CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187
https://doi.org/10.5281/zenodo.7971727

Available online at: http://www.iajps.com Research Article

TO DESIGN AND DEVELOPMENT NOVEL EFFERVESCENT ANTIMICROBIAL MOUTHWASH

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Abstract:
Plaque control is utmost essential for the suppression of gingivitis, dental caries, and halitosis-causing microorganisms. The most commonly used tool in the treatment of supragingival plaque are the tooth brushing either mechanical or electrical, dental floss, or interdental brushing. Other means of plaque control are chemical therapeutic agents such as mouthwashes, sprays, chewing gums and varnishes; aid in an effective home care. Nevertheless, mouthwashes have been accepted as the simplest and easiest mode of oral hygiene aid.This could be the main mode of oral cleansing in medically compromised patients and elderly where adequate oral hygiene maintenance could be a major concern. Chlorhexidine (CHX) has been the most widely used mouthwash and is considered as the gold standard in dental practice for about three decades, but not without certain disadvantages such as taste perturbation, tooth discoloration, oral ulcerations, unilateral, or bilateral parotid swelling. Considering these drawback of CHX mouthwash, alternative antiplaque agents have been developed in the recent years with the use of herbal products. Herbs have been the main source of medications since the ancient times of Charaka and Sushruta and have conquered the confidence of the people of Asia. Naturally available herbs such as tulsi, triphala, neem, honey, ajwain, turmeric, Zingiber Officinalis, etc., have been commonly used either alone or in combination as safe and effective antibacterial agents

KEYWORDS- Effervescent, Zingiber Officinale, Antimicrobial, Mouthwash.

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Please cite this article in press Mayuri Ashok Borkar et al, ***To Design And Development Novel Effervescent Antimicrobial Mouthwash.,*** *Indo Am. J. P. Sci, 2023; 10 (05).*

1. INTRODUCTION:

Antimicrobial mouth rinses are much more powerful than over-the-counter mouthwashes, reducing certain bacteria that cause gum disease to an almost undetectable level. The most commonly prescribed is Chlorhexidine, and your dentist can recommend how to use it as part of your treatment regimen. Your everyday over-the-counter mouthwashes are the mildest form of antimicrobials, meaning that they can reduce the number of microbes or bacteria in the mouth. Certain bacteria are contributing factors for both tooth decay and gum disease. Chlorhexidine is the most often prescribed oral mouth rinse, used to reduce the number of bacteria in the mouth. Used as directed by your dentist, Chlorhexidine can reduce certain gum disease-causing bacteria to an almost undetectable level. And in some cases your dentist may also prescribe an oral antibiotic or locally applied chemotherapeutic to help further reduce other bacteria causing your gum disease. Studies have shown that combinations of antibiotics, chemotherapeutics, and Chlorhexidine can reduce the need for periodontal surgery by upwards of 80%

As health awareness in population is increasing day by day in the present era, healthcare systems are finding an ample scope for growth, e.g. Community based health programs. Community based health programs are the health programs arranged by an organization to provide basic help and medical care to their community. Programs are arranged for mental health, maternity health (prenatal, obstetric), AIDS and cancer related programs, Counseling's for STD's tuberculosis etc. Besides, there are screening programs for preventing examination like PAP test, HPV Testing, Blood testing for Cholesterol, glucose, checking blood pressure, vaccination programs etc. In some developed countries like New York, programs for diabetes are also being arranged. Along with all these programs, there are programs for oral health care also, which includes increasing the awareness amongst community, setting goals and objectives and respective plans and strategies to meet the same. Many community-based programs and efforts to prevent oral disease by promoting science-based prevention strategies and monitoring oral health status and risk factors have been established1. Many committees and bodies like Healthy People are engaging programs and setting their objectives for oral health care. Some of the objectives of healthy people 2020 are2, 3:

- To increase the detection of the oral and pharyngeal cancers at the earliest stage.
- To increase the proportion of population served by community water systems with optimally fluoridated water.
- To increase the proportion of children and adults who use the oral health care system each year.
- To increase the proportion of low-income children and adolescents who received any preventive dental service during the past year.
- To increase the number of Stares and the District that has an oral and craniofacial health surveillance system
- To reduce the proportion of children and adolescents who have dental caries experience in their primary or permanent teeth.

2. NEED:

The literature reveals the wide applicability of chlorhexidine gluconate in several fields mentioned elsewhere. One among its applications is that the chlorhexidine gluconate act as an antimicrobial agent. At physiologic pH, chlorhexidine salts dissociate and release the charged chlorhexidine cation. The bactericidal effect may be results of the binding of this cationic molecule to charged bacterial cell walls. At low concentrations of chlorhexidine, this leads to a bacteriostatic effect; at high concentrations, membrane disruption ends up in death, facultative anaerobes, aerobes, and yeasts. Hence this phenomenon can provide an aerobic environment in mouth when formulation of chlorhexidine gluconate solution is swished within the rima oris. ginger juice (Zingiber officinale var rubrum) is effectively able to inhibit the growth of Aggregatibacter actinomycetemcomitans bacteria. The extract gel of red ginger which is about 4% proved successfully to provide the effect of anti-inflammation bigger than the extract gel of turmeric rhizome 4%. The other values of red ginger can also be found on its hot but fresh in taste, cheap price, and easy to get. So far, it has not found yet the research about making such a mouth rinse using the antiseptics and deodorizing from the red ginger juice and the receptivity in using it. This study aims to describe and analyze the difference in receptivity of antiseptics mouth rinse with red ginger juice (Zingiber officinale var rubrum) at different concentrations. The research objectives are to take the potential benefits of Indonesia's natural resources which does not only support its cheap price, but it also prevents periodontal disease, safe also refresh the throat and oral cavity.

3. PLAN OF WORK

1. Literature survey
2. Procurement of raw material
3. Lyophilize the chlorhexidine gluconate solution
4. Characterization and evaluation of Lyophilized mixture.
   a. Analysis of the content

b. FTIR

5. Formulation design of fast-dissolving tablet of lyophilized mixture.
6. Evaluation of fast-dissolving tablet
   a. Appearance
   b. Thickness and diameter
   c. Hardness
   d. Friability
   e. Disintegration time
7. Reconstitution study
   a. Drug content analysis

❖ **Zingiber Officinalis**

1. Collection and Authentication
2. Formulation
3. Preparation
4. Evaluation

4. DRUG PROFILE

4.1 Chlorhexidine gluconate solution

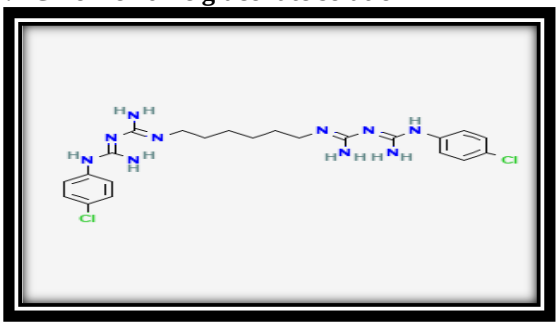

Fig.No 1: Structure of chlorhexidine gluconate.

Chlorhexidine Gluconate Solution is an aqueous solution of 1, 1'-hexamethylenebis [5- (4-chlorophenyl) biguanide] digluconate.

4.2 Zingiber Officinale

Ginger

Ginger is believed to be a native of south-eastern Asia and belongs to the family Zingiberaceae. It is cultivated through rhizomes and grows well in tropical and subtropical areas, perennially. The rhizomes are full of aroma and have thick lobes with ring-like scars, growing up to a size of 30-90 cm Origin of the word "ginger" can be traced back to the Sanskrit/Pali word "singabera," meaning "shaped-like a horn" based on its appearance. It was well-known to Indian and Chinese medicine and was referred to as "maha aushadhi" (the great medicine) in Vedic literature. The trade of ginger was extended widely by 1st century A.D. making it a popular spice in the Mediterranean region, England, Spain, Greece, and Rome. The Greek physician Galen believed ginger was a purificant of the body and can treat diseases caused by bodily imbalances.[3] It was used primarily as a condiment, however, slowly the medicinal usages of ginger were recognized, and formulations were prepared to treat symptoms of nausea, vomiting motion sickness, and to stimulate the appetite as well.

5. EXCIPIENT PROFILE

Table 1. Excipient Use in Mouthwash Tablet Formulation

Excipient	Category
Sodium Bicarbonate	Effervescent Agent
Citric Acid (Monohydrate),	Effervescent Agent
Tartaric Acid,	Effervescent Agent
PEG 6000,	Thickeners
Glycine	Bulking Agent
Sodium Benzoate,	Preservative
Manitol,	Sweetener
Menthol	Cooling Agent
Aspartame	Sweetning Agent
brilliant blue	Coloring Agent
Orange Peel	Flavouring Agent

6. EXPERIMENTAL WORK

6.1 Zingiber Officinalis-

Ginger contains raffinose and gingerol, two compounds that have been shown to help temporarily reduce inflammation and pain. The compounds in ginger can also help reduce the oral bacteria that lead to cavities and gum disease, making it a generally effective ally to your oral health regimen

A proper method has to be carried out while formulating the antimicrobial Mouthwash,

1) **Selection of active**
2) **Collection and Authentication**
3) **Extraction Method**
4) **Preparation**

6.1.1 Methods:-

1) Selection of active

The analysis of *Zingiber Officinalis* plant parts showed the presence ginger contains monoterpenoids, sesquiterpenoids, phenolic compounds, and its derivatives, aldehydes, ketones, alcohols, esters, which provide a broad antimicrobial spectrum against different microorganisms and make it an interesting alternative to synthetic antimicrobials.

2) Collection and Authentication

Herb authentication is a quality assurance process that ensures the correct plant species and plant parts are used as raw materials for herbal medicines. The proper authentication of herbal raw materials is critically important to the safety and efficacy of herbal medicines.

Zingiber Officinalis were purchased from local market and authenticated in botanical department by botanist.

3) Extraction Method

a. Grinding Mill:-

A mill is a device that breaks solid materials into smaller pieces by grinding, crushing, or cutting. Such comminution is an important unit operation in many processes. There are many different types of mills and many types of materials processed in them.

b. Soxhlet Extraction:-

Soxhlet extraction is a continuous solid/liquid extraction. A solid which contains the material to be extracted is placed in what is called a thimble. A thimble is made out of a material that will contain the solid but allow liquids to pass through. A lot like filter paper. The thimble containing the material is placed in the Soxhlet extractor. An organic solvent is then heated at reflux. As it boils its vapors rise and are condensed by a condenser

6.2 Preparation of antimicrobial Mouthwash

To make mouthwash, chlorhexidine gluconate and Zingiber Officinalis was taken and added to the water while mixing at appropriate speed.Composition used for mouthwash is as follows: Sodium Bicarbonate, Citric Acid (Monohydrate),Tartaric Acid, PEG 6000,GlycineSodium Benzoate, Manitol, Menthol Aspartame brilliant blue, Orange Peel

6.3 Lyophilize the Mouthwash solution

Mouthwash solution (IP) was dried using freeze dryer (lyophilizer). Take a Mouthwash solution 100 ml of and add sorbitol 80 gm. as bulking agent. These mixture thoroughly mix then transfer into a lyophilization tray. This lyophilization tray was placed in a lyophilization shelf chamber also temperature probe was kept in that lyophilization trays properly.

Table 2: Lyophilized mixture composition

Sr. No.	Lyophilized mixture composition	Quantity
1	Mouthwash solution (20%)	100 ml.
2	Sorbitol	80 gm.

6.3.1 Characterization and Evaluation of lyophilized mixture

6.3.1.1 Fourier Transform Infra-Red Spectroscopy

FTIR spectrum of the lyophilized mixture was obtained by scanning over a range of 4000- 400cm^{-1} and spectrum was recorded.

6.3.1.2 Content analysis (Assay %)

The analysis of content of the lyophilized mixture of Mouthwash solution was carried out utilizing IP assay of Mouthwash solution by High-Performance Liquid Chromatography method (HPLC).

6.4 Formulation studies

6.4.1 Selection of Process

A method of direct compression was selected for the preparation of a reconstituted fast-dissolving tablet.

6.4.2 Mixing and Blending

All the components were weighed and triturated in glass mortar in ascending order of their quantities and were taken in an air-tight sealable poly bag and mixed for 5-6 minutes.

6.4.3 Evaluation of tablet blend

The evaluation of tablet blends for different flow properties study as given below all the components were weighed and triturated in glass mortar in ascending order of their quantities and were taken in an air-tight sealable poly bag and mixed for 5-7 minutes.

6.4.3.1 Angle of repose

The frictional forces in a loose powder or granules can be measured by the angle of repose. Angle of repose was determined by funnel method.

Table 3: Relationship between Angle of repose (θ) and Flowability

Angle of repose (θ)	Flowability
< 25	Excellent
25-30	Good
30-40	Passable
> 40	Very Poor

6.4.3.2 Bulk density (Db)

It is the ratio of total mass of the powder to the bulk volume of powder. It was measured by pouring the weight powder (passed through standard sieve # 44) into a measuring cylinder and initial volume is called the bulk volume.

6.4.3.3 Tapped density (Dt)

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 100 times and the tapped volume was noted if the difference between these two volumes is less than 2%. If it is more than 2%, tapping is continued for some times and tapped volume was noted.

6.4.3.4 Carr's index

The simplest method of measurement of free flow of powder is compressibility, an indication of the ease with which material can be induced to flow is given by the compressibility index (I) which is calculated as follows.

Table 4: Flow properties according to Carr's index and flowability

Carr's index (%)	Type of Flow	Hausner's Ratio
≤10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very poor	1.46-1.59
>38	Extremely poor	>1.60

6.4.3.5 Hausner's ratio

This is an indirect ratio for ease of powder flow. It was calculated by the following formula:

6.5 Preformulation

Table. 5. Composition of preliminary formulations (ratio) with their effervescence time, pH and solubility (Mean ± SD).

Formulations	Tartaric acid	Citric acid	Na bicarbonate	Effervescent time(s)	pH	*Solubility
S_1	-	0.5	0.5	105 ± 2.08	5.9 ± 0.05	3
S_2	-	0.5	1	40 ± 1.52	6.2 ± 0.1	3
S_3	1	0.5	1	39 ± 1.51	6.1 ± 0.04	1
S_4	0.5	1	1	36 ± 2	6.1 ± 0.05	2
S_5	-	1	1	50 ± 2.13	5.9 ± 0.06	5
S_6	1	1	1	48 ± 2.01	6.1 ± 0.06	2
S_7	1.5	0.5	1	52 ± 1.8	6.1 ± 0.1	2
S_8	2	0	1	55 ± 1.83	6.1 ± 0.08	1
S_9	-	1	1.5	43 ± 1.51	6.1 ± 0.7	4
S_{10}	-	1	0.5	30 ± 3.11	5.6 ± 0.4	4
S_{11}	-	1.5	1.5	25 ± 2.13	5.6 ± 0.05	5
S_{12}	-	1.5	1	49 ± 1	5.6 ± 0.04	4
S_{13}	-	2	2	20 ± 2.07	5.5 ± 0.06	4
*Solubility was defined by Likert Scale from 1= very poor, 2 = poor, 3 = average, 4 = good and 5 = excellent						

Table.6 Formulation design for fast dissolving tablet.

Batch	Lyophilized mixture	Sorbitol	Aspartame	Glycine	Menthol	Orange peel	BB	PEG 600	Total wt. (mg)
F1	146.41	14.64	0.57	2.92	0.44	1.46	0.0025	1.46	168
F2	146.41	14.64	0.58	5.85	0.44	1.46	0.0025	1.46	171
F3	146.41	14.64	0.58	8.78	0.44	1.46	0.0025	1.46	174

6.6 Methods of Anti-Microbial Effervescent Tablets Production

a. Direct Compression

According to Table 2, raw materials of each formulation were weighed and were mixed in a tumbling cubic blender for 15 minutes.

Table 7 Different components of prepared tablets from the direct compression (D) and fusion (f) methods.

Ingredients (mg)	Formulations					
	F_1	F_2	F_3	F_4	F_5	F_6
K citrate	2700	2700	2700	2700	2700	2700
Citric acid	570	850	850	850	850	850
Na bicarbonate	500	750	750	750	750	750
Mannitol	-	-	60	120	-	60
Sorbitol	-	-	-	-	60	-
Aspartame	-	-	-	-	-	1.5

After the preparation of the primary powder mixtures, sweeteners including aspartame, sorbitol, mannitol and fruit flavoring agents were passed through the appropriate mesh and were added to the powders and these were mixed all together for 5 minutes. Finally, the selective lubricants including sodium benzoate (10 mg) and PEG 6000 (30 mg) were added and again mixed for about 2-5 minutes with other material

b. Fusion Method

According to the formulations which are shown in Table 2, amounts of citric acid, sodium bicarbonate, Active and mannitol (sorbitol) were weighted accurately and were mixed for about 15 minutes in a tumbling cubic blender. Then, the obtained mixture was placed in an oven at 54 °C. The powder was mixed regularly until the crystallization water of citric acid was released as binder factor (approximately 30 minutes). After obtaining an appropriate pasty mass, this wet mass was passed through sieve No. 20 and the obtained granules were dried in an oven at 54 °C for 1 hr.

c. Wet granulation Method

Wet granulation was performed on F5 and F6 formulations. First, citric acid and sodium bicarbonate and Active were milled by using miller so that all powders were passed through sieve No. 35 and were blended for 10 minutes. Then 9.5 % w/v PVP solution in absolute ethanol was added with the mixture so that a white pasty mass was formed.

6.7 Evaluation of tablet

6.7.1 Appearance and Shape

The general appearance of the tablet includes morphological characteristics like size, shape, color, odor, etc.

6.7.2 Uniformity of thickness and diameter

The uniformity of the diameter and thickness was measured using Vernier caliper. The average thickness of the 20 tablet was calculated. The test was positive if none of the individual thickness value deviated by ±5% of the average.

6.7.3 Hardness

Hardness of the tablet was tested by Monsanto Hardness tester which measures the diametrical crushing strength of the tablets. The tablet to be tested was placed in between the fixed and movable jaw after adjusting the reading to zero. By moving the screw knob the force on the tablet was gradually increased until the tablet broke. The pressure required in kg to break the tablet was noted from the scale on the tester. The hardness of the tablet depends on the weight of the material used and the compression force applied during compression.

6.7.4 Friability

Tablets require certain amount of strength or hardness and resistance to friability. It is necessary or important to withstand mechanical shocks of handling while manufacturing, packaging and shipping. This test was performed by using Roche Friabilator. Six tablets were weighed and tumbled at a rate of 25 rpm for 4 min. The tablets were weighed and percent friability was calculated by the following formula.

6.7.5 Disintegration test
The disintegration test was performed by placing one tablet in 15 ml water. The time required for the complete disintegration is noted as disintegration time.

6.7.6 Weight Variation test:
The weight of tablets is measured to ensure that a tablet contain the proper amount of drug. Twenty tablets were selected at random and the average weight was determined.
USP official limits of percentage deviation of tablet are presented in the table no. 19

Average weight of tablet Percent deviation
130 mg or less 10
More than 130 mg or less than 324 mg
More than 324 mg or more 5 100
Initial weight of the tablets
Initial weight of the tablets – Final weight of the tablets
% Friability X
In all the formulations the tablet weight was 400 mg, hence 5% maximum difference allowed.

7. RESULT AND DISCUSSION:

7.1 Lyophilize the Mouthwash solution

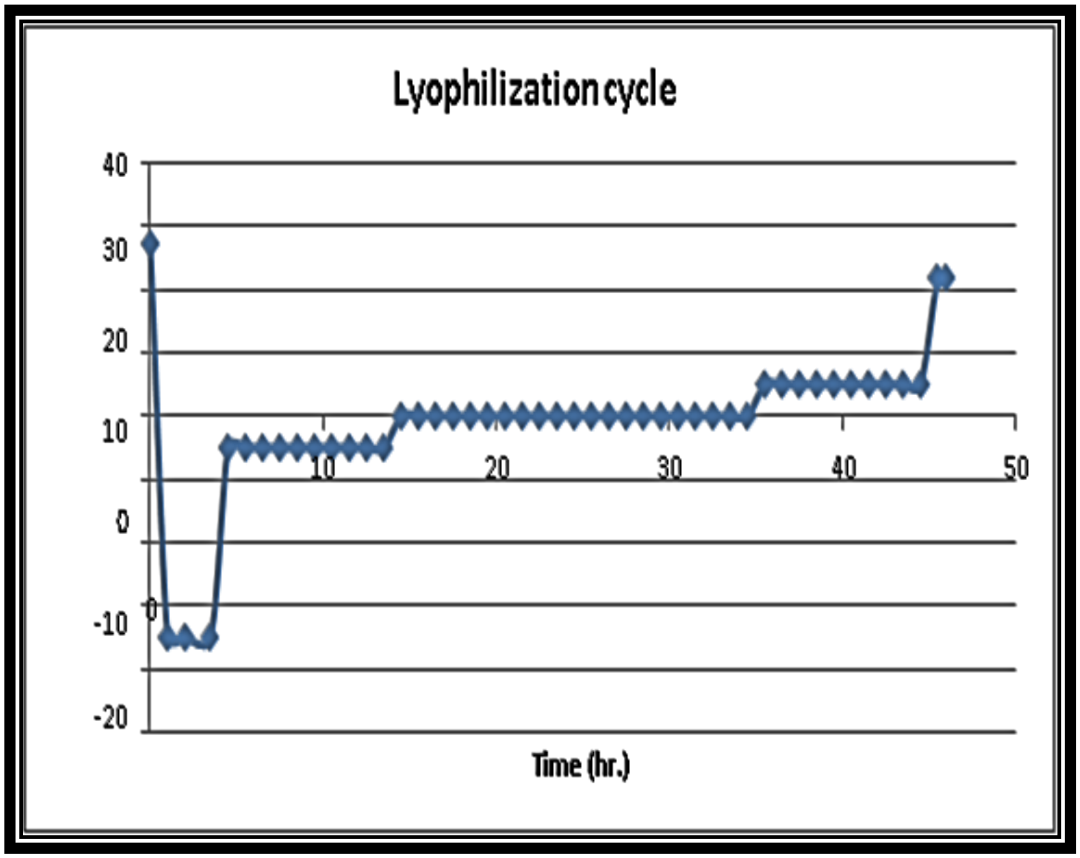

Fig.No 2: Lyophilization Cycle Of Mouthwash Solution

Table 8: Time and temperature for Segment 1 and Segment 2

Parameter	Segment 1				Segment 2									
Time(hr.)	0	1	2	3.5	4.5	5.5	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5
Temp.(^{0}C)	27	-35	-35	-35	-5	-5	-5	-5	-5	-5	-5	-5	-5	-5

Table 9: Time and temperature for Segment 3

Parameter	Time (hr.)	Temperature (^{0}C)
Segment 3	14.5	0
	15.5	0
	16.5	0
	17.5	0
	18.5	0
	19.5	0
	20.5	0
	21.5	0
	22.5	0
	23.5	0
	24.5	0
	25.5	0
	26.5	0
	27.5	0
	28.5	0
	29.5	0
	30.5	0
	31.5	0
	32.5	0
	33.5	0
	34.5	0

Table 10: Time and temperature for Segment 4 and Segment 5

Parameter	Segment 4										Segment 5	
Time(hr.)	35.5	36.5	37.5	38.5	39.5	40.5	41.5	42.5	43.5	44.5	45.5	46
Temp.(^{0}C)	5	5	5	5	5	5	5	5	5	5	22	22

7.2 Characterization and evaluation of lyophilized mixture

7.2.1 Fourier Transform Infra-Red Spectroscopy

The IR spectrum of Mouthwash solution lyophilized mixture showing following characteristics peaks confirming its structure

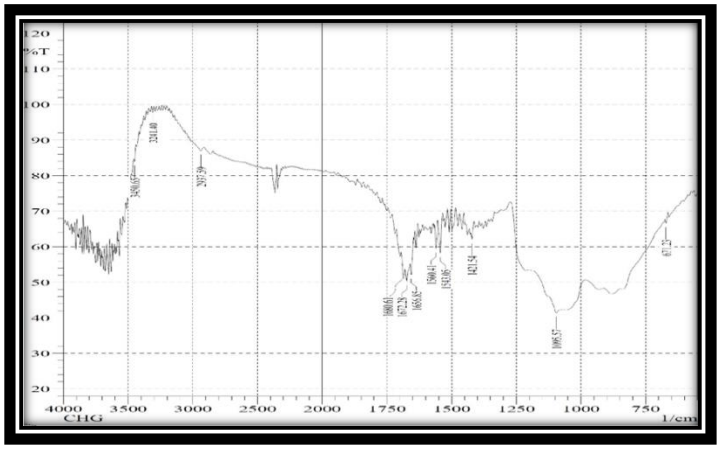

Fig. No 3: FT-IR Spectrum of Mouthwash solution Lyophilized Mixture.

7.2.2 Content analysis (Assay %)

Content analysis of the Mouthwash solution lyophilized mixture by using HPLC assay IP method.

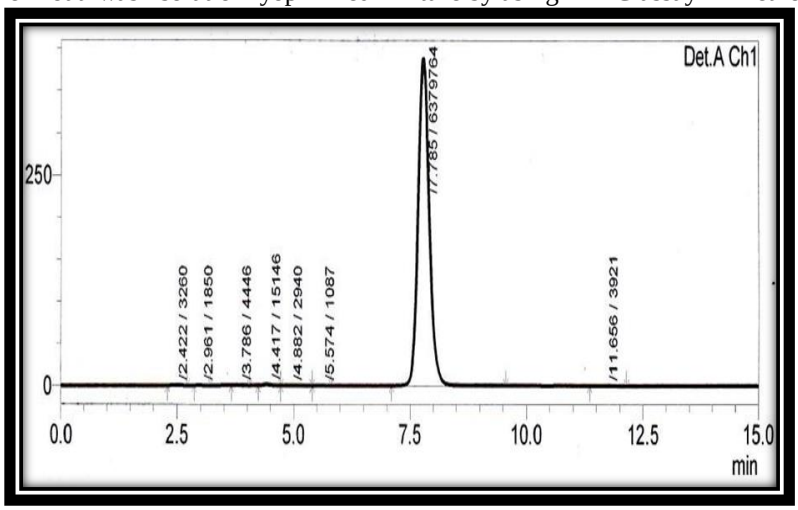

Fig. No 4: HPLC Chromatogram of Standard Chlorhexidine Acetate WS

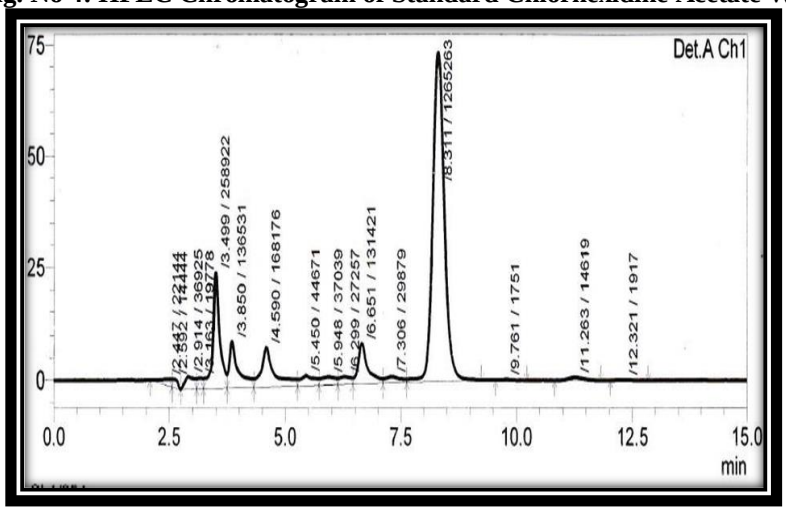

Fig. No 5: HPLC Chromatogram of Lyophilized Mixture of Mouthwash Solution

Run standard solution six times and test solution in duplicate. By using standard Average peak area and test sample peak area calculate the content of lyophilized mixture. Content analysis of the lyophilized mixture was found to be 20.49% within the specified limit as per I.P.

Table 11: Content Analysis of Lyophilized Mixture

Lyophilized mixture	Assay (%)
Mouthwash solution + Sorbitol	20.49 %

7.3 Formulation studies

7.3.1 Excipients

The prerequisite for selection of the excipients for preparation of a fast-dissolving tablet was reconstituted as the ultimate goal was to develop a mouthwash with water as the final vehicle. So with a view to formulate a mouthwash, excipient chosen were glycine as disintegrant, menthol as a flavoring agent, Ecocool as cooling agent, ribitol and aspartame used as sweetening agent, brilliant blue as a coloring agent, PEG 6000 as a lubricant

7.3.2 Selection of Process

Method of direct compression was selected for the preparation of fast dissolving tablet.

7.3.3 Evaluation of tablet blend

The prepared blend was subjected for the study of different micromeritics properties. The result for analysis of F1, F2 and F3 batches were summarized in the table 17.The analysis result of tablet blend

indicates that all the batches possess good flowability and compressibility.

7.3.4 Tablet Evaluation Parameter

7.3.4.1 Appearance and Shape

All the tablets of design batches were having light blue color uniformly distributed, 8 mm in diameter with circular curved surface.

7.3.4.2 Thickness

Excessive variation in tablet thickness can result in problem with packaging as well as consumer acceptance. There was no marked variation in thickness of tablet within each formulation (5%) indicating uniform behavior of blend throughout the compression process. Thickness of design batches were found in range of 2.46 to 2.48 mm.

7.3.4.3 Friability

Friability of the tablet is measure of the tablet strength. Tablets with friability less than 1% of their weight are acceptable. The friability of the design batches were in the range of 0.34 to 0.79.

7.3.4.4 Disintegration test

Fast-dissolving tablets are expected to disintegrate within 3 min. The disintegration time of optimized batch was found to be 160 seconds.

Table 12: Evaluation of Tablet Blend

Batch Code	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.4873 ± 0.010	0.6137 ± 0.012	20.59 ± 3.354	1.25 ± 0.027	30.11 ± 1.12
F2	0.4529 ± 0.008	0.5406 ± 0.005	19.36 ± 1.215	1.19 ± 0.044	29.24 ± 1.40
F3	0.430 ± 0.012	0.493 ± 0.010	12.92 ± 2.231	1.14 ± 0.033	28.31 ± 1.23

 # all the reading taken in replicate represented as mean ± SD

Table 13: Evaluation Tablets Properties

Batch Code	Diameter (mm)	Thickness (mm)	Friability (%) (n=3)	Hardness (kg/cm^2)
F1	8	2.46 ± 0.029	0.34	3.1 ± 0.287
F2	8	2.48 ± 0.017	0.79	3 ± 0.268
F3	8	2.48 ± 0.023	0.44	3.1 ± 0.290

Table 14: Formulation Characteristics of Tablets

Batch Code	Disintegration time (sec.)
F1	195
F2	180
F3	160

7.4 Reconstitution study

7.4.1 Content analysis (Assay %).

The analysis of content of the batch F1, F2 and F3 reconstituted solution of chlorhexidine gluconate tablet was carried out utilizing IP assay of chlorhexidine gluconate solution by High Performance Liquid Chromatography method (HPLC). Run standard sample six times and test sample duplicate.

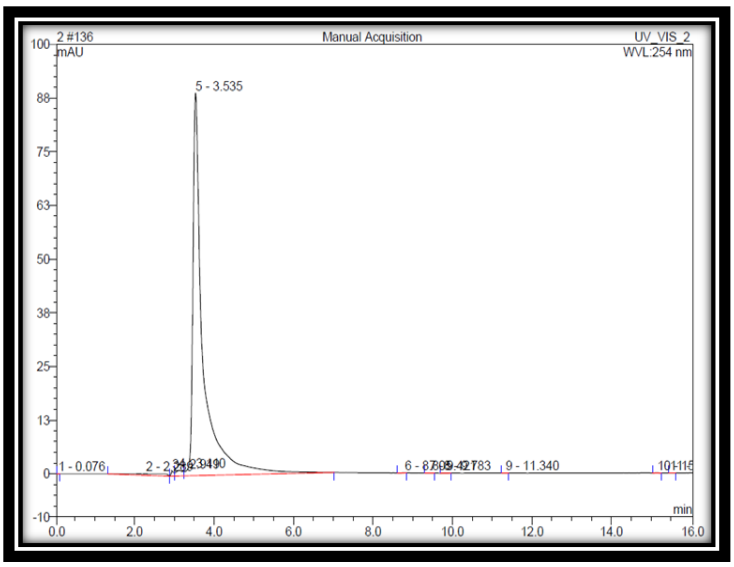

Fig.No 6: HPLC Chromatogram of Batch F1 Mouthwash Solution

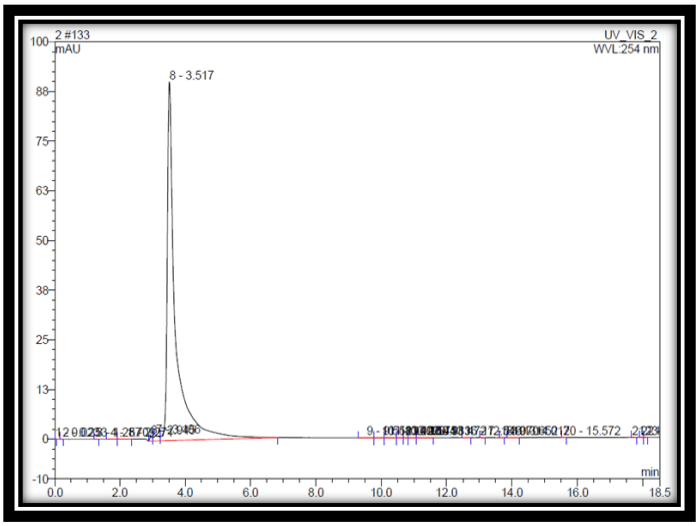

Fig.No 7: HPLC Chromatogram of Batch F2 Mouthwash Solution

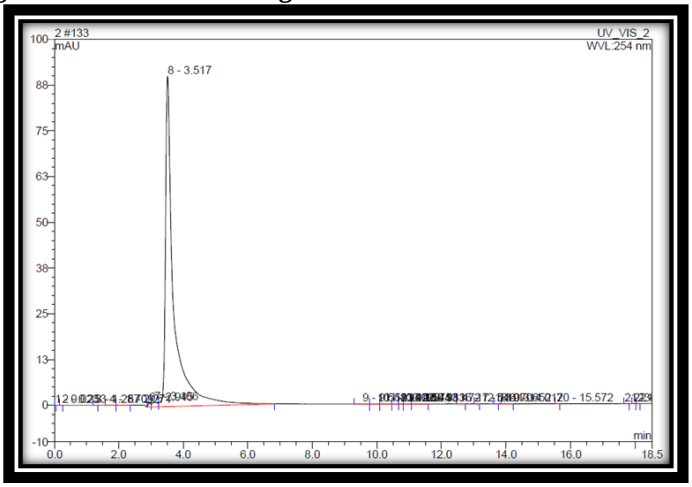

Fig.No 8: HPLC Chromatogram of Batch F3 Mouthwash Solution

Table 15: Reconstituted Formulation Batches Content Analysis (Assay %)

Batch code	Average peaks of sample (mAU)	Average peaks of standard (mAU)	Assay (%)
F1	34.64	41.3316	98.20
F2	34.47	41.3316	97.70
F3	35.17	41.3316	99.68

7.5 Optimized batch

F3 batch was selected as optimized batch amongst design batches for the reconstitution of mouthwash tablet. Depending upon the evaluation of the tablet blend, tablet properties like hardness, friability, and disintegration time. Also reconstitution study of the F3 batch assay within the specified limit as per I.P.

7.6 Antibacterial activity

The result for antibacterial activity of optimized EG6 was 85% inhibition which confirmed its antibacterial effects on the skin against microbes. The optimized Solution has strong antibacterial and antimicrobial activities, so considered safe for oral use. Similar findings have been reported in previous studies of formulations. Mouthwash Solution is to decrease inflammation. also good analgesic and anti-inflammatory activity due to the presence of vitamins.

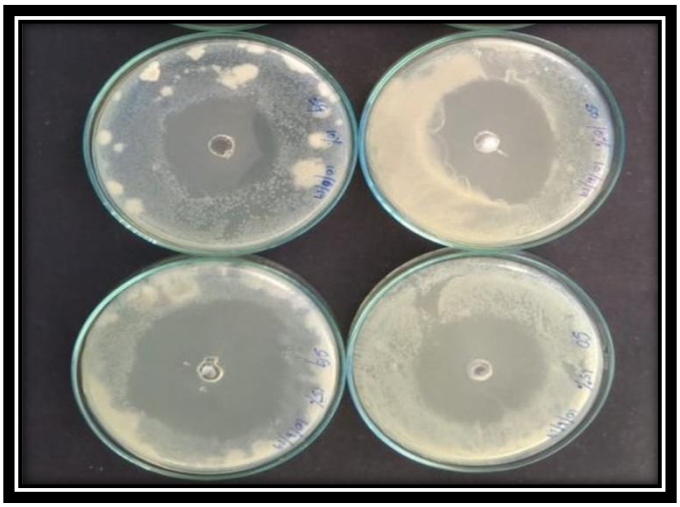

Fig. No 9 Antibacterial activity

8. CONCLUSION:

Recent trends in patient-oriented practice demand the design of patient-oriented dosage forms to achieve patient compliance and a better therapeutic profile. The number of formulation-related aspects contributes to non-compliance and insufficient drug release profile. Hence, there is a necessity to design a patient-oriented drug delivery system.

Present work leads to the optimization of the process for the preparation of lyophilized chlorhexidine gluconate solution and the development of an effervescent tablet comprising a solid water-soluble excipient i.e. glycine, ribitol, aspartame which dissolves in 160 seconds. Formulation being a solid dosage form, the predicted stability of chlorhexidine gluconate is more, as chlorhexidine gluconate is available in liquid form and possesses stability problems if not stored at low temperatures. Further, a fast-dissolving tablet strip will always be preferred by an end user over a liquid mouthwash bottle. The said formulation will be widely useful for a traveler, tourist, or camper, as it is difficult to carry liquid mouthwash bottles with him because of weight, fragility, or bulk hence offering patient compliance and also solving the problem of shelf space at the retail outlet and home.

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