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Formulation and Evaluation of Herbal Emulgel

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ABSTRACT:-

Herbal antifungal treatments offer a safer alternative to conventional therapies, addressing issues of adverse effects and resistance. This study aimed to formulate and evaluate an herbal antifungal emulgel using Agave Tequilana extracts known for their antifungal properties. The emulgel was prepared by incorporating an emulsion containing the herbal extract into a gel base of carbopol 940. The formulation was assessed for physical properties, stability, and in vitro antifungal activity against Candida albicans, Aspergillus niger, and Trichophyton rubrum. Results demonstrated that the emulgel had a suitable pH, viscosity, and spread ability, remained stable under various conditions, and exhibited significant antifungal activity. Ex vivo skin permeation studies confirmed effective penetration of the herbal extract. This herbal emulgel presents a promising alternative for antifungal treatment, combining the benefits of natural extracts with enhanced drug delivery. Further clinical studies are recommended to validate its efficacy and safety.

1. INTRODUCTION

Emulgel is a combination of emulsion and gel, which is a new approach for topical delivery of drugs. It has a double control release like emulsion and gel. Gel is new class of formulation, it releases the drug faster in comparison of ointment, cream and lotion.

Drugs derived from natural sources play a significant role in prevention and treatment of Human diseases in many developing countries, traditional medicine is one of the primary health care systems. Herbs are widely exploited in the traditional medicine and their curative potentials are well documented.

Herbal medicines have been known to man for centuries. Therapeutic efficacy of many indigenous plants for several disorders has been described by practitioners of traditional medicine. About 61% of new drugs developed between 1981 and 2002 were based on natural products and they have been very successful, especially in the areas of infectious disease and cancer. Recent trends, however, show that the discovery rate of active novel chemical entities is declining. Plants are rich in a wide variety of secondary metabolites such as tannins, terpenoids, alkaloids flavonoids glycosides etc. which have been found in antifungal properties. In the current investigation carried out, a screening of emulgel of Agave tequilana tree leaves against fungi is done in order to detect new source of antifungal agents.

Agave tequilana, usually called blue agave (agave Azul) or tequila agave, is an agave plant that is a significant financial result of Jalisco, Mexico, because of its job as the base element of tequila, a famous refined drink. The high creation of sugars named agavin, generally fructose, in the centre of the plant is the vitally trademark that makes it appropriate for the arrangement of cocktails.

The tequila agave is local to the provinces of Jalisco, Colima, Nayarit and Aguascalientes in Mexico. The plant Favors elevations of in excess of 1,500 meters (5,000 ft) and fills in rich and sandy soils. Blue agave plants develop into enormous succulents, with spiky plump leaves, that can arrive at north of 2 meters (7 ft) in level.

Blue agaves sprout a tail when around five years of age that can grow an extra 5 meters (16 ft); they are finished off with yellow flowers. The tail is cut off from business plants so the plant will invest additional time into the heart.

The blossoms are pollinated by the more noteworthy long-nosed bat (and by bugs and hummingbirds) and produce a few thousand seeds for each plant, large numbers of them sterile. The plant then kicks the bucket. Developed plants are replicated by establishing the recently taken out shoots; this has prompted an impressive loss of hereditary variety in developed blue agave.

It is seldom kept as a houseplant, however a 50-year-old blue agave in Boston grew a 9 m (30 ft) tail requiring an opening in the nursery rooftop and blossomed in the late spring of 2006.

Agave Azul (blue agave) is utilized in the creation of tequila. It is local to the Caribbean as well as numerous districts of Mexico like Colima, Nayarit, Jalisco and that's just the beginning. In 2001, the Mexican government and European Association settled upon the characterization of tequila and its

classes. All 100 percent blue agave tequila should be produced using the A. tequilana 'Weber's Blue' agave plant, to thorough particulars and just in specific Mexican states.

Blue agave is altogether unique in relation to different kinds of agave since it is higher in fructose and a lot better contrasted with the rest. It is likewise the essential hotspot for agave nectar, a sugary sugar made for utilization.

NEED OF WORK

Herbs have been prized for their healing abilities and today we still rely on the curative properties of plants. After nearly two centuries of inexorable decline in the use of herbal medicines; herbs, which have always been the principal form of medicine in developing countries, are once again gaining popularity throughout the developed world. Post 2005, with the new patent regime knocking the doors of the pharmaceutical industry, standardization of herbals were a key issue.

Ayurveda is a potential source of indigenous drugs. It is the ancient Indian system of medicine strongly believes in polyherbal formulations and scientists of modern era often ask for scientific validation of herbal remedies, therefore there is a ne d for exhaustive study on the various herbal medicinal plants from Phyto- chemical and pharmacological point of view.

The medicinal herb is a biosynthetic laboratory as it contains number of chemical compounds like glycosides, alkaloids, resins etc. These compounds exert therapeutic effect and account for medicinal property of the medicinal herb.

Medicinal plants are also important for pharmacological research and drug development, not only when plant constituents are used directly as therapeutic agent, but also when they are used as basic materials for synthesis of drugs or as models for pharmacologically active compounds.

In the present dissertation work has been performed on leaves of A. tequilana. Different parts of A. tequilana are reported in ayurvedic medicines for valuable treatment of variety of conditions like counter- irritant in rheumatism, neuralgia, headache otalgia, earache and anthelmintic and fungal treatments. Efforts have been made to find out the antifungal activity of the hydroalcoholic extract along with screening of emulgel formulation an its evaluation for antifungal activity.

2. Aim and Objectives:

AIM: - Research work is based on the evaluation of herbal Emulgel of Agave tequilana Tree leaves for human pathogenic anti-fungal potential

The aim of the study is to assess the antifungal activity and to determine the zone of inhibition of extracts on some fungal strains.

Objective: -

This study is carried out with an objective to investigate the antifungal potentials of leaves Agave tequilana Tree.

In the present study, the antifungal activity of hydroalcoholic extracts of leaves of Agave tequilana Tree plant is planned to evaluate for potential antifungal activity against human pathogenic plant using disc diffusion method.

The formulation of emulgel and its antifungal activity were studied in this review.

3. PLAN OF WORK

- **A. Material and Method:**
- **B. Collection of plant material.**
- **C. Pharmacogenetic study.**
- **D. Formulation of emulgel**
- **E. Evaluation test for phytoconstituents**
- **F. Evaluation for formulated product.**

A. Material and Method

Figure 1. Agave Tequilana Leaf.

Figure 2. Dried leaves of Agave Tequilana Plant.

a) Plant Material

- **Organoleptic properties: -**

Plant is spread around 1.8-3.0 m (6-10 ft) with grey-green leaves of long that may reach a total

Color: Dark-Green, **Odour:** Characteristic **Taste:** Bitter

Height: 0.9-1.5 m (3-5 ft) to 8-9 m (25-30 ft).

B. Collection and Drying-

Mature leaves of Agave tequilana Tree were collected From the Hadapsar Industrial estate. They were cleaned and dried at room temperature in shade and away from direct sunlight. The dried leaves will be coarsely powdered in grinder. Large difference in particle size of crude drug results in long extraction time as the coarse particles increases the extraction time and fine may form bed, so the powdered material was sieved through 60-120 mesh to remove fines and larger particles and the powder is subjected for further study.

Figure 3. Grinded Powder of Agave Tequilana Leaves

C) Pharmacognostic Study

- **PLANT NAME: - Agave tequilana**

Figure 4. Vertical image of leaves of Agave

- **Scientific Classification**

  - Kingdom: Plantae
  - Class: Liliopsida
  - Order: Asparagales
  - Family: Asparagaceae
  - Genus: Agave
  - Species: A. tequilana

- **Botanical Name**: -

Agave tequilana Tree

- **Synonyms: -**

Blue Agave, Agave Azul

- **Description**

Agave rosettes are generally monocarpic; however, a few animal categories are polycarpic. During blooming, a tall stem or "pole" ("quiote" in Mexico), which can develop to be 12 meters (40 feet) high, develops apically from the focal point of the rosette and bears an enormous number of short, rounded blossoms and in some cases vegetatively delivered bulbils (a type of agamic propagation).

After fertilization/treatment and ensuing natural product advancement, in monocarpic species, the first rosette passes on. Nonetheless, all through the lifetime of numerous Agave species, rhizomatous suckers foster over the roots at the foundation of the rosette.

These suckers proceed to frame new plants after the first rosette dries up and dies. Not all agaves produce suckers all through their lifetimes; a few animal types seldom or never produce suckers, while others may just foster suckers after definite development with inflorescence.

A few assortments can live for a considerable length of time before flowering.

- **Habitat**

The tequila agave is native to the Different states of India. The plant favors altitudes of more than 1,500 meters (5,000 ft) and grows in rich and sandy soils. Blue agave plants grow into large succulents, with spiky fleshy leaves, that can reach over 2 meters (7 ft) in height. Blue agaves sprout a stalk (quiote) when about five years old that can grow an additional 5 meters (16 ft); they are topped with yellow flowers. The stalk is cut off from commercial plants so the plant will put more energy into the heart.

- **Parts used: -**

-Aerial part of plants like

- Penca (leaf) cabeza (leaf bases)

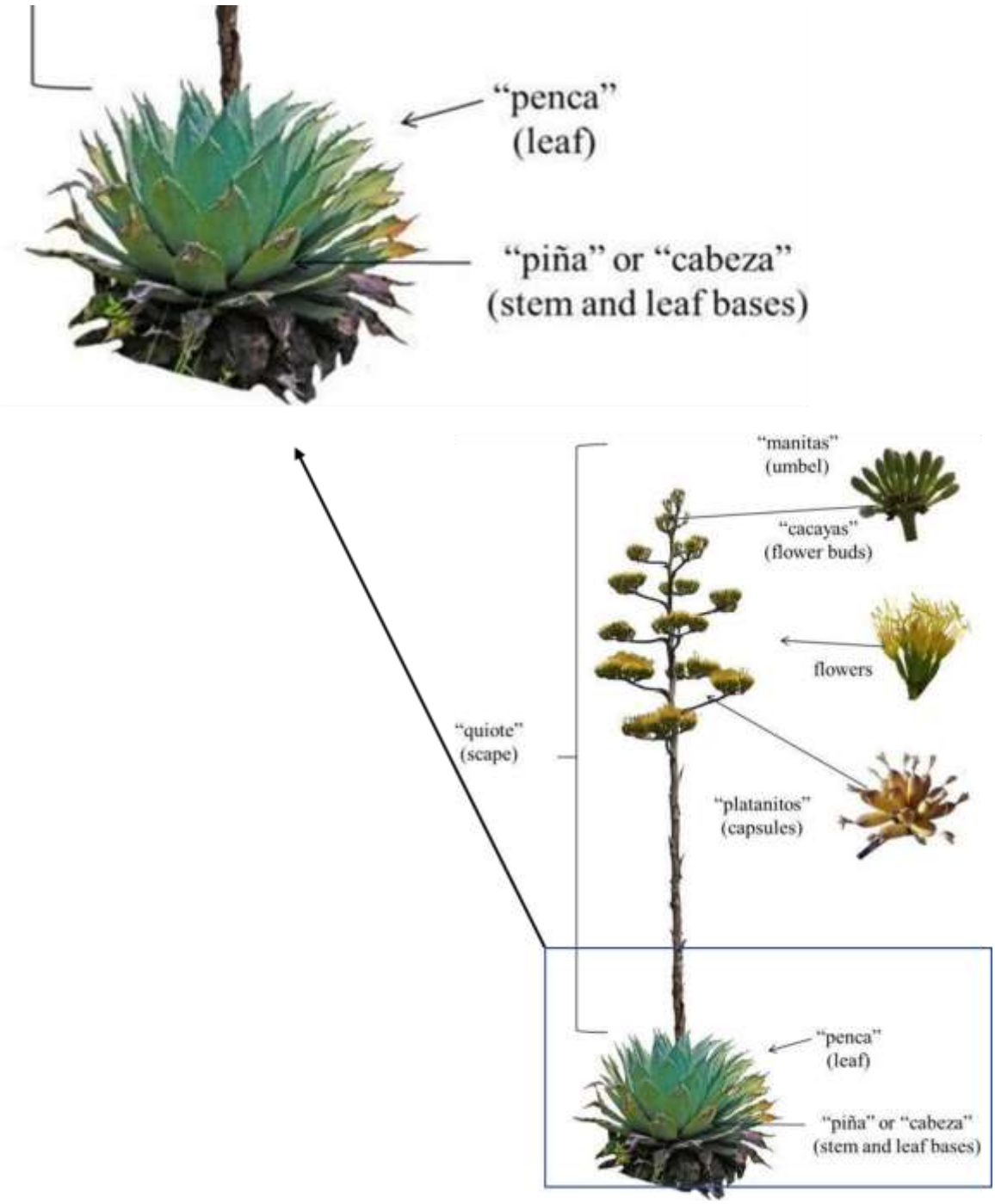

Figure 5. Agave Tequilana Plant

- **Traditional use**

1. Aguamiel or agave juice is the yellow sap with herbaceous scent that is obtained from the ripe maguey that contains various sugars principally sucrose and fructose, and other macronutrients such as protein, micronutrients such as amino acids, minerals and vitamins, and also has composites with a potential functional such as the phenolic compounds and *saponins*.
2. Agave syrup (commonly called agave nectar), a sweetener derived from the sap, is used as an alternative to sugar in cooking, and can be added to breakfast cereals as a binding agent.
3. The agave sweetener is marketed as natural and diabetic-friendly, without spiking blood sugar levels

D) FORMULATIONS OF EMULGEL

Sr. No	INGRIDIENTS	WEIGHT	USES
1	Hydro alcoholic extract	5 gm	Amelioration
2	Carbopol -934	0.75 gm	Polymer
3	Span - 80	0.45 ml	Surfactant
4	Tween - 80	0.50 ml	Emulsifier
5	Liquid paraffin	2.5 ml	Emollient
6	Propylene Glycol	3.5 ml	Maintaining moisture
7	Methyl paraben	0.01 gm	Preservative
8	Water	q.s for 20 gm	Vehicle

Table 1. formulation table

Figure 12. Ingredients and Drugs

Procedure for extraction:-

Figure 13. Extraction of Agave Tequilana

- Step 1. –

Take a clean conical percolation / maceration apparatus. aand lock the knob.

- Step 2. –

Add cotton at the bottom of apparatus.

- Step 3. –

Add drug i.e agave tequilana powder 10gm.

- Step 4. –

Add the organic solvent disttiled water / ethanol . we have added 100 ml of ethanol for the extraction process.

- Step 5. –

Keep the apparatus in dark place for 24 hours.

- Step 6. –

Open the knob in such a way that drop wise extraction is collected in beaker.

- Step 7. –

Filter the collected extract using whatman filter paper. And keep the extract in well closed container.

Procedure for formulation:-

1. The gel portion of the emulgel were made by dissolving carbopol-934 in cold water with constant stirring at a moderate speed until uniform mixture were made.
2. The pH was then adjusted to 6-6.5 using triethanolamine (TEA). Tween80 was dissolved in distilled water to prepare the aqueous phase of the emulsion while for the preparation of the oil phase of the emulsion, span 80 were dissolved in liquid paraffin.
3. To preserve the emulsion, methyl parabene was dissolved in propylene glycol and the extract were dissolved in ethanol then both solutions were mixed with the aqueous phase.
4. Both the aqueous and the oil phase is heated in a water bath at 70 °C separately.

Figure 12. Heating at 70°C

5. Then the oil phase was added drop wise to the aqueous phase with continuous stirring using homogenizer 50 at speed of 3000 rpm for 10 min then cold to room temperature.
6. At the end the gel and emulsion portions were mixed in 1:1 ratio with moderately stirring to prepare emulgel.

E) EVALUATION TEST FOR PHYTO-CONSTITUENTS

1. <u>Test for Steroids</u>

a) Salkowski test:-

One ml of concentrated sulphuric acid was added to 10 mg of extractdissolved in 1 ml of chloroform. A reddish brown colour exhibited by chloroform layer and green fluorescence by the acid layer suggests the presence of steroids.

Expected result for steroids – should show presence in hydro-alcoholic extract.

2. <u>Test for Saponins.</u>

Figure. 6. Sakowski Test

a) Foam formation test

One ml solution of the extract was diluted with distilled water to 20 ml liquid shaken in a graduated cylinder for 15 minutes. The development of stable foam indicates the presence of saponins.

Expected result for saponins:- should show presence in hexane extract and hydro alcoholic extract.

3. Test for Alkaloids

a) Dragendorff's test

01 ml dilute hydrochloric acid and 0.1 ml Dragendorff's reagent was added in 2 ml of extracts in test tube. Formation of orange brown precipitate indicates thepresence of alkaloids.

Figure.7. Dragendroff Test

b) Wagner's test

2 ml of extract was treated with 0.2 ml dilute hydrochloric acid and 0.1 ml of Wagner's reagent. Formation of reddish-brown precipitate indicates the presenceof alkaloids.

Expected result for alkaloids- should show presence in hydro alcoholic extract.

4. **Test for Tannins**

a) Ferric Chloride test

Five ml of extract solution was allowed to react with 1 ml of 5% ferric chloride solution. Greenish black colouration indicates the presence of tannins.

Figure 9. Ferric Chloride Test

Expected result For Tannins – should show presence in hydro alcoholic extract.

6. Test for Carbohydrates.

Figure 10. Molisch Test

a) Molisch test

Two ml of extract solution was treated with few drops of 15 per cent ethanolicalpha-naphthol solution in a test tube and 2 ml of concentrated sulphuric acid was added carefully along the sides of the test tubes. The formation of a reddish violet ring at the junction of two layers indicates the presence of carbohydrates

Expected result For Carbohydrates :- should show presence in hexane extract and hydro alcoholic extract

7. Test for reducing sugars

a) Fehling's test

Five ml of extract solution was mixed with 5 ml of Fehling's solution equal mixture of Fehling's solution A&B & boiled. Formation of brick red Precipitate indicates the presence of reducing sugars.

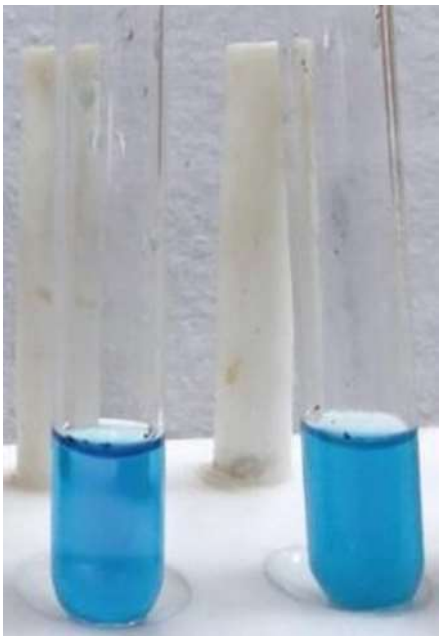

Figure 11. Fehling's Test

Expected result For Reducing sugars:- should show presence in hydro alcoholic extract.

Figure 13. Formulation

Figure 14. Label of Formulation A

Figure 15. Label of Formulation B

F) EVALUATION OF FORMULATION: -

A. Physical evaluation:-

Colour, odour, texture, and state of serum.

Sr.no.	Evaluation parameter	Batch 1
1.	Colour	Pal green
2.	Odour	Pleasant
3.	Texture	smooth
4.	State.	Semisolid.
5.	Homogeneity	complies

Table 2. Physical evaluation

Figure 16. Physical Evaluation

B. pH: -

pH measures the acidity or alkalinity of a solution on a scale from 0 to 14, with 7 being neutral, below 7 acidic, and above 7 alkaline. It's the negative logarithm of hydrogen ion concentration in moles per Liter.

The pH of human skin typically ranges from 4 to 6, slightly acidic, which helps maintain the skin's natural barrier function and protect against harmful microbes.

Figure 17. pH Reading

Sr. no.	Evaluation parameter	Batch 1
1.	pH	5.83

Table 3. pH values.

C. Phase separation: -

Phase separation occurs when the different components of a mixture, such as water-based extracts and oil-based carriers, separate into distinct layers over time. This can happen due to differences in polarity, density, or solubility. To prevent phase separation in herbal roll-on deodorants, emulsifiers (like beeswax or lecithin) can be added to stabilize the mixture, ensuring a consistent product. Regular shaking before use can also help maintain the uniformity of the deodorant. The prepared cream was kept at Room temperature for about 15- 30 days. Away from light, in a sealed / air tight container.

Figure 18. Phase Separation

Sr. no.	Evaluation parameter	Batch 1
1.	Phase separation	No phase separation

Table 4. Phase Separation.

D. Irritation and Edema: -

On the dorsal surface of the left hand, a $1cm^2$ mark was made. Serum was applied to the area. The area was monitored for 24 hours, and any signs of irritancy or edema were noted and reported.

Figure 19. Before and After Application of Emulgel

Sr.no.	Evaluation parameter	Batch 1
1.	Irritation	yes
2.	Edema	no

Table 5. Irritation and edema result.

5. Antifungal Assay

- The fungal strains of Rhizopus were collected .
- This strain has been selected for the basis of its application purpose of further formulation study.
- Anti-fungal potential of extracts were assessed in terms of zone of inhibition of bacterial growth

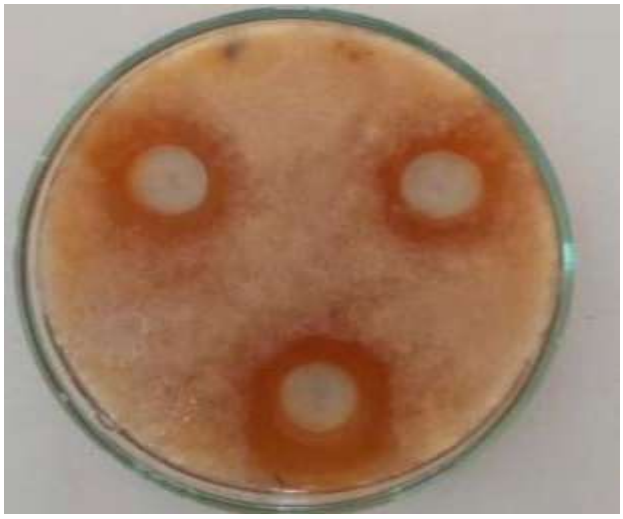

Figure 20. Zone of Inhibition

- Antifungal activities of the extracts increased linearly with increase in concentration of extracting (µg/ml).
- As compared with standard drugs, the results revealed that in the extracts for fungal activity, Rhizopus shows good result as compare with Aspergillus Niger and Mucor.

- The growth inhibition zone measured ranged from 11 to 20mm for all the sensitive bacteria, and ranged from 14 to 20 mm for fungal strain.

8. Conclusion

Hydro-alcoholic Extract of Agave tequilana Tree leaves will show prominent anti-fungal activity against human pathogenic, thus Agave tequilana Tree leavescan be used as a potential antifungal drug against human pathogenic fungal infection.

Agave tequilana Tree showing Preliminary Phytochemical screening

Hydro- Alcoholic Extract shows presence of Steroids, Saponins, Tannins, Flavonoids. Benzene Extract shows presence of Steroids,Saponins, are present.

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