FORMULATION AND EVALUATION OF POLYHERBAL MOUTHWASHES

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ABSTRACT

The purpose of this research is to formulate and evaluate herbal mouthwash in order to treat and prevent oral microbial burden by using the extract of curcumin and Xylitol. The curcumin added in the preparation to serves as anti-inflammatory and antioxidant. Xylitol formulation helps in preventing harmful bacterial development and helps in maintaining oral hygiene. The mouthwash prepared using curcumin and xylitol was subjected to various evaluation parameters like PH, appearance, odor. Here the herbal mouthwashes containing five formulations as f1, f2, f3, f4 and f5. The PH (6.76) standard preparation was compared with four preparations (f1,f2,f3,f4).The PH of f1 preparation is 5.78,f2 was 6.0 ,f3 was 6.43,f4 was 6.66. As compared to standard preparation f4(6.66) shows the nearer value of PH. The Appearance of the prepared mouthwash was found to be blue colour clear liquid. The odor of prepared mouthwash was found to be odor of fresh mint with Nutmeg oil, Eucalyptol oil and fennel oil. The HPLC analysis of Sodium methyl paraben was found to be (0.142,0.141,0142,0.141,0.141%w/w). and sodium Propyl Paraben was found to be (0.050,0.050,0.051,0.051%w/w). The Evaluation parameter confirmed that the formulated mouthwash served the purpose.

KEYWORDS: Sodium Propyl Paraben, Herbal mouthwash, Curcumin and Xylitol.

INTRODUCTION

Mouthwash is a medicinal liquid that is held in the mouth and swished around by the perioral muscle to kill oral microorganisms and to mask the bad breath caused by the microorganisms.[1]
Types of mouthwash
Mouthwash is divided into two categories: aesthetic and medicinal. Cosmetic mouthwashes may momentarily reduce foul breath and leave a nice flavor in the mouth, but they have no chemical or biological application beyond that. For example, if a product does not destroy bacteria that cause bad breath, it is regarded to provide only a cosmetic advantage. Therapeutic mouthwash, on the other hand, contains active components that can help control or prevent problems including bad breath, gingivitis, plaque, and tooth decay.[2]

Advantages of mouthwash
1. Mouthwash can boost the oral health.
2. Curcumin, which is used, as an ingredient in the mouthwash possess anti-inflammatory and antimicrobial activity.
3. Mouthwashes also prevents the dry mouth.
4. Mouthwashes prevents the gum diseases, gum inflammation, and reduce the risk of cavities.

Xerostomia
The subjective complaint of dry mouth is known as xerostomia. 1 Patients with xerostomia frequently do not display any objective signs of hypo salivation, and their symptoms may be caused by changes in the composition of saliva on a qualitative and/or quantitative level. The typical stimulated salivary flow rate is 1.5–2.0 mL/min, while the unstimulated salivary flow rate is 0.3–0.4 mL/min.[3]

Figure 1: Xerostomia (Dry mouth).

From ancient times to the present, the importance of oral and dental care has been recognised.
Discords, a Greek physician, is said to have made a mouthwash mixture comprised of plant extracts, milk, oil, or vinegar. Mouthwashes are oral solutions or liquids that are swished around the mouth to eliminate bacteria, act as an astringent, deodorize the oral cavity, and have a medicinal impact by alleviating infection or preventing dental decay. As a result, they're regarded as one of the most effective and safe ways to reduce oral bacteria.\[8\]

Gingivitis is mostly a microbiological condition that begins with plaque formation. Incorporating antiseptic chemicals in mouthwashes to improve the outcome of mechanical oral hygiene practices is one of the most effective ways to combat tooth plaque-induced gingivitis.\[10\]

Chlorhexidine (CHX), a broad range antibiotic with considerable antibacterial activity on both gramme positive and gramme negative bacteria, as well as fungi and some viruses, has been the most commonly utilized chemical. As meta-analysis studies have clearly demonstrated, the efficacy of chlorhexidine mouth rinses in controlling gingivitis is well recognised. Synthetic chemicals, on the other hand, have some drawbacks, such as tooth discoloration and altered taste sensations3, which have been described with CHX use. The clinical drawbacks of CHX necessitate the use of reasonably safe herbal components, prompting us to investigate herbal extracts as an alternative therapy.\[10\]

Mouthwashes with antibacterial and antimicrobial qualities can help prevent cavity-causing germs from growing, decrease plaque, fight bad breath, and keep teeth and gums strong and healthy. Exosmosis, which is produced by salt, relieves mouth sores and improves swollen gum conditions in many periodontal illnesses. Because it is a hypertonic solution, saline exerts a mechanical cleaning and antibacterial effect on germs that undergo lysis. The heat of the solution promotes heating by causing a therapeutic increase in blood flow (hyperemia) to the surgical site. It also promotes the drainage of dental abscesses.\[11\]

Gingivitis is a condition in which the gums become inflamed and bleed. Plaque that accumulates on the teeth and gums is the main cause of focus.\[11\]

The mouth cavity begins to be colonized by diverse types of bacteria around the time of birth. Few bacteria among them can eventually cling to the host, producing dental plaque and causing infectious disorders as gingivitis and periodontal disease. Periodontal disease is thought to be initiated and progressed only as a result of dental plaque.\[12\]
Plaque control can be achieved using both mechanical and chemical methods (brushes, floss, and interdental aids). Chemical plaque control, like mechanical plaque control, has grown in popularity due to its distinct properties. Chlorhexidine has been the most popularly rewarded chemical means of keeping good dental hygiene in the realm of dentistry. Due to its numerous qualities, it is regarded as the gold standard. It has the best bacteriostatic and bactericidal action due to its antimicrobial and antiplaque.\[12]\n
The gingival crevicular fluid acts as a leaching medium, allowing a drug to be released from its dosage form and distributed throughout the periodontal pocket. These features, together with the fact that the periodontal diseases are localized to the immediate environment of the pocket, make the periodontal pocket a natural site for treatment with local sustained-release drug delivery systems.\[13]\n
When antibacterial drugs are delivered in solution, the duration of action is usually short, and repeated treatment is required to maintain effective concentrations in the periodontal pocket. This makes patient compliance critical to ensure optimal clinical efficacy. Due to the drawbacks of the above methods of delivery, researchers have concentrated their efforts on the development of long-acting intra-pocket delivery systems, such as dental films.\[13]\n
Because the average depth of a periodontal pocket is between 6 and 8 mm, the therapeutic drug delivery device should be small and not extend beyond the gingival margin when inserted. Furthermore, the drug in the device must be highly effective as a therapeutic agent even at a low dosage. Ideally, these systems should deliver the antibacterial agent for prolonged periods to the affected pocket(s) at levels in excess of the minimum inhibitory concentration for the causative organism.\[13]\n
**AIM & OBJECTIVE**

**Aim**

To Formulate and evaluate the herbal mouthwash in order to achieve therapeutic action by using Xylitol and Curcumin with observe fast result in Xerostomia with very good onset of action with minimum side effect.

**Objectives**

1. To improves the oral health
2. To reduce the plaque growth and Xerostomia (dry mouth).
3. To decreases, the chances of developing gum disease.
4. The main function of most mouthwashes is to freshen breath, although if you suffer from severe chronic bad breath (halitosis).
5. To treat dental plague and severe tooth ache.

**Drugs and Excipients profile**

**Drug profile**

Curcumin (Curcuma longa)

Synonym: Haldi

Biological source: Curcumin is the active ingredient of the dietary spice turmeric and is extracted from the rhizomes of C. longa, a plant in the Zingiberaceae family.

![Figure 2: Curcumin.](image)

**Description:** Curcumin is a bright yellow chemical produced by plants of the Curcuma longa species. It is the principal curcuminoid of turmeric (Curcuma longa), a member of the ginger family, Zingiberaceae. It is sold as an herbal supplement, cosmetics ingredient, food flavoring, and food color.

**Uses**

It is use an Antiinflammatory and antioxidant. It is use as antiseptic.

It may also help to improve symptoms of depression and arthritis.

**Clove oil**

Synonym (caryophyllum, clove buds, clove flowers, Lavang)

**Biological source**

It is obtained from Dried flower buds of Eugenia caryophyllus.

**Family:** Myrtaceae

**Description:** clove (Syzygium aromaticum), tropical evergreen tree of the family Myrtaceae and its small reddish brown flower buds used as a spice. Cloves were important in
the earliest spice trade and are believed to be indigenous to the Moluccas, or Spice Islands, of Indonesia.

Figure 3: Clove.

Uses
- Contain important nutrients. High in antioxidants & May reduce stomach ulcers.
- May improve liver health. May help regulate blood sugar. May promote bone health.

Anise oil

Synonym (Anise oil)

Biological source
Anise consists of **dried ripe fruits of Pimpinella anisum Linn.**, belonging to family Umbelliferae.

Description: Aniseed is commonly used in meat and vegetable dishes. It makes a **soothing herbal tea** and has been used medicinally from prehistoric times. The essential oil is used to flavour absinthe, anisette, and Pernod liqueurs. Dried fruits of anise (Pimpinella anisum), known as aniseed.)

Figure 4: Anise oil.
Xylitol

Xylitol is a naturally occurring alcohol found in most plant material, including many fruits and vegetables. It is extracted from birch wood to make medicine. Xylitol is widely used as a sugar substitute and in "sugar-free" chewing gums, mints, and other candies. ... People use xylitol to prevent cavities.

\[
\text{HO-CH}_2-\text{CH}_2-\text{OH}
\]

Nutmeg oil

**Synonym:** (Mrytile oil)

**Biological source:**

Nutmeg is the kernel of the dried ripe seed of Myristica fragrans Houtten., belonging to family Myristicaceae.

**Description:**

Nutmeg oil is a volatile essential oil from nutmeg (Myristica fragrans). The oil is colorless or light yellow and smells and tastes of nutmeg. … The oil also contains small amounts of various phenolic compounds and aromatic ethers, e.g. myristicin, elemicin, safrole and methyl eugenol.

![Figure 5: Nutmeg oil.](image-url)
Excipients

**Sorbitol**: sorbitol is used to preserve moisture, add sweetness, and provide texture to products, as well as potentially support digestive and oral health.

**Glycerol**: Glycerol is a common energy yielding food and is widely distributed in food, both as a natural constituent and as a GRAS (generally recognized as safe) additive.

**Cremophor**: Cremophor is *polyoxyl-ethylated castor oil* in which fatty acid esters of glycerol represent the hydrophobic portion, and the polyethylene glycol represent the hydrophilic portion of the surfactant having an HLB value of 12–14

**Sodium methyl paraben**: Sodium methyl paraben is a compound with formula Na. It is the sodium salt of methylparaben. It is a food additive with the E number E219 which is used as a preservative.

**METHODOLOGY**

Table no. 1: Mouthwash formulation 4.

<table>
<thead>
<tr>
<th>Ingredients (Raw Materials)</th>
<th>Uses</th>
<th>Quantity (%w/w)</th>
<th>Quantity (300g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purified water</td>
<td>Vehicle</td>
<td>91.362</td>
<td>274.09</td>
</tr>
<tr>
<td>Xylitol- Yesweet</td>
<td>Moisture stabilizing agent</td>
<td>1.028</td>
<td>3.08</td>
</tr>
<tr>
<td>Sorbitol (70% soln, IP)-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Godrej</td>
<td>Humectant</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Glycerol (Glycerin)- Godrej</td>
<td>Sweetening agent</td>
<td>0.02</td>
<td>0.06</td>
</tr>
<tr>
<td>Nutmeg oil- D.S fragrances</td>
<td>Anti-cavity agent</td>
<td>0.4</td>
<td>1.2</td>
</tr>
<tr>
<td>Clove oil- Blossom Kochhar</td>
<td>Anti- inflammatory agent</td>
<td>0.03</td>
<td>0.09</td>
</tr>
<tr>
<td>Anise oil-Silverline</td>
<td>ant- malodor agent</td>
<td>0.15</td>
<td>0.45</td>
</tr>
<tr>
<td>chemicals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cremophor (RH40) – BASF</td>
<td>Solubilizer for hydrophobic</td>
<td>1.5</td>
<td>4.5</td>
</tr>
<tr>
<td>Sodium Methyl paraben-SD</td>
<td>Preservative</td>
<td>0.15</td>
<td>0.45</td>
</tr>
<tr>
<td>fine chem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Propyl paraben-SD</td>
<td>Preservative</td>
<td>0.05</td>
<td>0.15</td>
</tr>
<tr>
<td>fine chem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brilliant Blue FCF-Neelicon color</td>
<td>Coloring agent</td>
<td>0.01</td>
<td>0.03</td>
</tr>
<tr>
<td>Fresh mint-International</td>
<td>Flavoring agent</td>
<td>0.3</td>
<td>0.9</td>
</tr>
<tr>
<td>flavors and fragrances (IFF)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>100</td>
<td>300</td>
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</tbody>
</table>
RESULTS

General procedure for all the formulations prepared

Step 1: Take purified water (250 ml) add sodium saccharin mix well at 600-700 RPM in an overhead stirrer (Main vessel)

Step 2: To the main vessel add sorbitol and glycerol mix well at the same RPM followed by addition of xylitol.

Step 3: In a separate vessel heat and melt Cremophor RH40 cool and add Nutmeg oil, Clove oil and anise oil slowly till the solution is clear. This was followed by addition of Flavor (Fresh mint) to the mixture.

Step 4: Add the Step 3 ingredients to the main vessel and mix well at 1000RPM for 15mins.

Step 5: Take remaining water add the preservatives (Sodium methyl paraben and sodium propyl paraben) then pour it into the main vessel.

Step 6: Add the color (Brilliant Blue FCF) to the main vessel and mix well at 1000RPM for 30mins.

Step 7: Filter using muslin cloth and store the prepared formulation in a clean mouthwash bottle at room temperature and label the same.

Step 8: Check for the clarity, odor, pH and other analytical parameters once the preparation is ready.

Method of analysis

pH measurement: The electrode of the pH meter (Make: Thermo-scientific Model: Orion Versa star pro) was directly placed on to the mouthwash liquid contained in a glass beaker and awaited till the constant reading is displayed on the screen. Further the pH was adjusted using citric acid solution.

Appearance: The liquid was taken in a clean glass beaker and observed under the light background with clear blue solution.

Odor: The odor of the liquid was determined by inhalation of the prepared mouthwash taken in a glass beaker.

Analysis of Sodium Methylparaben and Sodium Propyl paraben in Mouth wash formulations by HPLC.

Sodium propyl paraben standard solution: Weighed about 17.5mg of sodium propyl paraben into 10ml volumetric flask dissolved and make up to the mark with mobile phase. Diluted 2.0 ml of this solution to 100.0 ml with the mobile phase.
Sodium methyl paraben standard solution: Weighed about 10.0mg of sodium methyl paraben into 100ml volumetric, dissolved and make up to the mark with mobile phase.

Sample solution: weighed about 0.1mg of sodium methyl paraben and 3.5mg of sodium propylparaben containing mouth wash into to 100.0 ml volumetric flask. Diluted to 100.0 ml with the mobile phase.

Chromatographic system

Buffer preparation: dissolved 6.8 gm potassium dihydrogen phosphate in 1000 ml double distilled water. The solution was filtered through 0.45µm filter and sonicated for 15 min.

Mobile phase: a mixture of 35 volumes buffer and 65 volumes of methanol, the prepared mobile phase was degassed by ultrasonication for 20 min, so as to avoid the disturbances caused by dissolved gases. The degassed mobile phase was filtered through 0.45µ filter to avoid the column clogging due to smaller particles.

HPLC Column: C18,150 cm x 4.6 mm, (5µm). Flow rate: 1.3 ml per minute.


Oven temperature: Ambient.

Retention Times: Sodium methylparaben about 2.9minutes and Sodium propyl paraben about 15.0minutes.

Table 2: Comparison of different formulations.

<table>
<thead>
<tr>
<th>Test parameters</th>
<th>Formulation 1</th>
<th>Formulation 2</th>
<th>Formulation 3</th>
<th>Formulation 4</th>
<th>Formulation 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Light green color clear liquid</td>
<td></td>
<td></td>
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<tr>
<td>Odor</td>
<td>Odor of fresh mint with Nutmeg oil, eucalyptol and fennel oil</td>
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<tr>
<td></td>
<td>Assay for sodium methyl paraben by HPLC (%w/w)</td>
<td>Test for sodium propyl paraben by HPLC (%w/w)</td>
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<tr>
<td></td>
<td>0.142</td>
<td>0.05</td>
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<td></td>
<td>0.141</td>
<td>0.05</td>
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</table>

**DISCUSSION**

The present work is aimed with the formulation of mouthwash using the extracts of curcumin and neem oil. The formulations are prepared using Purified water, Xylitol -Ye sweet, Sorbitol (70% soon, IP), Sodium Methyl paraben, Sodium Propyl paraben, Light green and Fresh mint.

Here the five formulations of mouthwashes formulated with curcumin and xylitol are i.e., F1 F2 f3 f4 f5 are all evaluated for its analytical parameters, where the f4 shown that the Assay for sodium methyl paraben by HPLC (0.141%w/w) Test for sodium propyl paraben by HPLC (0.050%w/w) and pH is (6.0).

The appearance of all the 5 formulations is in Blue color clear liquid and the odor is fresh mint with nutmeg oil, eucalyptol and fennel oil.

Hence formulation 4 has shown Better analytical parameters when compared to other four formulations.

Based on this study it assumed to be a successive product.

**CONCLUSION**

The current project work of formulation of mouthwash using the extracts of curcumin and xylitol is prepared. The mouthwash is formulated with the objective of treating the malador and xerostomia, a disorder of oral dryness.

Here the five formulations of mouthwashes formulated with curcumin and neem oil are ie. F1 F2 f3 f4 f5 are all evaluated for it analytical parameters, where the f4 shown that the Assay for sodium methyl paraben by HPLC (0.142%w/w), Test for sodium propyl paraben by HPLC
(0.050% w/w) and pH is (6.0).

The appearance of all the 5 formulations is in light blue color clear liquid and the odor of fresh mint with nutmeg oil, eucalyptol and fennel oil.

Hence, f4 has shown better analytical parameters when compared to other four formulations.

Hence, it is concluded that formulation f4 is better and effective treatment for xerostomia, which can be standardized as a commercial mouthwash and alternative for the treatment of xerostomia.

SUMMARY
The present work is aimed with the formulation of mouthwash using the extracts of curcumin and Xylitol for the treatment of xerostomia.

Cosmetic mouthwashes may momentarily reduce foul breath and leave a nice flavor in the mouth, but they have no chemical or biological application beyond that. For example, if a product does not destroy bacteria that cause bad breath, it is regarded to provide only a cosmetic advantage. Therapeutic mouthwash, on the other hand, contains active components that can help control or prevent problems including bad breath, gingivitis, plaque, and tooth decay. The subjective complaint of dry mouth is known as xerostomia. Patients with xerostomia frequently do not display any objective signs of hypo salivation, and their symptoms may be caused by changes in the composition of saliva on a qualitative and/or quantitative level. The typical stimulated salivary flow rate is 1.5–2.0 mL/min, while the unstimulated salivary flow rate is 0.3–0.4 mL/min. Hence treating of dry mouth with herbal therapeutic mouthwash is essential.

Here the 5 formulations are prepared using Purified water as vehicle, Sorbitol (70% soln, IP)-as stabilizing agent, Glycerol (Glycerin)- as Humectant, Sodium Methyl paraben and Sodium Propyl paraben as and light green color clear liquid, odor of fresh mint with nutmeg oil, eucalyptol and fennel oil.

The appearance of all the 5 formulations is in light green color clear liquid and the odor is found to be of fresh mint with tea tree oil & curcumin essence.

Here the five formulations of mouthwashes formulated with curcumin and xylitol ie.f1 f2 f3 f4
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f5 are all evaluated for it analytical parameters, where the f2 shown that the Assay for sodium methyl paraben by HPLC (0.142%w/w), Test for sodium propyl paraben by HPLC (0.050%w/w)

Hence f2 has shown Better analytical parameters when compared to other four formulations. Hence it is concluded that formulation f2 is better and effective treatment for xerostomia, which can be standardized as a commercial mouthwash and alternative for the treatment of xerostomia.

BIBLIOGRAPHY
