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FORMULATION AND EVALUATION OF TOOTHPASTE CONTAINING COMBINATION OF ALOE AND SODIUM CHLORIDE

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Toothpaste, *Aloe vera*, Sodium Chloride, Antimicrobial activity, Future scope, *etc* **Correspondence to Author:** Pallavi L. Phalke

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ABSTRACT: The formulation and evaluation of toothpaste contain *Aloe vera* along with the combination of sodium chloride. Aloe vera shows a number of uses either internally or externally, and the number of uses also increases as the research going on. In this formulation, we tried to find out the antimicrobial activity of Aloe vera in toothpaste formulation, for the said purpose we use S. *aureus* culture. After designing the batches in software Design Expert[®] 10, the batches were formulated and evaluated. At the end of work, we found that the prepared toothpaste shows considerable zone of inhibition which concludes its antimicrobial activity. The formulation also shows sufficient foaming power for its cleansing action. The observed results were found to significant concerning the chosen cubic model in software Design Expert® 10. Thus from the collected results, we concluded that the toothpaste containing a combination of Aloe and sodium chloride possesses antimicrobial activity, but for its practical use its necessary to determine its effect on oral cavities and probable side effects after its long tern use of its oral application as its future scope. The present work provides hint for those who prefer herbal formulations.

INTRODUCTION: To promote the attractiveness and to maintain the health of teeth the formulation is used called as toothpaste ¹. For cleaning the teeth, toothpaste are widely used preparations ². This primary function of cleaning is carried out with the help of a toothbrush. The objective behind the use of tooth paste is its ability to deliver preventive and therapeutically active agents such as fluoride, metal salts and pyrophosphate. These agents may be useful for calcium inhibition also reduce the growth of plaque and to treat dentine hypersensitivity along with dental hygiene.



Along with refreshing breath, removal of food particles, reduction of superficial plaque or stain, polishing of tooth surface is the function of toothpaste or dentifrices. Some therapeutic and cosmetic functions may be desired such as whiting, bleaching, desensitizing, inhibition of plaque formation and protection against periodontal problems.

Active pharmaceutical ingredients, abrasives, humectants, detergents, binders, sweeteners, preservatives and antioxidants, and flavors are the most commonly used ingredients of toothpaste^{1, 2}. There is a number of materials, and their combinations were used in the formulation of toothpaste but they might damage teeth and gums. Hence, nowadays there is a need for safe, effective and well-formulated dentifrices ³. To achieve this, present work deals with formulation and evaluation of toothpaste containing aloe and sodium chloride

the rationale behind the combination is to fight against the bacteria that cause problems regarding to teeth like gum, dental cavity and gingivitis.

Aloe vera is the oldest medicinal plant ever known and the most applied medicinal plant worldwide ⁴. The Aloe vera plant shows antimicrobial activity due to the presence of plant's natural anthraquinones: aloe emodin, aloetic acid, aloin, anthracene, anthranol, barbaloin, chrysophanic acid, ethereal oil, an ester of cinnamonic acid, isobarbaloin, and resistannol ⁵. The paste containing a high concentration of Sodium chloride content prevent the formation of the coat because of Leptotrichae is the coating around the teeth which absorbs colors. It is very difficult to remove such coating by a dentist might cause harm to enamel. To prevent the formation of such layers and their spreading sodium chloride may be used in high concentration ⁶.

There are several uses of *Aloe vera* in dental practice some uses are enlisted as below: ⁷⁻¹⁴

- 1. In dental implants
- 2. In periodontal surgery
- **3.** Can be applied on gum tissues when they are scratched by toothbrush, sharp foods or by toothpick injuries.
- **4.** Chemical burns from aspirin.
- **5.** Application in extraction sockets.
- **6.** It can be directly applied at the site of periodontal surgery.
- **7.** Its application around the dental implants to control inflammation caused by bacterial contamination.
- **8.** Acute mouth lesion is known as a hepatic viral lesion, aphthous ulcers, cancer cracks and cracks arising at the corners of our lips.

MATERIALS AND METHODS:

Materials: *Aloe vera* obtained from medicinal plant garden of VJSM's Institute of Pharmacy. sodium chloride, saccharine, calcium carbonate, dicalcium phosphate, glycerine, sodium lauryl sulphate, gum tragacanth, methyl paraben, propyl paraben were issued from a central store of VJSM's Institute of Pharmacy & Vishal institute of pharmacy education and research. Autoclave and Hot air oven (Make Lab Hosp.) were used to maintain the sterile condition and culture of nutrient agar bored with bacteria were incubated using Incubator (Make Lab Hosp.) during the Microbial assay. Distilled water was used throughout the study.

Methods:

Preparation of Fresh Juice of *Aloe vera*: Leaves of Aloe plant was procured from medicinal garden wash thoroughly. Then the pulp was removed by giving incisor on the leaves. The collected pulp was mixed thoroughly by using a juicer and passed through muslin cloth to remove any unwanted debris.

General Procedure for Preparation of Tooth Paste: 3^2 factorial designs were used for designing the experimental work and the batches were designed from software Design Expert® 10. The concentration of various ingredients was decided as per the standard formulae ^{2, 15}. Factors selected were Antimicrobial activity, and foaming power and the levels are chosen were low (-1), medium (0), and high (+1) as tabulated in **Table 1**. Development of different formulations was carried as per the formula is given in **Table 2**.

 TABLE 1: FACTORIAL DESIGN

Factor (2) \rightarrow Level (3) \downarrow	Concentration of Aloe	The concentration of Sodium Lauryl Sulphate
Low	-1 (3 %)	-1 (1%)
Medium	0 (4 %)	0 (1.5%)
High	1 (5 %)	1 (2%)

TABLE 2: DEVELOPED BATCHES FROM F1 TO F9AS PER FACTORIAL DESIGN

Batch	Concentration	The concentration of		
	of Aloe	Sodium Lauryl Sulphate		
F1	0	1		
F2	0	0		
F3	1	0		
F4	0	-1		
F5	1	1		
F6	1	-1		
F7	-1	-1		
F8	-1	0		
F9	-1	1		

For each formulation, ingredients were used as per their appropriate scales and measures as shown in **Table 3**. All the powder materials were passed through sieve 60#. A solution of all the watersoluble ingredients like sodium chloride, saccharine, methylparaben and propylparaben, *etc.* was prepared. Di-calcium phosphate, calcium carbonate, sodium lauryl sulphate, and *Gum* *tragacanth* were geometrically mixed and then transferred to clean Mortar Pestle. Then to this mixture fresh juice of aloe was added and paste was prepared by slowly adding above solution of water-soluble ingredients.

S.	Ingredients	All quantities are expressed in gm/ 100 gm								
no.		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Aloe	4	4	5	4	5	5	3	3	3
2	Sodium Chloride	1	1	1	1	1	1	1	1	1
3	Dicalcium Phosphate	23	24	23	25	22	24	26	25	24
4	Calcium Carbonate	21	20	20	20	21	20	20	20	21
5	Glycerine	30	30	30	30	30	30	30	30	30
6	Gum Tragacanth	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
7	Saccharine	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
8	Sodium Lauryl Sulphate	2	1.5	1.5	1	2	1	1	1.5	2
9	Methyl Paraben	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
10	Propyl Paraben	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
11	Distilled Water	16.3	16.8	16.8	16.3	16.3	16.3	16.3	16.8	16.3

TABLE 3: COMPOSITION OF THE BATCHES: (ALL QUANTITY IN % w/w)

Evaluation of Formulations: ³ Preliminary Test:

Drying Tendency: All the formulated batches were evaluated for their drying tendency at room temperature for a week. The observations were tabulated in **Table 4**.

Organoleptic Characters: Formulated batches were also evaluated for their organoleptic characters as shown in **Table 4**.

Physicochemical Parameters:

Determination of Grittiness: The presence of hard, sharp-edged abrasive particles were evaluated by extruding near about 15 to 20 mm length paste from a collapsible tube of each sample on butter paper then pressed it along its entire length by finger.

Determination of pH: In 100 ml cleaned beaker, accurately weighed 5 gm of sample was transferred. To this freshly boiled and cooled water was added and stirred well to get a uniform suspension. The pH was determined within 5 min by using a pH meter (M/s. Systronics Ltd. Ahmedabad). Results were tabulated in **Table 5**.

Performance Evaluation:

Determination of Foaming Power: In 100 ml glass beaker near about 5 gm of sample was taken. To this 40 ml, water was added, and the beaker was allowed to stand for 30 min by covering with a watch glass for dispersion of toothpaste in water. Then the content was stirred with glass rod and slurry was transferred to a 250 ml graduated measuring cylinder. Precaution was taken at the

time of transfer that no loss was produced. The reaming residue in the beaker was transferred with 5 to 6 ml of another portion of water. The volume make up to 50 ml by adding sufficient quantity of water and the temperature of the content is maintained near about 30 °C, meanwhile stirring was continued to ensure uniform suspension. When the temperature of the content was reached to 30 °C the stirring was stopped and 12 complete shakes were given and allowed to stand for 5 min. The foaming power was determined by measuring volume of foam with water (V₁) and water only (V₂) was noted for all samples.

Foaming power = $V_1 - V_2$

 V_1 = Volume in ml of foam with water V_2 = Volume in ml of water only.

Microbial Study: Modified agar well diffusion method was used to determine the antimicrobial activity of formulation, where nutrient agar plates were seeded with 0.2 ml of 24 h broth culture of *S. aureus*. After solidifying the agar plates, wells were cut at equal distance in each plate by using a sterile 8 mm borer. The wells of plates were filled with near about 0.5 ml of formulation. The plates were then incubated at 37 °C for 24 h. The antibacterial activity was evaluated by measuring zones of inhibition (in cm).

RESULT AND DISCUSSION: Table 4 showed that prepared toothpaste formulations were evaluated concerning various evaluation parameters; such as its Drying Tendency, Color, Appearance, Extrudability, Texture and After Taste. As the base material for all the formulations was same, it was found that none of the batches showed dried nature, the colour of the formulations was cream white, their appearance was paste-like and all the batches were easily extruded from the collapsible tube and were found of smooth texture. E-ISSN: 0975-8232; P-ISSN: 2320-5148

Due to the addition of sodium chloride and a sweetener like saccharine, the toothpaste possesses slightly sweet and salty taste. Also, the rationale behind the use of saccharine was to mask the slightly bitter taste of *Aloe*.

TABLE 4: PRELIMINARY EVALUATION OF THE TOOTHPASTES

Batches	Evaluation parameters					
	Dryness test	Colour	Appearance	Extrudability	Texture	After taste
F1	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F2	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F3	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F4	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F5	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F6	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F7	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F8	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty
F9	Not Dried	Cream white	Paste-like	Easy	Smooth	Slightly Sweet & Salty

As shown in **Table 5**, the performance-based evaluation was done concerning Foaming power and Microbial study. The foaming power varies from 28 ml to 42 ml depending on the concentration of Sodium Lauryl Sulphate. The pH of prepared formulations was within the range of 5.87 to 6.54. The microbial study was evaluated by determining Zone of Inhibition in nutrient agar plates seeded with S. aureus culture broth. Zone of inhibition can be observed pictorially in Fig. 1, which indicates that the prepared formulations of Aloe vera containing toothpaste showed Antimicrobial activity against S. aureus.

TABLE 5: DETERMINATION OF FOAMING POWER,pH AND ZONE OF INHIBITION

Batches	Evaluation Parameters					
	Foaming pH		Zone of			
	power		Inhibition (cm)			
F1	35	5.93	3.2			
F2	32	6.13	3.5			
F3	40	6.43	5			
F4	31	6.37	3.5			
F5	42	6.24	4.8			
F6	29	6.54	4.6			
F7	33	5.87	2.5			
F8	30	6.33	2.8			
F9	39	6.22	2.9			

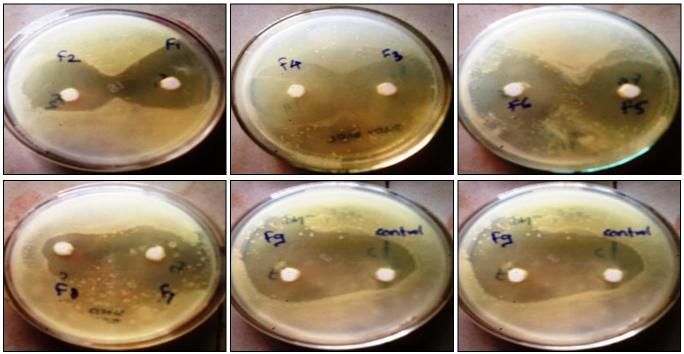


FIG. 1: MICROBIAL STUDY ON S. AUREUS OF PREPARED TOOTHPASTE

The collected results were put in Software Design Expert® 10 to determine optimum batch from prepared 9 formulations. The discussion is summarised as follows:

Effect of Independent Variable on Foaming Power: After applying experimental design, the chosen cubic model was found to be significant with the model F value of 916.43, *p*-value less than 0.05 and R^2 =0.99. There is only a 2.54% chance

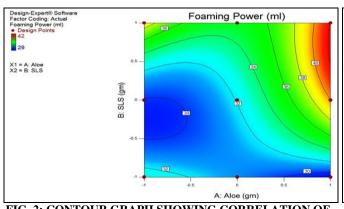


FIG. 2: CONTOUR GRAPH SHOWING CORRELATION OF FACTORS WITH RESPECT TO FOAMING POWER

Effect of Independent Variable on Zone of Inhibition: After applying experimental design, the chosen cubic model was found to be significant with the model F value of 887.29, *p*-value less than

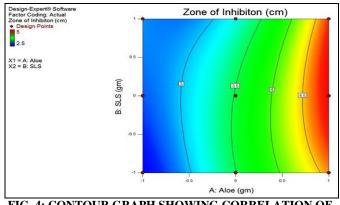


FIG. 4: CONTOUR GRAPH SHOWING CORRELATION OF FACTORS WITH RESPECT TO ZONE OF INHIBITION

Final Equation in Terms of Code Factors: For Zone of Inhibition:

Zone of Inhibition = $+3.52+1.10*A-0.15*B-0.050*AB+0.37*A^2-0.18*B^2+0.30*A^2B-0.100*AB^2+0.000*A^3+0.000*B^3$

From the above summarize data, the results were found to be significant with the chosen cubic model in software Design Expert® 10, and the optimum batch was found to be F3, as it shows highest Zone inhibition and also shows the sufficient foaming power. that F value large, could occur due to noise. **Fig. 2** contour graph is showing a correlation of factors concerning foaming power.

Final Equation in Terms of Coded Factors: Foaming Power:

Zone of Inhibition = $+32.11+5.00*A+2.00*B+1.75*AB+2.83*A^2+0.83*B^2+2.75*A^2B-5.25*AB^2+0.000*A^3+0.000*B^3$

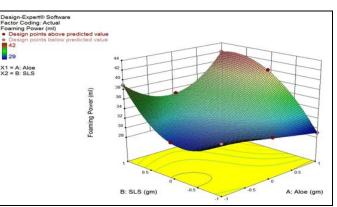


FIG. 3: 3D SURFACE GRAPH SHOWING CORRELATION OF FACTORS WITH RESPECT TO FOAMING POWER 0.05 and $R^2 = 0.99$. There is only a 2.58 % chance that F value large, could occur due to noise. Fig. 4 contour graph is showing a correlation of factors concerning zone of inhibition.

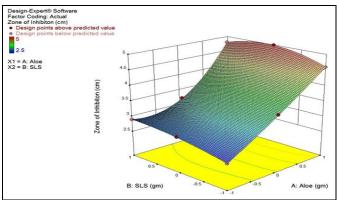


FIG. 5: 3D SURFACE GRAPH SHOWING CORRELATION OF FACTORS WITH RESPECT TO ZONE OF INHIBITION

CONCLUSION: *Aloe vera* showed a number of the beneficial uses in the dentistry as concluded in various journals. Also, Sodium Chloride has the use in dentistry from ancient time, because of this use now a day many multinational companies tried to market their toothpaste containing Sodium Chloride. In the present work, we used the combination of these two ingredients to determine possible antimicrobial activity. After finishing the work and analyzing collected data of obtained

results, we concluded that the present combination showed antimicrobial activity against *S. aureus*. Near about 5% w/w concentration of *Aloe vera* was found to effective as antimicrobial activity. Sodium chloride content may prevent the formation of Leptotrichae coating, and thus may prevent the harm to enamel.

We also conclude that 1.5 to 2% w/w concentration of sodium lauryl sulphate has sufficient foaming power which can be used for the cleansing purpose. Thus, our results offer the real-world clue for the possible use of *Aloe vera* along with sodium chloride as an antimicrobial effect for those who prefer herbal medicines.

Future Scope: In the present work, antimicrobial activity was conducted by using the culture of *S. aureus*. In future, we can evaluate the same combination of optimized batches on the culture of plaque obtained from the human oral cavity. Also, it would be beneficial to define its effect on oral cavities and probable side effects after its long tern use.

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CONFLICT OF INTEREST: The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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