as vaccines are being formulated with OTFs with the aim of providing improved patient compliance. However it is important to note that the proscriptions available for the OTFs are less currently.

In general, OTFs are more expensive to develop and manufacture than the conventional ways of drug delivery. Currently they are considered only as an alternative for the patients with pediatric, geriatric and dysphasia disorders who find it difficult to swallow. Due to the established nature of the manufacture of the conventional tablets, the costs are cheaper than the OTFs.

7. CONCLUSION

Oral Thin Films are beyond doubt emerging as platforms for drug delivery. They have many advantages the major ones being their ease of administration in the case of pediatric and geriatric patients as also patients with swallowing difficulties and have accurate dosing and quick action. This being said, currently oral thin films target only a limited section of the consumer market. OTFs are currently more costly to develop and manufacture as compared to tablets. The OTFs currently available in the market are for a limited number of drugs manufactured by the major companies involved in research and production of these OTFs, which has led to monopoly and consolidation in the thin film market. Tablets have been around for a lot longer and hence their market is well established. OTFs could be alternatives to the convenient dosage forms. However there needs to be extensive research put into their manufacture and clinical studies. Though at present the OTF technology is confronted by many challenges, optimizing the research, formulation and manufacture shows a promising picture and huge scope for OTFs in the future.

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Design And Development Of Water Purifier For Rural Population

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ABSTRACT

In rural India, people are not much aware of the purity of drinking water. In present status available water sources are getting polluted through different chemical mixtures and water treatment. So the importance for purification of water becomes a necessity for life. A water purification device which neither consumes electricity nor requires any pipeline connection fulfils the requirements of people in rural areas. So there is lot of scope to introduce a storage type water purifier for this segment.

This project deals with the design and development of water purifier for the rural population. The project was carried out in the Isometric solutions Bangalore. A water purifier is designed and developed which meets the customer requirements and manufacturing requirements. Multiple concepts are generated and concept selection based on Pugh matrix is employed to select the best concept for future design and development.

A low cost water purifier is designed and developed which satisfies the customers of the rural areas which helps them to achieve healthy lifestyle. This is highly benefits the Indian rural population..

Keywords: Design and development of water purifier

1. INTRODUCTION

One of the most pervasive problems afflicting people throughout the world is inadequate access to clean water. Problems with water are expected to grow worse in the coming decades, with water scarcity occurring globally, even in regions currently considered water-rich. Addressing these problems calls out for a tremendous amount of research to be conducted to identify robust new methods of purifying water at lower cost and with less energy, while at the same time minimizing the use of chemicals and impact on the environment.

It is but an irony that though 70% of the earth's surface is covered by water yet it cannot be consumed without purification. Less than 1% of the water available on earth can be used for drinking purposes and that too is increasingly getting polluted. Pure water once naturally available is a long gone affair now in many parts of the country. According to World Health Organization 80% of diseases are water borne. The water that we get in our tap may be contaminated with physical, chemical and microbiological impurities and may also have a high TDS (Total Dissolved Solids) Level. [1]

Although freshwater as a water resource might be plentiful and fully accessible to some populations, for

others this is not the case. Natural disasters and atmospheric and climate conditions can cause drought,

which can be problematic for many who rely on a steady supply of water. Arid areas around the world are

most vulnerable to drought due to high annual variations in rainfall. In other cases water

overconsumption can lead to problems that affect entire regions both environmentally and economically.

[2]

In this context, this project deals with design and development of a water purifier for rural population.

2. NEED FOR WATER PURIFIER

India faces an enormous challenge in providing its citizens with clean potable water free from

pathogenic bacteria, viruses, and cysts which cause diseases such as diarrhea, cholera, typhoid, and

amoebiasis. It is estimated that about 10 million illnesses and 700,000 deaths in India could be attributed

to diarrhea of which 400,000 are children under the age of five. [2]

Due to climatic changes, draughts, industrial wastes and alarming levels of salinity sources like rivers,

catchments and reservoir systems are under dire stress resulting in the deteriorating water quality day by

day. Due to the increased pollutants, river water is getting contaminated with dissolved impurities,

bacteria and viruses.

The present day water has different types of deadly contaminants unheard in the past. Total dissolved

solids in excess, heavy metals like lead, copper, iron, mercury and arsenic and other pollutants like

insecticides and pesticides in the water can wreak havoc on the human body.

Mental retardation, cancer, kidney stones, digestive disorders, cardiac problems, intestinal catarrh,

fluorosis are some of the long term effects caused as a result of these water contamination. 85% of all

human diseases are due to water contamination. The rural population is the major sector suffering from

this issue. Hence there is a real demand for the pure drinking water. [2]

All these needs collectively focus on the need for low cost, flexible and portable water purifiers which

keeps the in line with healthier environment. In this context, this project deals with design and

development of a water purifier for rural population.

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3. OBJECTIVES OF THE STUDY

- a) To review the available literature and collect data to understand the user aspirations, market and the competitors of water purifiers.
- b) To analyze the collected data to arrive at Product Design Specification (PDS), after Quality Function Deployment preparation to overcome the usability issues, cost and aspects of appealing aesthetics of water purifier.
- c) To generate concepts of storage type water purifier based on arrived PDS and to select final concept for development.
- d) To fabricate a 1:1 scale mock-up of the final concept to end up with a low cost water purifier.

4. METHODOLOGY

With the above objectives in mind following methodology is adopted.

- a) Literature review for water purification is carried out by referring reviewed journals, books, manuals and related documents.
- b) Data collection is done by user study and market study through questionnaires, interviews, images, videos etc. to study and understand the water purifier, its market and users.
- c) QFD generation based on the customer requirements and corresponding technical requirements, and PDS is generated prioritizing the features in the QFD.
- d) Concepts are generated by sketching, adopting various concept generating technique like brain storming.
- e) Few concepts are selected and the selected model will be created with the detailed features using CATIA-V5R17.

- f) Concept evaluation for selecting the final concept is carried out by Pugh's method.
- g) 1:1 scaled physical model will be made with good aesthetics and detailed features.

5. DESIGNAND DEVELOPMENT OF WATER PURIFIER

In this study deals with the detail design of the concept selected on the basis of Pugh matrix. From the Pugh matrix concept selection process, there are ten basic parts which are assembled to arrive at the final design of the product. The part drawings and their respective drawings are shown below.

1) lid

The lid is the upper most part of the purifier which covers the pre-filter from any damages. The lid is designed so that it is easily lifted while pouring or filling water to the purifier. Three dimensional view and part drawing are shown in the figures 5.1 and 5.1a respectively.

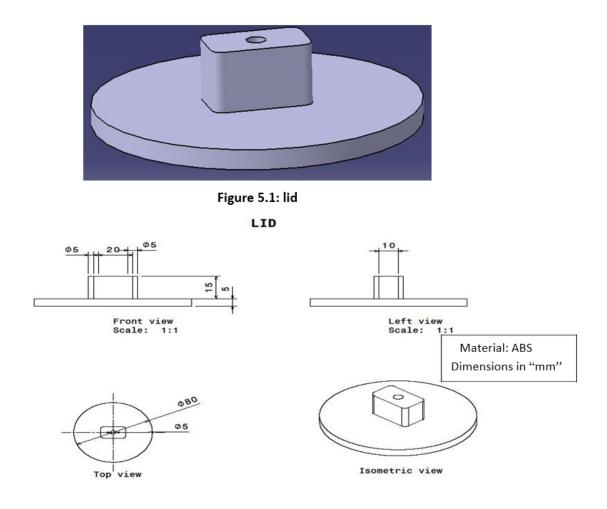


Figure 5.1a: Drawing of lid

2) Cover

The second part of the water purifier is the cover. This is attached to the top chamber to protect it from any external damages and also supports the pre filter when it is placed in the top chamber. Three dimensional view and part drawing are shown in the figures 5.2 and 5.2a respectively.

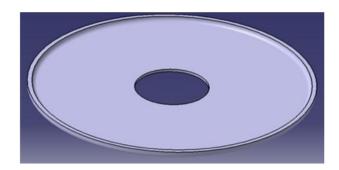


Figure 5.2: Cover

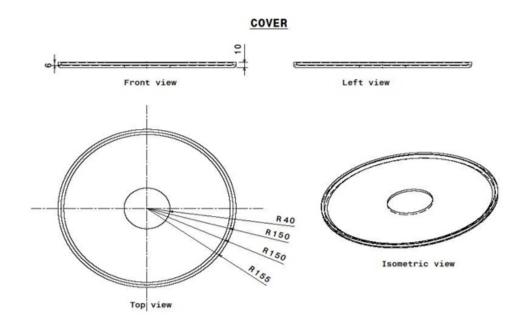


Figure 5.2a: Drawing of Cover

3) Part 3: Top Chamber

The top chamber is the main part of the water purifier which generally decides the capacity of the purifier. The top chamber is designed with less sharp inside edges and complications. A counter bore hole is provided at the top of the top chamber where pre-filter is placed. The base of the top chamber is opened which provides for the easy assembly and disassembly of the purifier. Three dimensional view and part drawing are shown in the figures 5.3 and 5.3a respectively.

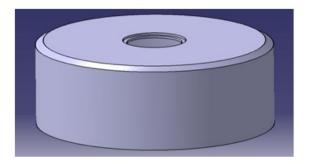


Figure 5.3: Top Chamber

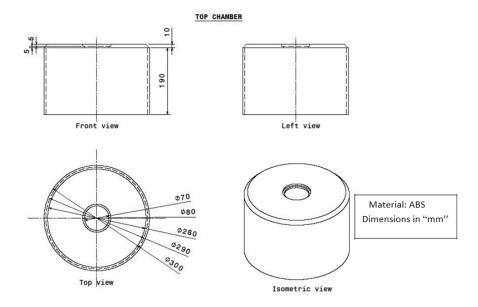


Figure 5.3a: Drawing of Top Chamber

4) Pre Filter

The pre filter is placed in the top chamber which acts as the barrier and removes lager size contaminants initially while filling water itself. Hence supports the purifying cartridge to survive for longer period. Three dimensional view and part drawing are shown in the figures 5.4 and 5.4a respectively.

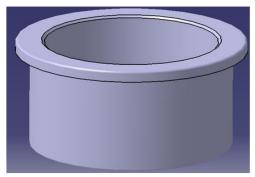


Figure 5.4: Pre Filter

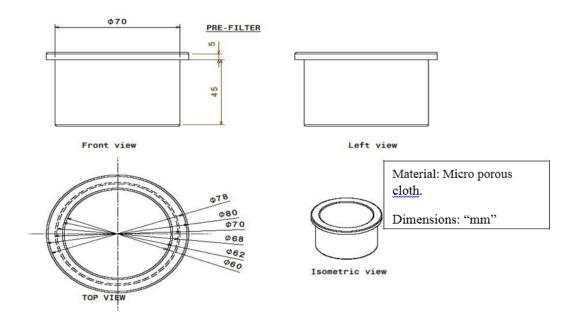


Figure 5.4a: Drawing of Pre filter

5) Carbon filter

The carbon filter is the next part which is assembled to the middle support of the water purifier. This filter contains pores through which water flows. During the flow, the filter adsorbs the chlorine leaving the clean water for next purification. Three dimensional view and part drawing are shown in the figures 5.5 and 5.5a respectively.

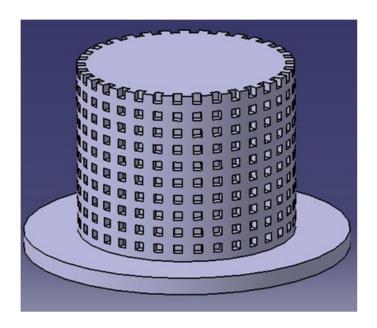
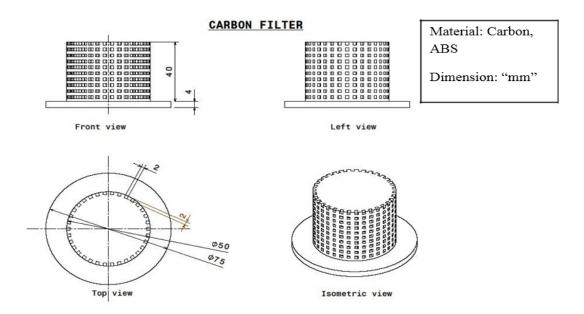


Figure 5.5: Carbon Filter

Figure 5.5a: Drawing of Carbon Filter



6. Middle Support

The middle support acts as the intermediate to the top and the bottom chamber. The water flows from the connectivity of middle support to the bottom chamber. The diameter of the support is made lager so that it gives necessary rigidity to the top chamber when place on it. Three dimensional view and part drawing are shown in the figures 5.6 and 5.6a respectively.

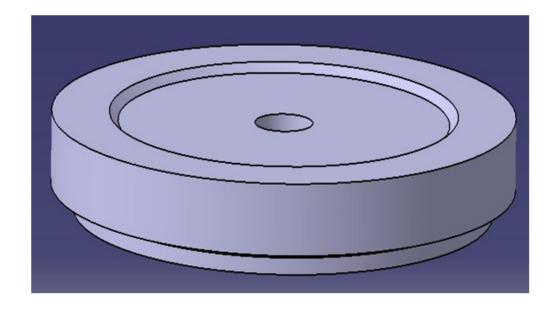


Figure 5.6: Middle Support

MIDDLE SUPPORT

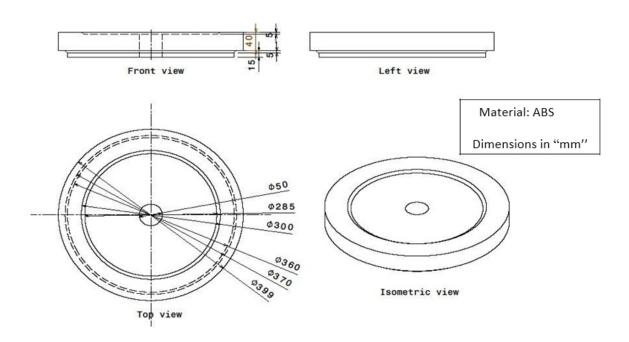


Figure 5.6a: Drawing of Middle Support

7. Purifying Cartridge

The purifying cartridge is designed to remove contaminants in the water. This is placed in connection to the middle support and the bottom chamber. Three dimensional view and part drawing are shown in the figures 5.7 and 5.7a respectively.

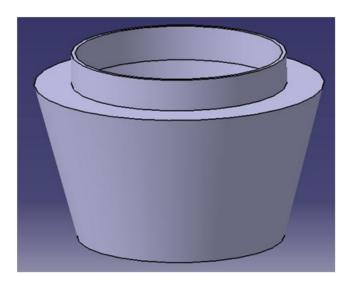


Figure 5.7: Purifying Cartridge

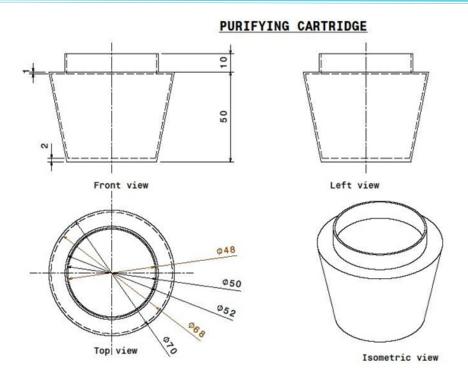


Figure 5.7a: Drawing of the Purifying Cartridge

8. Bottom Chamber

The purified water from the purifying cartridge gets collected in the bottom chamber. The diameter of the bottom chamber is 400mm so that it collects more water for the use. The chamber is provided with two taps which may serve the people on the rural better during the functions. The base of the chamber is concave so that the flow of water is directed to either taps with no wastage of water at the bottom of the chamber. 'D' shaped cut is provided at the tap so as to place a tumbler without any adjustments. Three dimensional view and part drawing are shown in the figures 5.8 and 5.8a respectively.

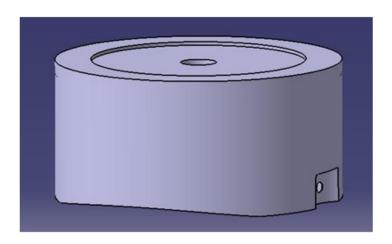


Figure 5.8: Bottom Chamber

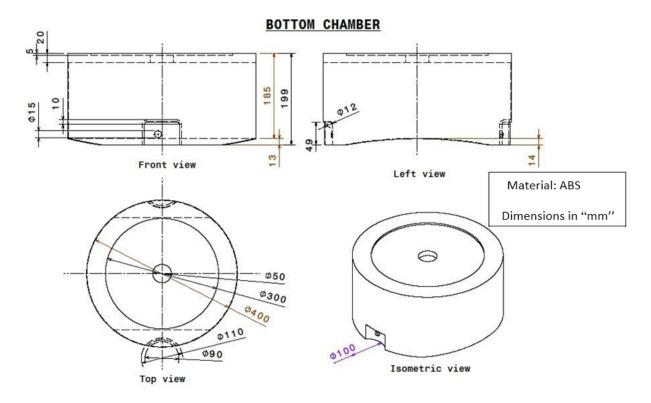


Figure 5.8a: Drawing of Bottom Chamber

9. Tap

The tap is positioned at the base of the bottom chamber so that the flow rate is even. The D shaped cut also at the tap reduces the damages to the tip of the tap. Three dimensional view and part drawing are shown in the figures 5.9 and 5.9a respectively.

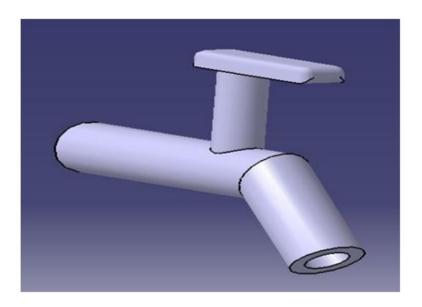


Figure 5.9: Tap

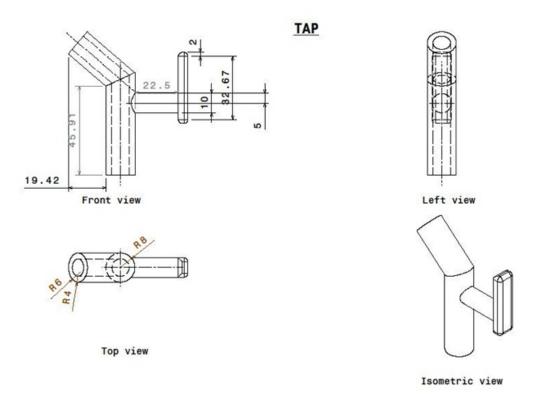


Figure 5.9a: Drawing of Tap

10. Base

The final part of the water purifier is the base. The height of the base should be nominal to all the other design parameters. The position of the tap has an adverse effect if the base is either too high or too small. The diameter of the base should be such that it should be stable when all components are placed on it. Three dimensional view and part drawing are shown in the figures 5.10 and 5.10a respectively.

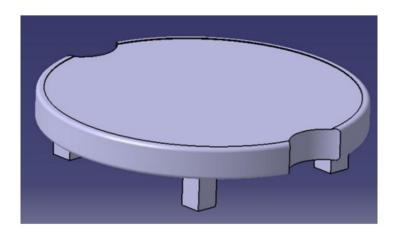


Figure 5.10: Base

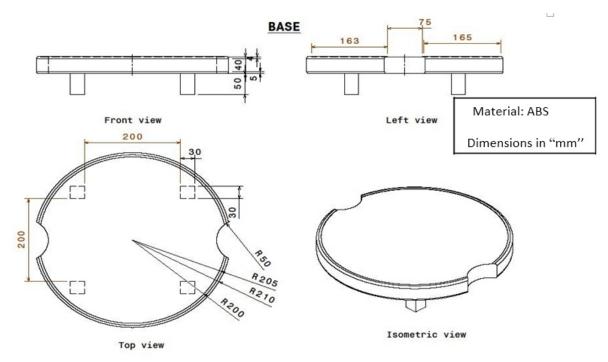


Figure 5.10 a: Drawing of the Base

11. Assembly

The figure 5.11 shows the assembly of the water purifier. The figure 5.11a shows its drawing of the water purifier.

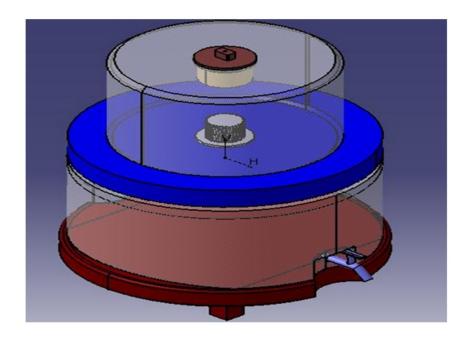


Figure 5.11: Assembled View of the Purifier

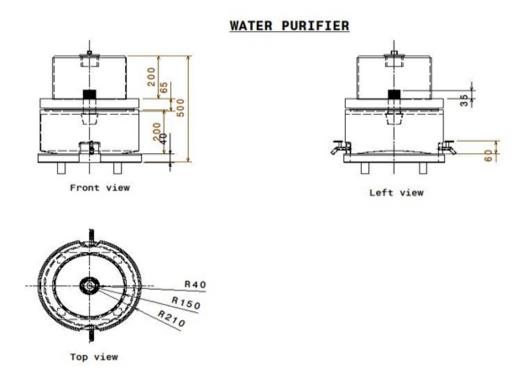


Figure 5.11a: Drawing of the Water Purifier

12. Exploded View

The figure 5.12 shows the explode view of the water purifier with all its components named at their respective positions.

The above figure 5.12 shows exploded view of the water purifier. The purifier consists of ten main parts of which the top and the bottom chambers decide the storage capacity of the purifier. The prefilter is of 160*100 diameters so that contaminants are retained in it. Both the top and bottom chambers are almost of the same capacity which is the basic customer requirement in the rural areas. The chambers are also transparent so that anyone could replenish the water when the water level is less in the purifier. A middle support acts as the connectivity between the top and bottom chamber. The purifying cartridge is assembled inside the middle support through which the water flows down to the bottom chamber. The base of the bottom chamber is curved upwards so that the water is not collected at the base below the level of tap. The water flows equally to the two taps provided. At the tap position, 'D' cut is provided which helps to place the tumbler without any adjustments. The total height of the purifier is around 500mm so that it is not too risky to fill the water especially for the women when purifier is placed on the table. The spherical shape of the purifier provides the necessary stability. The parts are all assembled as snap fit so that regular cleaning of the inner surface can be done with ease.

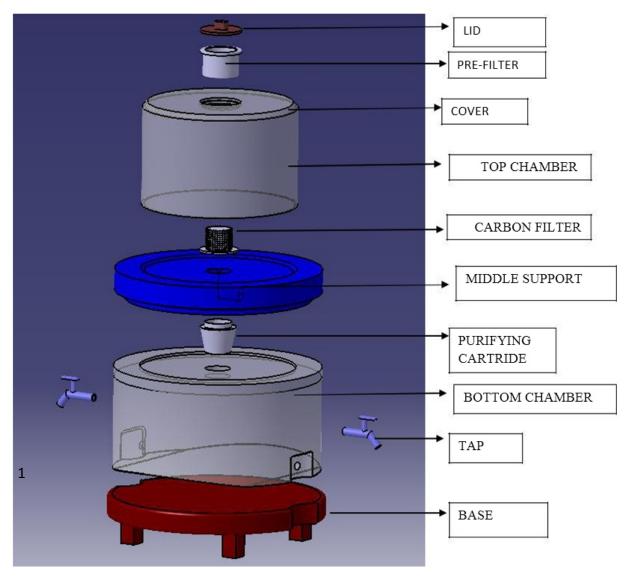


Figure 5.12: Exploded View of the Water Purifier

The above design of water purifier meets most of the requirements of the people in the rural areas where power is the major issue. Hence the development of this purifier may serve many people across.

6. BILL OF MATERIAL

The table 6.1 shows s the bill of material of the water purifier which is designed and developed.

Table 6.1 Bill of Material of Purifier

Sl. No	Name	Numbers	Material
1	Lid	1	Acrylonitrile Butadiene Styrene
2	Pre-filter	1	Micro porous cloth

3	Cover	1	Acrylonitrile Butadiene Styrene
4	Top chamber	1	Acrylonitrile butadiene styrene
5	Pre-filter	1	Carbon
6	Middle Support	1	Acrylonitrile Butadiene Styrene
7	Purifying Cartridge	1	Plastic and Carbon
8	Bottom Chamber	1	Acrylonitrile Butadiene Styrene
9	Тар	2	Poly Vinyl Chloride
10	Base	1	Acrylonitrile Butadiene Styrene

7. PROTOTYPE

Considering all the design parameters, a final prototype is generated. The figure 5.13 shows the prototype of the water purifier which will fulfill the customer requirement by is less complicated design and operating parameter.

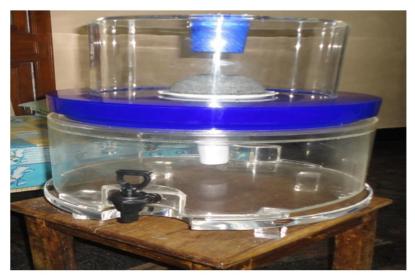


Figure 7: Prototype

8. CONCLUSION

In rural India, people are not much aware of the purity of drinking water. In present status available water sources are getting polluted through different chemical mixtures and water treatment. So the importance for purification of water becomes a necessity for life. A water purification device which neither consumes electricity nor requires any pipeline connection fulfils the requirements of people in rural areas.

Hence the design and development of the water purifier may be beneficial in several ways for the peoples in the rural areas. The design must consider the cost, storage capacity, portability, easily disassembled for cleaning purpose etc. Considering all these criteria, a well designed storage type water purifier may be developed.

Customer's needs are the basement for the design purpose. In this project the designed water purifier has the advantage of two taps which may be used to provide clean water with minimum delay during functions etc. The bottom of the base is provided with a bulge so that no water stays in the purifier and 100% flow rate can be achieved.

There is a 'D' shaped cut which is provided at the taps to ensure the placement of the tumbler without any harm to the taps. Both the chambers are almost of the same bigger capacity which may help for the families with more members providing each person pure water. The chambers are made transparent which may help in the replenishment of the water.

Hence this project of design and development of water purifier may be very beneficial especially for the rural population.

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Optimization Of The Sterilization temperature And Time For Palm Wine Preservation

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ABSTRACT

Studies were carried out to establish the optimum temperature and time for sterilization of palm wine to enhance its shelf life. In the studies, the temperature and time of sterilization of the beverage were varied within the range of 40-75oC and 10/20 minutes in order to establish the optimum time and temperature for its sterilization without affecting the beverage's quality in terms of the taste and aroma profile. Each 500ml of palm wine sample was respectively heat-treated at the respective temperatures for 10 and 20 minutes. The result of the studies showed that bacteria and yeast load decreased with the increase in temperature and time of sterilization. The taste and aroma profile diminished with the increase in temperature and time of sterilization. The temperature and the time at which there was complete destruction of organism with retention in taste and aroma of the beverage was 650C and 10 minutes respectively. A Plot of the number of surviving cells against the temperature of sterilization at a given time follows a log linear kinetics. The statistical evaluation of the sample sterilized at 650C for 10 minutes when compared with the fresh untreated sample (control) showed no significant different between the samples at 95% confidence level.

Keywords: Palm wine, Optimization, Sterilization temperature and time, Bacteria, yeast, Aroma and Taste

1. INTRODUCTION

Palm wine is a traditional alcoholic beverage popularly drunk in tropical countries of the world, including Nigeria. It is highly valued among the Igbos in the south Eastern part of Nigeria as the best alcoholic, especially for traditional ceremonies. It is sourced from the sap of male inflorescence (Elaeisguineensis). The sap which is rich in sugar is fermented naturally by yeasts of the genera, Saccharomyces. Lactic acid bacteria have been implicated to contribute to the characteristic aroma of fresh palm wine (Okafor, 2007). The sources of the yeasts and bacteria microflorae include the air, knife and the palm wine keg used by the tapper in harvesting the sap. The sap undergoes spontaneous fermentation which promotes the proliferation of microorganisms for the conversion of the sweet substrate into several metabolites which include: alcohol, lactic acid and acetic acid. The alcoholic content of the freshly harvested palm wine is about 3.0%. The alcoholic content increases with time due the fermentative activity of the yeasts. The major problem associated with the handling of the beverage is its short shelf life, due to the uncontrolled metabolic activity of the yeasts and bacteria (Chandrasekhar et al. 2012). Several attempts to preserve the beverage using chemical, ultraviolet and heat treatments have met with little success. (Eshie, 2001). The generally accepted view is that thermal death is a first order

process, which means that at any given temperature and time, the rate of death depends upon the number

of viable cells present (Adams and Moss, 1995). The establishment of the optimum temperature at

which the beverage will be sterile and still retains its aroma and taste would be a most welcome

development

.METHODOLOGY

Sterilization

Each 500ml sample of fresh palm wine, stored in a sterile 500ml glass bottle, was heat-treated at

respective temperatures of 400C, 450C, 500C, 550C, 600C, 650C, 700C and 750C for 10 and 20 minutes

in a thermostatically controlled water bath. The samples were cooled and cultured for bacteria and yeast

using nutrient agar and sabourand dextrose agar respectively to determine the effectiveness of the heat

sterilization.

Shelf stability test

The heat-treated samples were cooled to 300C and stored at room temperature for one month, after

which they were cultured for the growth of bacteria and yeast. The bacteria and yeast count of the

surviving organisms in the sample heat-treated at different temperatures were determined using serially

diluted samples.

Bacteria cultures were gram-stained and microscopically examined using oil immersion (×100)

objective lens. The yeast cultures were stained using lactophenol cotton blue solution and examined

under and $(\times 40)$

Organoplaetic analysis of treated and untreated (whole) palm wine samples

Sensory evaluation of the palm wine samples heated-treated at different temperatures and time and of

the control (whole, fresh palm wine sample) was carried out using scoring and grading methods. The

sensory attributes evaluated were taste and aroma.

International Journal of Advanced Research in Engineering and Applied Science (Vol- 13, Issue - 1 Jan-Apr 2024)

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RESULTS AND DISCUSSION

Table 1: Palm Wire Samples Treated For 10 Minutes

Sample	Bacteria count (CFU/ml)	Yeast count (CFU/ml)	Taste and aroma profile
Control			
40 ⁰ C	1.5×10 ⁴	2.0×10 ⁴	Off-taste /aroma
45 ⁰ C	1.2×10 ⁴	1.8×10 ⁴	Off-taste /aroma
50 ⁰ C	1.0×10 ³	1.3×10 ⁴	Off-taste /aroma
55 ⁰ C	1.0×10 ²	1.0×10 ²	Off-taste /aroma
60 ⁰ C	Nil	1.0 x 10 ²	Off-taste /aroma
65 ⁰ C	Nil	Nil	Taste and aroma intact
70 ⁰ C	Nil	Nil	Retention of taste but loss of aroma
75 ⁰ C	Nil	Nil	Retention of taste but loss of aroma
80 ⁰ C	Nil	Nil	Retention of taste but loss of aroma

The results of the bacteria and yeast count analysis showed that the population of surviving cells decreased with the increase in temperature and time of sterilization. The sample sterilized at 650C for 10 minutes was found to have zero count of bacteria and yeast while retaining taste and aroma. The samples heat-treated at 700Cand 750C, though sterile were found to have retained the taste but lost the aroma of the beverage. The decline in the number of both bacteria and yeast with the increase in temperature agreed with the findings of Adam and moss (1996) that thermal death is first order process which implies that the rate of death depend on the number of viable cells present. The plot of the number of surviving cells at a given temperature and time showed a downward slope.

Table 2: Palm Wine Samples heat-treated for 20 Minutes

Sample	Bacteria count	Yeast count	Taste and aroma profile
	(CFU/ml)	(CFU/ml)	
Control			
40 ⁰ C	1.2×10 ⁴	1.6×10 ⁴	Off-taste /aroma
45 ⁰ C	8.0×10 ²	1.4×10 ⁴	Off-taste /aroma
50 ⁰ C	5.0×10 ²	1.0×10 ³	Off-taste /aroma
55 ⁰ C	1.0 x 10 ²	6.0 x 10 ²	Off-taste /aroma
60 ⁰ C	Nil	1.0 x 10 ²	Off-taste /aroma
65 ⁰ C	Nil	Nil	Taste and aroma intact
70 ⁰ C	Nil	Nil	Retention of taste but loss of aroma
75 ⁰ C	Nil	Nil	Retention of taste but loss of aroma
80 ⁰ C	Nil	Nil	Retention of taste but loss of aroma

Table 2 shows that heat treatment for 20 minutes reduced the cell number of bacteria and yeast but impaired the aroma of palm wine samples at temperature above 650C.

The analysis of variance of the values obtained on the taste and aroma evaluation of the sample heat-treated at 650C and the control shows no significant (P < 0.05) difference. The samples sterilized within the temperature range of 450C to 600C were characterized by off-taste and aroma, while samples sterilized above 650C up to 750C retained their sweet taste but lost the characteristic aroma of palm wine. These findings implied that between 400C and 600C, some bacteria and yeasts survived the heat sterilization and metabolized the sugars and the macromolecules to alcohol and off- flavor compounds. The retention of taste in the samples sterilized above 650C can be attributed to the total extinction of microbial life. The loss of aroma of the sample heat-treated above 650C for 20 minutes could be due to the volatility of the flavor compounds especially the esters at high temperatures.

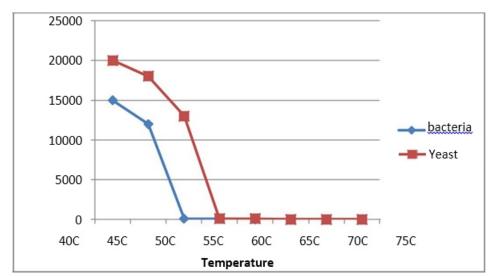


Fig 1: Effect of sterilization temperature on cell number of bacteria /yeast in palm wine treated for 10 minutes

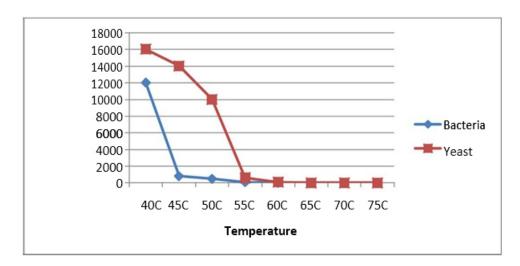


Fig 2: Effect of sterilization temperature on cell number of bacteria/yeast in palm wine treated for 20 minutes

CONCLUSION AND RECOMMENDATION

The results of the study have shown that the optimum sterilizing condition is 650C for a period of 10 minutes to enhance the shelf stability of the beverage with special reference to taste and aroma. Heat sterilization is preferred to the use of chemical preservatives as there is no side effect associated with heat treatment.

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