FORMULATION AND EVALUATION OF ALOE-VERA GEL WITH ACTIVE SALT AND ALUM : AS A NEW DENTIFRICE

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Abstract: Aloe vera is well known for its marvellous medicinal properties. These plants are one of the richest sources of health for human beings coming from nature. It has been grown as an ornamental plant widely. Products of the plant are used in the treatment of various ailments. Various parts of the plant have different effects on the body. Aloe vera is an ancient, natural ingredient that would be hailed as a major scientific breakthrough if it came out of a modern drug lab. It coats, soothes and can even heal ulcers and irritations. Proven in multiple clinical studies, Aloe vera has been used in dentistry for its wound-healing effects, gingivitis, plaque control & curing oral mucosal lesions. Aloe vera may also reduce the pain and duration of oral ulcers while speeding healing. The dentists should use Aloe vera at a level high enough to maximize its therapeutic benefit.

Keywords: Aloe tooth, *Escherichia coli, Candida albicans,* zone of inhibition, natural antimicrobial agents.

Introduction :

The Aloe vera plant has been known and used for centuries for its health, beauty, medicinal and skin care properties. The name Aloe vera derives from the Arabic word —Alloeh meaning —shining bitter substance, while —vera in Latin means —true. 2000 years ago, the Greek scientists regarded Aloe vera as the universal panacea. The Egyptians called Aloe —the plant of immortality. Aloe barbadensis Miller (Aloe vera) belong to the liliaceal family, of which there are about 360 species. The use of natural products in the prevention and treatment of oral conditions has increased recently and

could be of benefit to low socioeconomic level in urban and rural communities. Among the various currently available herbal agents the most popular and currently receiving a lot of scientific attention is Aloe vera. It is a perennial succulent xerophyte, which develops water-storage tissue in the leaves to survive in dry areas of low or erratic rainfall [1]. The plant has stiff grey-green lance-shaped leaves containing clear gel in a central mucilaginous pulp. Benefits associated with Aloe vera have been attributed to the polysaccharides contained in the gel of the leaves. It is a cactus like plant that grows in hot and dry climates. Numerous studies on Aloe vera are being done to demonstrate the antiviral, antibacterial, analgesic, antiinflammatory & wound healing properties. The Aloe barbadensis plant consists of two different parts, each of which produces substances with completely different compositions and therapeutic properties. The parenchymal tissue makes up the inner portion of the aloe leaves and produces the Aloe vera gel (or mucilage), a clear, thin, tasteless, jelly-like material. This tissue is recovered from the leaf by separating the gel from the inner cellular debris. The other part of the plant is a group of specialized cells known as the pericyclic tubules, which occur just beneath the outer green ring of the leaf. These cells produce an exudate that consists of bitter yellow latex with powerful laxative-like actions [2].

History: The plant Aloe-vera has a history dating back to biblical times. Aloe vera has been used for medicinal purposes in several cultures for millennia: Greece, Egypt, India, Mexico, Japan and China. Egyptian queens Nefertiti and Cleopatra used it as part of their regular beauty regimes. Alexander the Great, and Christopher Columbus used it to treat soldiers' wounds. The first reference to Aloe vera in English was a translation by John Goodyew in A.D. 1655 of Dioscorides Medical treatise De Materia Medica [3].

The Components or Elements in Aloe vera are [4]. Lignins, Saponins, Glycosides, Anthraquinones, Minerals. Vitamins, Mono and Polysaccharides and Amino Acids.

Mechanism of Action:

a) **Anti-Inflammatory Effects:** It inhibits the cyclooxygenase pathway and reduces prostaglandin E2.
b) **Antifungal Property:** A processed Aloe vera gel preparation reportedly inhibited the growth of Candida albicans [7].

c) **Antiviral Property:** This action may be direct and indirect; i.e. indirect due to stimulation of immune system, and direct due to aloe emodin.

d) **Immunomodulating Effects:** Aloe vera, a great immune stimulant, contains 90% rhodium and iridium (trace minerals) in the acemannan which is one of the polysaccharides which dramatically increases the white blood cells or macrophages and T cells.

e) **Antioxidant Property:** Aloe vera has very strong antioxidant nutrients. Glutathione peroxide activity, superoxide dismutase enzymes and a phenolic antioxidant were found to be present in Aloe vera gel, which may be responsible for these antioxidant effects.

f) **Antitumor Effect:** The two fractions from Aloes that are claimed to have anticancer effects include glycoproteins (lectins) and polysaccharides.

g) **Dental Implants:** Aloe vera gel placed around dental implants is found effective to reduce inflammation. Aloe vera reduces inflammation by its antimicrobial & antiinflammatory effects.

Materials and Methods:

Different concentrations of viscosity enhancer Carrageenam gum were tried and finally gel that showed good spreadability and consistency was selected for dentifrice property of herbal gel of Aloe vera, active salt and alum.

Carrageenam gum was purchased from Sarin Industries Pvt Ltd., Mumbai (India), precipitated and hydrated silica from Madhu Silica Pvt. Ltd (Gujrat), Methyl Paraben, Propyl Paraben, Sodium Chloride was Purchased from Titan Biotech Ltd. Rajasthan (India) and colours from Neelicon food dyes and chemicals ltd, Mumbai. Aloe vera (Aloe barbadensis) plant was obtained from Herbal Garden, Vidyabharti Pharmacy College – Amravati.

EXPERIMENTAL WORK

Analysis of Aloe – vera extract :

Complete analysis of Aloe – vera extract was done according to specification.

Thick succulent leaves of Aloe vera (*Aloe barbadensis*) plant obtained from Herbal Garden, Vidyabharti college of Pharmacy-Amravati, were used. To obtain Aloe vera extract, the mucilaginous jelly obtained from the centre (the parenchyma) of the plant

leaf of Aloe vera, the leaves of Aloe vera were collected, washed with water and a mild chlorine solution and were finally cut transversely into pieces. With a vegetable peeler, the thick epidermis was selectively removed and the inner gel-like pulp in the center of the leaf was separated with a spoon, minced, and homogenized in a mixer.

Selection, Optimization and Preparation of Aloe-Vera tooth gel :

One of the main ingredients of the formulation is the gelling agent. The concentration of viscosity enhancer or gel former is of immense value as a less concentration will lead to simple solution or lotion with very low consistency, while high concentration may lead to formation of gels with high viscosity leading to non-uniform distribution of drug and problem with handling of gel. Different gel formers were tried in order to select the best gelling agent.

So in order to optimize the concentration of gelling agent to achieve proper consistency of the gel formulations were prepared with different gel formers, Sodium Carboxy methylcellulose, Carbomer 934, 974, Carrageenam gum in different concentration of viscosity enhancer vis. 1.0, 2.0, 3.0 and 4.0 % were tried.

Gels containing aloe vera juice extract and Sodium CMC showed phase separation and were rejected. Aloe vera gels containing 1.0 % of carbomer 934 form a very thin gel that liquefies within 6h of preparation. With 2.0% gelling agent somewhat better gel was obtained but the problem of liquification after 24h was observed. Gel containing 3.0% of carbomer 934 formed uniform and smooth gel that does not liquefy upon keeping. At 4.0 % of carbomer gel was very thick and more sticky that could not be properly spread out. With carbopol974 the gels formed are poor in consistency and very thick as indicated by spreadability and extrudability values. Thus, 0.55% of carrageenam was selected as the optimized concentration of gelling agent.

Table 1: Formulation of Aloe-Vera Gel dentifrice

S. N.	Ingredients	% (w/w)
1	Sorbitol	65.00
2	VTP Gum (Carrageenan gum)	0.55
3	F - Sil 100 (Abbrasive Silica)	13.5
4	M - Fil 100 (Hydrated Silica)	6.5
5	Poly ethylene glycol 400	0.5
6	Sodium Saccharin	0.3
7	Sodium fluoride	0.22
8	Sodium lauryl sulphate	2.5
9	Methyl Paraben	0.1
10	Propyl Paraben	0.01
11	Colour	0.1
12	Flavour	0.5
13	Water	0.92
14	Aloe – vera gel	9.0
15	Sodium salt	0.2
16	Alum	0.1

Finalized base formulation for gel tooth paste with aloe – vera extract , salt and alum as an active ingredients with other common ingredients of gel dentifrice.

Procedure :

Weigh all the ingredients. Take sufficient quantity of water . Add sodium saccharin, Sodium fluoride , preservatives , colour, Sodium salt, alum in it . Mix it properly. Then warm the water up to 45 – 50^{0}c . Then at this temperature add VTP gum. Then add sorbitol, Poly-ethylene glycol. Then add both silica powder i.e. abrasive silica & hydrated silica to it. Mix it 15 minutes. The add Aloe – vera gel & flavour to it and mix it 10 -15 minutes properly. Lastly add sodium lauryl sulphate to the formulation by making a slurry. Slight amount of foam will generate. Remove air by vacuum.

Evaluation of Aloe-vera Tooth Gel

pH

1.0 g gel was accurately weighed and dispersed in 100 ml purified water. The *p*H of the dispersion was measured using digital pH meter, which was calibrated before use with standard buffer solution at 4.0, 7.0 and 9.0. The measurements of *p*H were done in triplicate and average values were calculated.

Spreadability

One of the criteria for a topical formulation to meet the ideal qualities is that it should possess good spreadability. It is the term expressed to denote the extent of area to which formulation readily spreads on application to skin or affected part. The therapeutic efficacy of a formulation also depends upon its spreading value. To determine the spreadability of formulation, 0.5 g of gel was placed within a circle of 1 cm diameter pre-marked on a glass plate of 20 × 20 cm, over which a second glass plate was placed. A weight of 500 g was allowed to rest on the upper glass plate for 5 min. The increase in the diameter due to gel spreading was noted.

Extrudability

To determine extrudability a closed collapsible tube containing formulation was pressed firmly at the crimped end. When the cap was removed, formulation extruded until the pressure dissipated. Weight in grams required to extrude a 0.5 cm ribbon of the formulation in 10 sec was determined. The average extrusion pressure in gms was reported.

Viscosity

The viscosity of the formulations was determined as such without dilution by R/S CPS Plus Rheometer (Brookfield Engineerring Laboratorie, Inc., Middleboro, MA, USA) using spindle No. 6, 50-1 having diameter of 50 mm using software RHEO3000.

Homogeneity

The developed formulations were tested for homogeneity by visual inspection after the gel had been filled in the container. They were tested for their appearance and presence of any aggregates.

Analysis of dentifrice Capacity as per IS6356:2001:

The formulated Aloe vera tooth gel sample was tested as per IS 6356 : 2001

(Specification for tooth paste.)

Antimicrobial Analysis of Aloe-vera Tooth Gel :

This in-vitro study was carried out to determine Antimicrobial efficacy of Aloe-vera tooth gel against oral pathogens. In order to study in their effectiveness against the test microorganisms , Escherichia coli, S. aureus S. mutans and Candida albicans were selected as test microorganisms ,against which the antimicrobial assay by modified agar well diffusion method as per NCCLS guide lines 2005 was performed.

- **Name of Test :** Anitibacterial property of test product by well diffusion method as NCCLS guidelines 2005

Test Inoculum :

1. Staphylococcus aureus ATCC 6538
2. Streptococcus mutans ATCC 25175 bacteria
3. Escherichia coli ATCC 10536
4. Candida albicans ATCC 10231

Test Procedure :

The test organisms diluted approx. 10^7-10^8 CFU/ml were individually spread by a sterile swab evenly over the face of Soyabean Casein digest agar. Using cork borer a well of 8 mm diameter was punched in the medium. Test material-as it is in 100 ul quantity was then applied to each well. Control plant comprised of 100 ul distilled water solution. The plates incubated at 37^0C/28^0C for 24/72 hrs. Zone of inhibition were measured by calibrated ruler.

Results and Discussion:

Analysis of Aloe-vera Extract:

Sr.No.	Parameter	Specification	Result
1	Botanical Source	Aloe Barbadensis Miller	Complies
2	Appearance	Colourless and Transparent	Complies
3	Solubility in Water	Soluble	Soluble 100%
4	Odor	Characteristic	Characteristic
5	pH	4.0 – 8.0	6.28
6	Specific Gravity @ 25 deg C.	1 to 1.1	1.0090
7	Refractive Index @ 20 deg. C.	1.3 to 1.5	1.3932
8	Loss on drying	About 97 -98%	Complies
9	Heavy Metals	10 ppm Max.	Less than 2 ppm
10	Arsenic	10 ppm Max. LT : NMT 10 ppm	Complies
10	Microbial Limits : Total Bacterial Count Yeast and Mold Count S. Aureus E Coli/g Salmonella/g Pseudomonas	100 cfu/gram Max. NMP 50 cfu/g	 Complies Complies Absent Absent Absent Absent

The pH of the formulation was determined in order to be sure that the formulation can be used without the risk of irritancy to the oral cavity. The *p*H was found to be 6.28 for gel which was very near to the neutral *p*H, thus the formulation can be used without the risk of irritancy to the oral cavity. This also indicated that the selected ingredients of the formulation did not alter the *p*H of the formulation.

The Spreadability of formulations was found to decrease with increasing the concentration of gelling agent. The value of Spreadability for optimized gel was found out to be 8.6 cm indicating that the gel easily spreadable by small amount of shear.

Table 3: Evaluation of Aloe Tooth Gel as per IS: 6356 : 2001 (Specification for tooth paste)

S.No.	Description	Standard	Results
1. i) ii)	Fineness 150 Micron 75 Micron	 Lt : Max.10% Lt : Max 2.5%	 0.004% 0.004%
2.	pH of Aqueous Suspension	5.5 to 10.5	6.60
3.	Foaming power	Lt : Min. 50ml	200ml.
4.	Heavy metals	Lt : Max 20ppm	Test Passes
5.	Arsenic	Lt : Max 2 ppm	Test Passes
6.	Viscosity	42000 to 60000	48,900 cps.
7.	Hard and sharp edge particles	To pass the test	No hard & sharp edge particles observed
8.	Spreadability	To pass the test	Test passes
9	Extrudability	To pass the test	20.3
10	Homogeniety	To pass the test	Homogenous

Results of anti-microbial Assay:

- Name of Test :
  Anitibacterial property of test product by well diffusion method as NCCLS guidelines 2005

Test Inoculum :

Staphylococcus aureus ATCC 6538
Streptococcus mutans ATCC 25175 bacteria
Escherichia coli ATCC 10536
Candida albicans ATCC 10231

The test organisms diluted approx. 10^7-10^8 CFU/ml were individually spread by a sterile swab evenly over the face of Soyabean Casein digest agar. Using cork borer a

well of 8 mm diameter was punched in the medium. Test material-as it is in 100 ul quantity was then applied to each well. Control plant comprised of 100 ul distilled water solution. The plates incubated at 37^0C/28^0C for 24/72 hrs. Zone of inhibition were measured by calibrated ruler.

Table 4: Antimicrobial Assay of Aloe-Vera tooth gel

Sample Identification	Test organism	Zone of Inhibition in mm (average)				
		1 : 1	1 : 2	1 : 4	1 : 8	1 : 16
Aloe vera gel T.P.	Staph. Aureus	21.6 mm	21mm	16.6 mm	15.3 Mm	14. 5 mm
Bright T.P		21 mm	20.3 mm	19.6 mm	14 mm	13 mm
Aloe vera gel T.P.	Strep. Mutans	20 mm	13 mm	17 mm	No. Zone	No. Zone
Bright T.P		25.3 mm	21.3 mm	18 mm	15. mm	13.2 mm
Aloe vera gel T.P.	Esch. Coli	No. Zone	No. Zone	No. Zone	No. Zone	No. Zone
Bright T.P		No. Zone	No. Zone	No. Zone	No. Zone	No. Zone
Aloe vera gel T.P.	can. albicans	29 mm	27 mm	24.6 mm	16 mm	15 mm
Bright T.P		30 mm	25 mm	23.2 mm	20 mm	12 mm

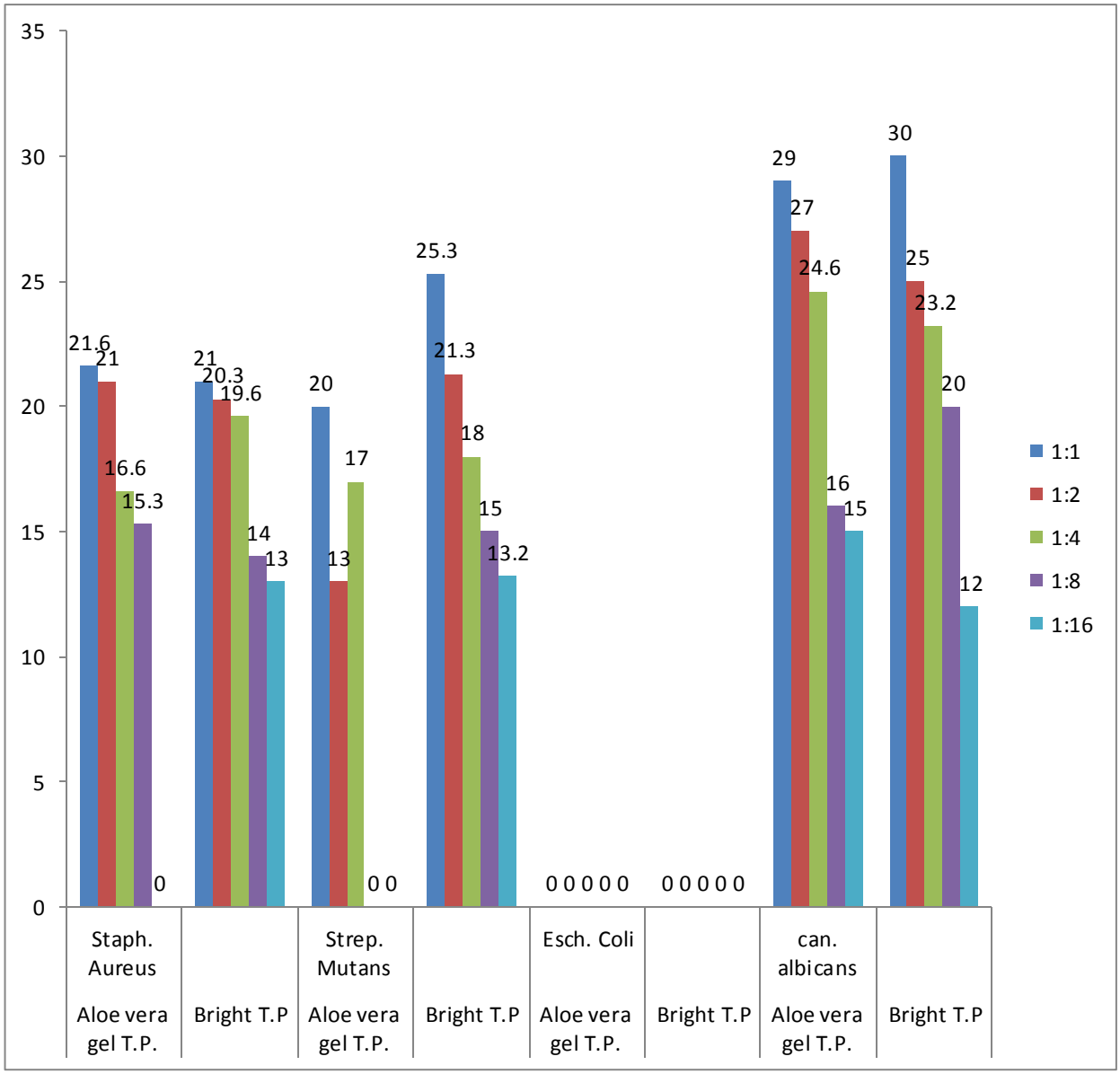


Figure no. 1: Biological indicator verses zone of inhibition of Aloe-Vera Tooth Gel

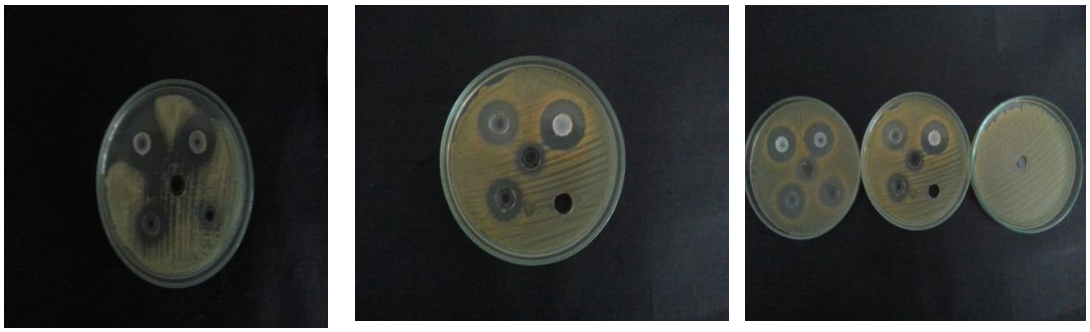
Graphical Representation of Result of Anti-microbial Analysis of Aloe Tooth Gel having active salt and alum.

Note :

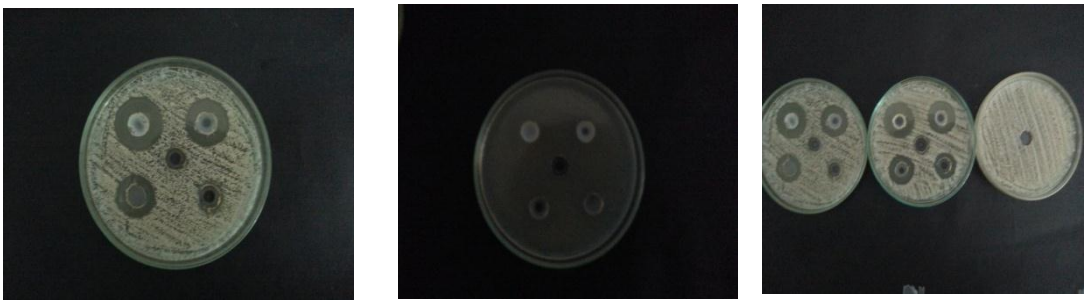
1. 100 ul was used per well
2. Presence on Antibacterial substance in Formulation is indicated by zone of Inhibition.
3. Larger the zone size more is the concentration of Antibacterial substance.

4. No. Zone of inhibition is no antibacterial activity unless material is non diffusible.

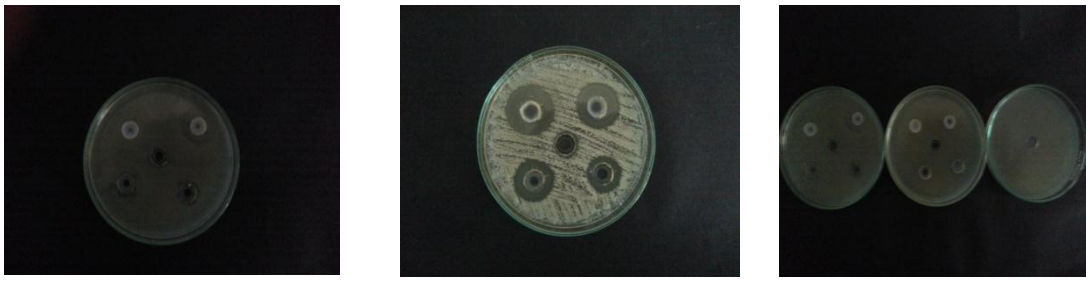
Staph. aureus :



Strep. mutans



Esch. Coli



Can. Albicans

Figure : Photographs of Antimicrobial Assay

The greater part of the world's population relies on traditional medicine for their health care. This is also the case in the treatment of teeth. In developing countries, formulations prepared from plants have been widely used for the treatment of dentifrice by medical personnel trained in western medicine as well as by traditional practitioners. Wound relating with teeth healing is a dynamic response to injury that results in wound contraction, wound closure and restoration of the functional barrier.[14] It has three overlapping phases: inflammation, granulation tissue formation and remodeling. During the wound healing process, especially the transition from granulation tissue to scar tissue formation, collagen remodeling occurs, which involves the degradation of collagen with the formation of larger collagen bundles and an increase in the number of intermolecular cross-linkages. This process is controlled by matrix metalloproteinases. They are proteolytic enzymes discharged by fibroblasts, macrophages, epidermal cells and endothelial cells. The tensile strength of a teeth can be related to its collagen formation and maturation.

The prepared Aloe-Vera Tooth Gel has promising effect on the teeth. Further studies need to be performed to understand the exact mechanism of teeth wound healing by Aloe vera gel.

CONCLUSION :

From all experiments conclusions can be drawn that Aloe-vera gel tooth paste were successfully prepared along with active sodium salt and alum. According to result of analysis, prepared gel dentifrice formulation is capable of reducing the bad odour, reduces plague, gives whitening effect to the teeth. Also the formulation is potentially effective against various micro- organisms like S. aureus, S. mutans, Candia albicans. Thus, it is a best formulation for dental care.

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