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Formulation & Evaluation of Herbal Mouth Gel Healing of Mouth Ulcer

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Abstract: *Aphthous Stomatis or mouth ulcer is the most common condition that we encounter clinically the lesions are single or multiple superficial and deep sealed and are associated with microbial invasions. Herbal gel formulated were stable, safe, and effective over to synthetic formulations for the treatment of mouth ulcer. Mouth ulcer often causes pain irritation of the sores salty, spicy, and sour food items and may cause discomfort while healing occurs due to use of chemical formulation. This project focused on the preparation of a herbal mouth ulcer healing gel because better cultural acceptability, better compatibility, with human body and less side effects.*

Keywords: Mouth ulcer, Aloe barbadensis and, Azadirachta indica, gel, Wound-healing

I. INTRODUCTION

Gels are mainly semi-solid formulations having a liquid phase that has been thickened with some other components. Topical gel preparations are used for the skin application or percutaneous penetration of medicament or local action to certain mucosal surfaces. Mouth ulcers are small sores or an abrasion that develops in mouth or at the base of gum. Mouth ulcers are also known as canker sores or aphthous ulcer. A break or breach in the mucous membrane, that lines within the mouth is also recognised as a mouth ulcer. It generally arises as a yellow or white colour depression in mouth. Mouth ulcers are usually generated by a number of causes, such as biting the inner layer of cheek, food allergies, hard teeth brushing, hormonal changes, vitamin deficiencies, bacterial infection and diseases .

Causes Of Mouth ulcer

There is no definite etiology and pathology known for mouth ulcer; although some factors are considered. considered important which include nutritional deficiencies such as iron, vitamins especially B12 and C, poor oral hygiene, infections, stress, indigestion, mechanical injury, skin disease etc. Some other factor include such as:

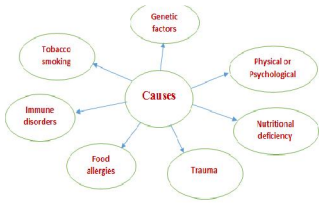

Fig 2: Causes of mouth ulcer

Pharmacognistic Investigation Herbal drug Profile Aloe barbedensis (Aloe Vera)

Fig 2: Aloe barbedensis Leaves

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Pharmacognostic study:

Synonym: Aloe

Aloe Vera: The biological source of Aloe Vera is Aloe barbadensis. It belongs to the family Xanthorrhoeaceae.

Morphology: Aloe Vera is a stemless or very short stemmed plant growing to 60–100 cm (24–39 in) tall, spreading by offsets. The leaves are thick and fleshy, green to grey-green, with some varieties showing white flecks on their upper and lower stem surfaces.

Chemical constituents: The chemical constituents in Aloe Vera are Anthraquinones, Saccharides, Prostaglandins and fatty acids. Others: Enzymes, amino acids, vitamins, minerals. Other compounds: Cholesterol, triglycerides, steroids, uric acid, lignins, beta- sitosterol, gibberellin, salicylic acid.

Uses: It is analgesic, antibacterial, antiviral, antifungal, antioxidant immune modulating, antiseptic, anti-inflammatory. Aloe vera is used in the sites of periodontal surgery, toothpick injuries, chemical burns, aphthous ulcers, gum abscesses, dry socket, lichen planus, benign pemphigus and gingival problems associated with AIDS, leukaemia, migratory glossitis, geographic tongue and burning mouth syndrome, denture sore mouth, candidiasis, desquamative gingivitis, vesiculobullous diseases, acute monocytic leukemia, xerostomia.

Azadirachta indica (Neem)

Fig 3: Azadirachta indica Leaves

Pharmacognostic study:

Common Name – Neem[50]

Botanical Name –Azadirachta Indica

Azadirachta indica Leaves of Azadirachta indica, commonly called as neem, belonging to family Meliaceae

Morphology. Neem is a medium-sized tree, reaching 15 to 30 m in height, with a large rounded crown up to 10-20 m in diameter. It is mainly evergreen but sometimes shed its leaves during the dry season. Neem has a deep taproot and is a mycorrhizal-dependent species.

Chemical Constituents are rich in several phytoconstituents such as nimbin, nimbidin, nimbolide, and limonoids, quercetin and sitosterol. Leaves contain mixture of compounds including nimbin, nimbanene, 6 desacetylnimbinene, nimbandiol, nimbolide, ascorbic acid, n-hexacosanol and different amino acids, and nimbiol and several other types of ingredients. In addition to this, the bark also contains nimbin, nimbinin, and nimbidin.

Uses They have very strong antibacterial, antifungal and anti-inflammatory, Wound healing activity and are quite commonly.

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Curcuma longa (Turmeric)

Fig 4: Curcuma longa Rhizome

Pharmacognostic study:

Common name: Curcuma[49]

Synonyms: Saffron, Haldi

Turmeric: The biological source of Turmeric is Curcuma longa which belongs to the family Zingiberaceae. Evaluation of turmeric has been done for gastric and duodenal antiulcer activity in rats. Volatile oil of Curcuma longa possess antiinflammatory and anti-arthritic activities. Water and fat soluble extracts of curcumin exhibited strong antioxidant activity comparable to vitamins C and E.

Fig 4: Curcuma longa Rhizom

Morphology: Turmeric is a perennial herbaceous plant that reaches up to 1 m (3 ft 3 in) tall. Highly branched, yellow to orange, cylindrical, aromatic rhizomes are found. The leaves are alternate and arranged in two rows. They are divided into leaf sheath, petiole, and leaf blade. From the leaf sheaths, a false stem is formed. The petiole is 50 to 115 cm (20–45 in) long. The simple leaf blades are usually 76 to 115 cm (30–45 in) long and rarely up to 230 cm (91 in). They have a width of 38 to 45 cm (15 to 18 in) and are oblong to elliptical, narrowing at the tip Plant part used: Rhizomes and stem.

Chemical constistuents: Phytochemical components of turmeric include diaryl heptanoids, a class including numerous curcuminoids, such as curcumin, demethoxycurcumin, and bisdemethoxycurcumin. Curcumin constitutes up to 3.14% of assayed commercial samples of turmeric powder (the average was 1.51%); curry powder contains much less (an

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average of 0.29%).Some 34 essential oils are present in turmeric, among which turmerone, germacrone, atlantone, and zingiberene are major constituents.[49]

Uses: Most turmeric is used in the form of rhizome powder to impart a golden yellow color. It is used in many products such as canned beverages, baked products, dairy products, ice cream, yogurt, yellow cakes, orange juice, biscuits, popcorn color, cereals, sauces, and gelatin. It is a principal ingredient in curry powders. Although typically used in its dried, powdered form, turmeric also is used fresh, like ginger. It has numerous uses in East Asian recipes, such as pickle that contains large chunks of soft turmeric, made from fresh turmeric.

BASIC INTRODUCTION ABOUT THE GEL

A gel is a semi-solid that can have properties ranging from soft and weak to hard and tough. Gels are defined as a substantially dilute cross-linked system, which exhibits no flow when in the steady-state, 1 although the liquid phase may still diffuse through this system.A gel has been defined phenomenologically as a soft, solid or solid-like material consisting of two or more components, one of which is a liquid, present in substantial quantity. By weight, gels are mostly liquid, yet they behave like solids because of a three dimensional cross-linked network within the liquid. It is the crosslinking within the fluid that gives a gel its structure (hardness) and contributes to the adhesive stick (tack). In this way, gels are a dispersion of molecules of a liquid within a solid medium.

Herbal Gel

A gel is a solid or semisolid system of at least two constituents, consisting of a more enhancing condensed mass enclosing and interpenetrated by a liquid. Gels and jellies are composed of small amount of solids dispersed in relatively large amount of liquid, yet they possess more solid-like than liquid-like character. The characteristic of gel and jelly is the presence of some form of cutaneous structure, which provides solid-like properties.Gels are generally considered to be more rigid than jellies because gels contain more covalent crosslinks, a higher density of physical bonds, or simply less liquid. Gel-forming polymers produce materials that span a range of rigidities, beginning with a sol and increasing in rigidity to a mucilage, jelly, gel, and hydrogel.

Advantages of Herbal Medicine

Herbal medicines have a long history of use and better patient tolerance and public acceptance.
Medical plants have a renewable source, so that we can have sustainable supplies of cheaper medicines for the worlds growing population Because of the rich agro-climatic, cultural and ethnic biodiversity of developing countries like India availability of medicinal plants is not a problem.
The cultivation and processing of medicinal herbs are eco-friendly.
Prolong and apparently uneventful use of herbal medicines is safe and efficacious.

Properties of Gel

Ideally, the gelling agent must be inert, safe and cannot react with other formulation constituents.
The gelling agent should produce a sensible solid-like nature at the time of storage, which is easily broken when exposed to shear forces produced by squeezing the tube, trembling the bottle, or at the time of topical application.
It should have suitable anti-microbial agent.
The topical gel must not be sticky

METHOD OF PREPRATION OF GEL

Gel can be prepared by three method.

Three methods can be used:
Cold method
After cooling water to 4 to 100 degrees, it was poured into a mixing vessel. The geling agent was added slowly and agitated until the completesolution was reached. Temperatures below 100 °Cwere maintained during the melting

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process. A solution of the drugs was slowly added while mixing gently. The liquid should be transferred to container and allowed to warm to room temperature, where it will become a clear gel.

"In this project we are going to use cold method for the preparation of herbal gel of Azadirachta indica, Aloe Barbedensis and curcuma longa."

Dispersion method

Stirring the gelling agent in water at 1200 rpm for 30 minutes dispersed the gelling agent. The nonaqueous solvent was used to dissolve the drug. The preservative was also added. Continuous stirring was performed while adding this solution to the gel above.

Fusion method

This method involves the use of various waxy materials as gallant in a non-polar medium. In this method, waxy materials are melted and drugs are added. A uniform gel was formed by stirring slowly until it was dissolved.

Commonly Used Gelling Agents

Acacia, Pectin, Starch,Tragacanth

Xanthan gum Alginic acid (seaweed)

Animal/vegatable fats: cocoa butter,Gelatin

Bentonite, veegum (magnesium aluminum silicate)

Preservatives

Preservative are those chemical used alone or in combination to prevent the growth of microrganism in solution e.g Methyl paraben , Propyl paraben.[31]

Buffering agent –

Buffers are compound or mixture of compounds that by their presence in the solution resist changes in the pH upon the addition of small quantities of acid or alkali Trietholamine.

Moisturizers – glycerin [30]

Moisturizer preparation used to prevent dryness

Antioxidants

Antioxidant are compound that inhibit oxidation a chemical reaction that can prouce free radicals and chain reaction that may damage the cells of organism Bases e.g Vitamin c,lutein

Binders

Binder excipients hold the ingredient of a formulation together e.g Tragacanth , Gelatin

EVALUTION OF HERBAL GEL

Physical Evaluation:[5]

Physical parameters such as colour and appearance were checked. Measurement of pH. The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours. The measurement of pH each formulation was done

Spreadibility:

Spreadability was determined by the apparatus, which consists of a wooden block, which was provided by a pulley at one end. By this method spreadability was measured on the basis of slip and drag characteristics of gels. An excess of gel (about 2g) under study was placed on this ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A. one kg weighted

Skin irritation study:

0.5 gm. of the herbal gel was used as the test substance was applied to an area of approximately 6 cm2 of skin and covered with a gauze patch. The patch was loosely held in contact with the skin by means of a semi occlusive dressing for the duration of 1 hour and gauze was removed. At the end of the exposure period, i.e., 1-hour, residual test substance was removed, without altering the existing response or integrity of the epidermis. Observations have recorded after removal of the patch. Control animals were prepared in the same manner and 0.5 gm. of the gel base i.e., gel

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formulated using all ingredients except the herbal mixture was applied to the control animals and observations were made as similar to the test animals.

Viscosity:

Viscosities of gels were determined using Brookfield viscometer. Gels were tested for their rheological characteristics at 25^0c using Brookfield viscometer (DV-III programmable Rheometer). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30seconds between 2 successive speeds and then in a descending order.

Stability Study:

The stability study was performed as per ICH guidelines 6. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz. 25^0 C± 2^0C/ 60% ± 5% RH, 30^0 C ± 2^0C/ 65% ± 5% RH, 40^0 C ± 2^0C/ 75% ± 5% RH for a period of three months and studied for appearance, pH, and spreadability.

Extrudabilty:

The gel formulation were filled in standard capped collapsible aluminium tubes and sealed by crimping to the end. The weight of tubes were recorded and the tubes were placed between two glass slides and were clamped. 500gm was placed over the slides and then the cap was removed. The amount of extruded gel was collected and weighed.

Measurement of pH :

The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours. The measurement of pH of each formulation was done.

Washability:

Formulation was applied on the skin and then ease extends periods of washing with water was checked.

MATERIAL AND METHODS:

Chemicals:

Ethanol, Carbopol 934, distilled water, methyl paraben and propyl paraben, Propylene glycol, Triethanolamine,
Chemicals used in formulation of gel

Carbopol 934,Methyl paraben, and Trietholanamine collected from the Research lab fine chem industries mumbai Glycerin are collected from Vikash pharma.

Equipment's and Instrumentations:

Digital balance, pH meter, Magnetic stirrer, Digital water bath, Autoclave, Hot air oven, Incubator, Spreadability Apparatus

COLLECTION OF MATERIALS:

The leaves of Azadirachta indica, Aloe barbadensis were collected from the medicinal garden and rhizomes of Curcuma longa were collected from the local area.

Formulation of gel:

A sufficient amount of Carbopol 934 was soaked in distilled water overnight, and then mixed with distilled water with continuous stirring using a mechanical stirrer. Another solution containing varying concentrations of Ethanolic extract of Azadirachta indica EEZ (ml) Ethanolic extract of aloe (EEA) (ml) Turmeric Rhizome extract and the required quantity of methyl paraben and propyl paraben were added with continuous stirring. Propylene glycol was also added to the solution. This prepared solution was further mixed with Carbopol 934 solution thoroughly with continuous stirring, volume was made upto 30ml with water and the pH was adjusted by addition of triethanolamine to obtain gel of required consistency. Seven formulations (F1 to F7) of the herbal gel were prepared.

METHOD OF PREPARATION OF HERBAL GEL

After cooling water to 4 to 100 degrees, it was poured into a mixing vessel. The Gelling agent carbapol 934 is added slowly and agitated until the completesolution istemperatures below 100 °Cwere maintained during the melting process. A solution of the drugs extarct Ethanolic extract of Azadirachta indica EEZ(ml)Ethanolic extract of aloe (EEA)

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(ml)Turmeric Rhizome extract is slowly added while mixing gently. The liquid should be transferred to container and allowed to warm to room temperature, where it will become a clear gel.

Evaluation of Gel:

Physical evaluation:

Physical parameters such as color, odour and consistency were checked visually.

Color: The color of the formulations was checked by visual inspection.

Consistency: The consistency of formulations was checked by applying on skin.

Odour: The odour of the formulations was checked by mixing the gel in water and observing the smell. Physical evaluations of gel formulations were reported.

Measurement of pH:

The pH of herbal gel formulations were determined by using digital pH meter. 1 gm. of gel was taken and dispersed in 10 ml of distilled water and keep aside for two hours. The measurement of pH of formulation was carried out in three times and the average values are reported. pH of gel formulation was reported.

Homogeneity:

All developed gel formulations were tested for homogeneity by visual inspection after the gels have been set in to the container. They were tested for their presence and appearance of any aggregates.

Spreadability:

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel that is placed in between the slides under the direction of certain load. If the time taken for separation of two slides is less then better the spreadability. Spreadability is calculated by using the formula:

II. RESULT AND DISCUSSION PHYSICAL EVALUATION

Physical parameters such as colour, odour and consistency were checked visually. colour of herbal gel was found yellowish color with good texture from F1 to F7 in all batches. But good colour dispersion uniformly was found in F4 than F7. Consistency good in all formulation and it is given in table.

pH

The Checked pH of all gels the diff pH of changes between ranges 6 to 6.40. The F5 pH is
6.39 is less than F7 6.40. The pH reported it is given in table.

Homogeneity

All developed gel formulations were tested for homogeneity by visual inspection after the gels have been set in to the container. All gels visual inspection after set the container the check the homogeneity all gels are homogeneous. The Homogeneity Reported in Table.

Spreadability

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel that is placed in between the slides under the direction of certain load. The check the spreadability of all gels the different spreadability of gels between the range 6.3 to 7.9. The spreadability Reported in table.

Percentage Yield

The percentage Yield of all gel Formulation Reported in table. The different percentage yield F1 to F7 gels.

Antimicrobial Activity

The antimicrobial activity was studied using the well diffusion method. Out of formulation F7 gel containing the F6 shown the highest zone of inhibition and it comparable with the marketed oracool gel formulation both against E. coli. The both product no inhibited growth.

Physical Evaluation

Physical parameters such as colour, odour and consistency were checked visually. Check the colour of gel yellowish colour and texture good F1 to F7.

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Table 2: Physical Evaluation of gel formulation

Formulation	Colour	Texture	Odour
F1	Yellowish	Good	Characteristic
F2	Yellowish	Good	Characteristic
F3	Yellowish	Good	Characteristic
F4	Yellowish	Good	Characteristic
F5	Yellowish	Good	Characteristic
F6	Yellowish	Good	Characteristic
F7	Yellowish	Good	Characteristic

pH

1 gm. of gel mix in 10 ml water mix and check the pH all F1 to F7 gels.

Table 3: pH of gel Formulation

Formulation	pH
F1	6.1
F2	6.1
F3	6.22
F4	6.33
F5	6.39
F6	6.27
F7	6.40

Spreadability

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel that is placed in between the slides under the direction of certain load.

Table 5: Spreadability of gel formulation

Formulation	Spreadability (g.cm/sec)
F1	6.3
F2	6.9
F3	7.5
F4	7.5
F5	7.3
F6	7.9
F7	7.8

Percentage Yield (%)

Weight the empty container in which the gel formulation was stored again weight the container with the gel formulation to obtain the practical yield subtract the weight of empty container with the container with gel formulation.

Table 6: Percentage Yield of Gel

Formulation	Percentage Yield (%)
F1	96.985
F2	98.210

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F3	95.421
F4	96.992
F5	98.876
F6	97.135
F7	96.123

III. CONCLUSIONS

Nowadays there is a lot of demand for herbal formulations in the market due to their cost effectively and absence of any side effects. From the above experimental data it is clear that a gel formulation with herbal ingredients such as aloe, neem and, haldi has good characteristics, viscosity and also possesses a good antimicrobial activity which is necessary in the management of mouth ulcers**.** Natural remedies are more acceptable in the belief that they are safer with lesser side effect than the synthetic medicines. Nowadays herbal formulation have increasing demand in the world market. New herbal gel formulation having good antimicrobial activity as well as anti-inflammatory activity so it is safe, stable and good for mouth ulcer treatment.

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