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Formulation And Evaluation Of Oral Antiulcer Gel From "Taproot Extract Of Daucus Carota"

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Abstract: The mouth ulcer often caused pain and discomfort and may alter the person choice of food while healing occurs. Mouth ulcer is small painful ulcers which typically have a red border and yellow-gray centers. Mouth ulcers can be treated by topical antihistamines, antacids, and corticosteroids, also there have natural method to treat the mouth ulcer which done by herbal medicine by using Daucus Carota. The purpose of present research work was to design, develop and evaluate of oral antiulcer gel containing ethanolic taproot extract of Dacus Carota. Carrot (Dacus Carota) is the main source of Beta Carotene. The beta carotene in carrot can be obtained by chemical preparation. In this project work the suitable solvent is selected for extraction of Daucus carota. By using excipients such as propylene glycol, Methyl paraben, Propyl paraben, Triethanolamine and water the gel is prepared in which Daucus carota extract is main active ingredient. The formulation and Evaluation of gel was carried out.

Keywords: Mouth ulcer, Herbal Gel, Carbopol 934.

Introduction:

Pharmaceutical gel:-

Gels are typically semi-solid formulations having a liquid phase that has been thickened with other components. Uses of topical gel preparations are for skin application or percutaneous penetration of medicament or local action to certain mucosal surfaces.

fig.1.antiulcer gel

A mouth ulcer is a break or breach in the mucous membrane, which is lines the inside of the mouth. It usually has yellow or white colour and usually looks like a depression in mouth that is the mucous membrane. We can use topical gel for the treatment of the mouth ulcer.The Commercially available gels containing synthetic and semi synthetic active agents like cabapol 934, acetone, triethanolamine, propylene, Glycol, propyl paraben.[1]
Gels formulations for skin application or to certain mucosal surfaces for local action. The gels formulations base must have acceptable mucoadhesion so that the medication remains on the spot of application for a longer time. The more acceptable remedies are natural that they are safer and lesser side- effects than the synthetic medicines.[8]

Properties of gel:-[2,3&4]

- Ideally, the gelling agent, safe and cannot react with other formulation constituents.
- They can be wash off easily and nontoxic in nature.
- It should have suitable anti-microbial agent.
- The topical gel must not be sticky.
- The ophthalmic gel must be sterile.
- The topical gel should be inert in nature.
- It can be adhered well to the site of application.

Advantages of gel:-[5]

- Stay away from the first-pass metabolism.
- Convenient, acceptable, and simple to implement.
- Increase patient adherence.
- It can be used for self-medication.

Disadvantages of gel: -.

- The medication and/or excipients can cause skin irritation in people with contact dermatitis.
- Some medications have a low permeability through the skin or mucous membrane, which might lead to allergic responses.

Mouth ulcer:-

An oral ulcer (also called a mouth ulcer or mucosal ulcer) is an ulcer that occurs in the mucous membranes of the mouth. They are painful round or oval ulcers that form in the mouth, inside the cheeks or lips.

Mouth sores, also known as aphthous sores, can be painful when we eat, drink, or brush our teeth. A mouth ulcer is a fracture or fracture of the mucous membrane, located in the middle of the mouth.

It is usually yellow or white and usually looks like pressure on the mouth which is a mucous membrane.[6]

Mouth ulcer it can be caused by various etiological factors such as chemical, dental injury, nutrition deficiency, hormones, acidic food. Although many formulations like solution, suspension and ointments are commercially available, no therapy can be said completely useful for the treatment of mouth ulcer.

fig.2.mouth ulcer

Symptoms of a mouth ulcer:-[5]

- Swelling around the ulcer.
- Increased soreness when brushing your teeth.
- Pain that worsens when eating spicy, salty, or sour foods.
- Problems with chewing or tooth brushing because of the tenderness.
- Appear as extremely painful ulcer in the mouth.
- Appear anywhere in the mouth.

Types of mouth ulcer:-[10&11]

Mouth ulcer can be classified as minor, major and herpetiform. The main types of mouth ulcer are:-

type 1.minor ulcer | type 2.major ulcer | type 3.herpetiform ulcer

Fig.3.types of mouth ulcer

Minor mouth ulcer: - Small round or oval ulcers known as mild canker sources Minor aphthous ulcers are less than 5 mm in diameter and heal in 7–14 days.

Major mouth ulcer: - Canker sources big in size and depth are larger and deeper than those are small. Major aphthous ulcers are large ulcers that heal slowly over weeks or months with scarring.

Herpetiform ulcers**:** - Herpetiform ulcers are small and most commonly affect to the adults, multiple pinpoint ulcers that heal within about a month.

Causes of mouth ulcer: -

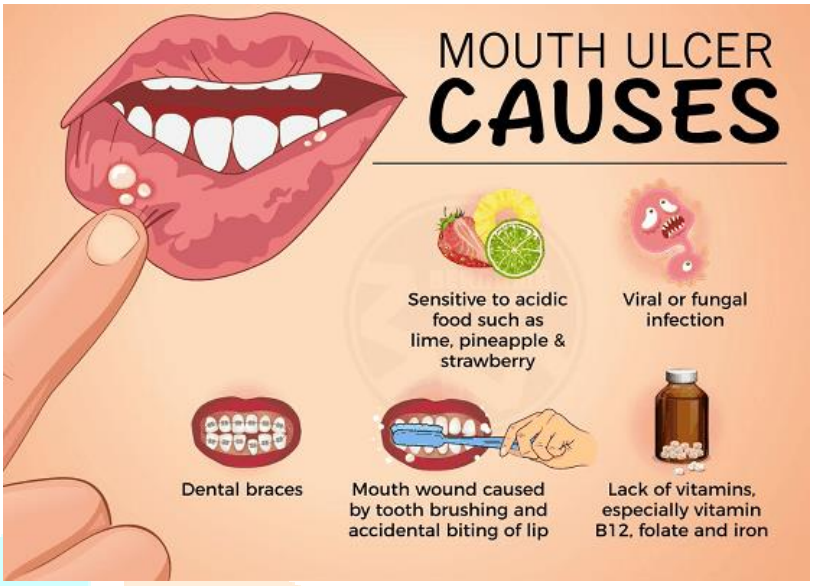

fig.4 cause of mouth ulcer

There are different causes which can contribute to the development of sores: -

- Quitting smoking.
- Citrus fruits and other foods high in acidity or spice.
- Biting the tongue or inside of the cheek.
- Braces, poor-fitting dentures, and other apparatus that may.
- Stress or anxiety.
- Hormonal changes during pregnancy, puberty, and menopause.
- Medications including beta-blockers and pain killers.
- Genetic factors.
- Lack of sleep.
- Viral, bacterial, and fungal infection.
- Allergic reaction due to certain bacteria.
- Vitamin deficiency.

How to get rid of mouth ulcer: -

There are many factors responsible for development of mouth ulcer, mouth sores are quite painful and also cause discomfort while eating. Adjusting your diet like avoiding spicy and sour foods in addition to taking medicines is normally recommended, there are effective natural ways to deal with mouth ulcer. The different effective herbal remedies that might help in relieving pain and discomfort caused due to mouth ulcers.

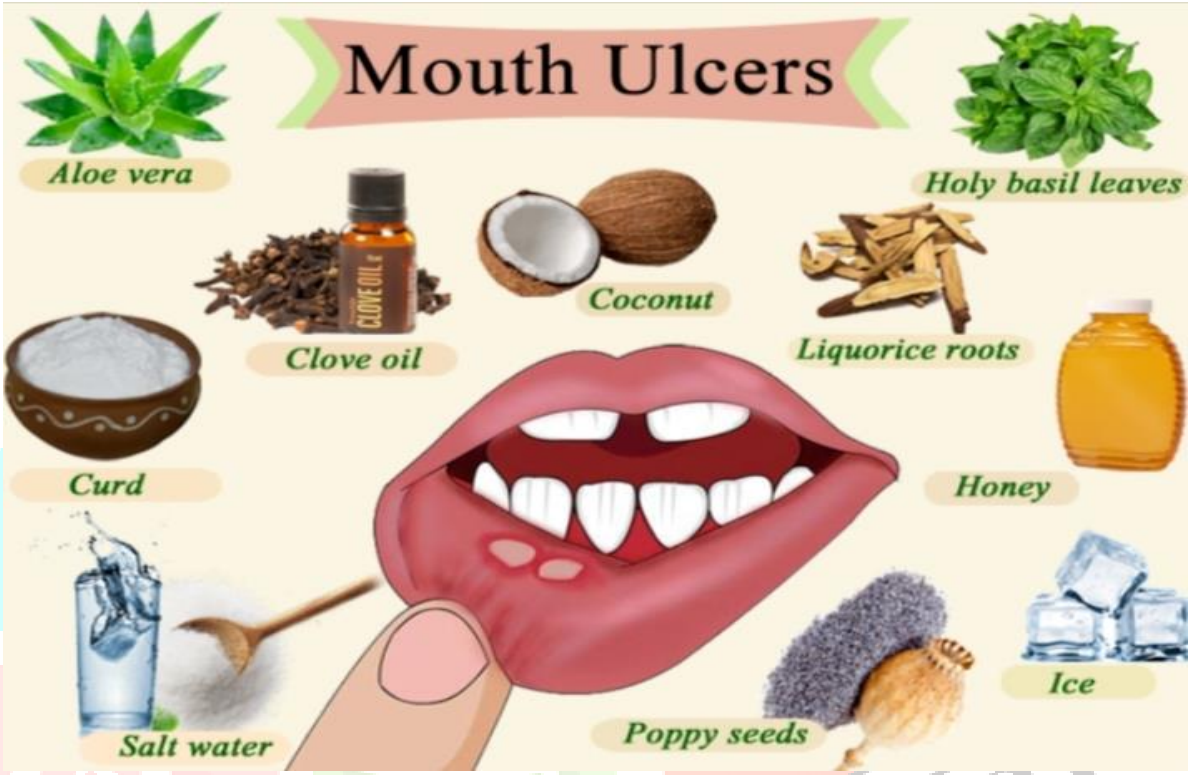

fig.5.natural remedies for mouth ulcer

Plant profile of "Daucus carota L":[12 &13]

The carrot (Daucus carota L.) is one of the richest sources of naturally occurring β-carotene while red and yellow carrot varieties contain large quantities of lycopene and lutein. The human body utilizes carotenoids, particularly β-carotene (provitamin A) as a precursor for the production of retinol. Carrots contain an impressive selection of phytochemicals, including carotenoids, anthocyanins, and other phenolic compounds.

The most eaten part of the plant is the taproot although the steam and leaves are also eaten. The domestic carrot has been selectively bred for it's enlarged, more palatable, less woody textured taproot.

Fig.6.carrot

Synonym: Carota sativa, gajor, Daucus sativus.
Biological source: It can be obtained from the root part of 'Daucus carota sativus'.
Family: it can be belonging to the family **Apiceae**'
Chemical constituent: Carrot contains carotenes, especially alpha and beta carotenes, vitamin A, vitamin C and dietary fibre. It is rich in calcium and potassium; red carrots also contain lycopene.
Geographical source: Europe and West and central Asia.
Cultivation and collection: At first, it grows a rosette of leaves while building up the enlarged taproot. Fast growing cultivars mature within three months (90 days) of sowing the seed, while slower maturing cultivars need a month longer (120 days).
Uses:-

- Juice of carrot, beetroot and cucumber eliminates headache and cures rheumatism.
- Protects skin from sun damage and regulates sebum production.
- Anti-aging properties & treat skin infection, inflammation. A potassium deficiency may result in consistent dry skin.
- However, carrots are a rich source of potassium that helps to hydrate and moisturise your skin. Slices of raw carrot and beetroot with lemon juice sprinkled on it cures anemia.
- It acts as an antioxidant so it can be helpful for to cure wound healing.

Beta carotene:[15,16,17&18]

Beta-carotene is a pigment found in plants, especially in carrots, that gives them their characteristic orange colour. It is a precursor to vitamin A, which is essential for maintaining healthy vision, skin, and immune function.

Beta-carotene extract from carrots is a popular dietary supplement due to its antioxidant properties. It helps protect cells from damage. Additionally, betacarotene has been linked to potential health benefits such as reducing the risk of certain cancers, improving skin health, and supporting eye health.

Beta-carotene has been studied for its potential benefits in promoting oral health and wound healing, including in the treatment of mouth ulcers. Mouth ulcers, also known as canker sores, are painful sores that can develop on the inside of the mouth, lips, or throat.

Beta-carotene is a precursor to vitamin A, which plays a crucial role in maintaining healthy mucous membranes, including those in the mouth. Vitamin A is essential for cell growth and repair, which are important processes in wound healing.

Determination of carotene with the help of thin layer chromatography:[14&18]

Determination of $\boldsymbol{\beta}$ carotene from extracts:

For determination of beta carotene, we performed the thin layer chromatography (TLC).

Mobile phase – Acetone: Water 9: 1

Procedure:

1. Slurry of silica gel was prepared with appropriate thickness and consistency.
2. Slide was prepared by spreading silica gel for preparing continuous film on the slide.
3. The slide was kept an oven at 37 °c temperature for appropriate time for activation.
4. Small part of extract was taken into the capillary and a drop of extract was applied on the activated slide.
5. Mobile phase of acetone and water was prepared with given concentration.
6. The prepared slide was kept into the mobile phase and allowed it to run over up to 80 % of the slide.
7. The slide was removed and allowed to dry, and Ninhydrin reagent was spread on the slide till the formation of spot was observed.
8. Once the spot was detected calculation for Rf value was done for confirmation of β carotene.

Extraction of Beta carotene from carrot:

Glassware:
Beaker, Stirrer, Funnel, Separating funnel, Stand, Petri Plate, Measuring cylinder, Glass, Stirring rod, Thermometer, water bath , Pipette, Spatula.
Chemicals:
Alcohol, Petroleum ether, Carrot.
Equipment:
Mixer

Procedure:

1) Fresh carrots were collected and washed thoroughly and cutted into small pieces.
2) These cutted pieces of carrots was grinded with 166.6 ml of ethanol, boiled on hot water both for 15 min and kept it closed for 5 mins.
3) The grinded mixture was filtered off and the filtrate (extract) of carrot was Collected.
4) Then, 20 ml of extract was added to a separating funnel & 20 ml of petroleum Ether was added in the same separating funnel and these two layers were gently shaken for about 15 mins.
5) The separating funnel was kept stable until two layers get separated.
6) The upper layer containing beta carotene was collected.

fig.7.

fig.8.

fig.9.

fig.10

fig.11.

fig.12.

fig.13.

AIM AND OBJECTIVES: -

Aim: -

Formulation and Evaluation of oral antiulcer gel from Daucus carota extract.

Objective: -

1 .To determine the prepare gel formulation is effective in the management of mouth ulcer.

2. Mouth ulcer is painful sore on the tongue, the inner surface of lip and inside of cheeks.

3. It can be cause by disease, nutrition deficiencies, stress.

4. They are usually self heal in 10-15 days.

Need of Investigation:

Methods and Materials for preparation of mouth ulcer gel:

table no. 1: formula

Materials	Quantity	Role
carbopol 934	2.4 gm	Gelling agent
Methyl paraben	0.6 gm	As preservative
Propyl paraben	0.4gm	As preservative
Propylene glycol	4ml	Base
Triethanolamine	Adjust pH 6.5 to 7	To adjust the pH
Distilled water	Sufficient quantity	Aqueous base
Extract(Daucus carota)	8ml	Antiulcer activity

Preparation of herbs gel:

- Take 15 ml of distilled water in a beaker and disperse specified amount of Carbopol 940 in it with Continuous stirring.
- Kept the beaker aside to swell the Carbopol for half an hour.
- In another beaker take 5 ml of distilled water and add required quantity of methyl paraben and propyl paraben to it by heating on water bath.
- Cool the solution then add Propylene glycol 400.
- Further required quantity of extract was added to the above mixture and this solution was mixed properly to the Carbopol 940 gel with Continuous stirring.
- Finaly volume made up to 30 ml by adding remaining distilled water and Triethanolamine was added drop wise to the formulation for adjustment of required mouth skin pH (6.8-7) and to obtain the gel at required consistency.

fig.14.

Evaluation parameter:[19,20,21,22]

1] Ph of the gel:

The pH of a mouth ulcer gel is an important factor to consider, as it can affect the efficacy and comfort of the product when applied to the sensitive tissues inside the mouth. The ideal pH for a mouth ulcer gel is typically in the range of 5.5 to 7.0, which is close to the natural pH of the oral cavity. It can help promote healing, minimize discomfort, and maintain the natural balance of the oral cavity.

Determination of pH:

The pH of herbal gel formulations was 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.

Result: pH of the gel was found to be 6.7.

2] Determination of visual appearance:

The prepared gels were tested for colour, clarity, texture, transparency, and presence of any gritty particles.

Result: colour: white
Odour: natural aroma
Taste: sweet

3) Clarity

The clarity it can be determined by visual inspection.

4) Extrudability:

The gel formulations were filled in standard capped collapsible aluminium tubes and sealed to the end. The Extrudability was determined by pressing of the Thumb.

5) Homogenosity:

All developed gel formulations were tested for homogeneity by visual inspection after the gels have been set in to the container. By visual appearance we have to observe any aggregate can be formed in formulation or not.

Result: The result was found to be a good homogenosity.

6) Spreadibilty:

In this we have check the gel is easily spread or not at the site of action. It can be gives any side effects or not the test it can be done after the spreading gel on mouth sores.

Result: It was found that the gel it can be easily spread and it can't be felt irritated at the site of action.

7) Viscosity:

The viscosity of all the prepared formulations was analyzed by the Brookfield viscometer.

Result: The result was found that the prepared gel is viscous in nature.

8) Stability study:

table no. 2 : stability study

Open container	**Closed container**
Not stable	Stable

One month stability study was done with open and close container and it's showed that open container containing gel was not stable and close container gel was stable. Formulated gel containing open container when expose to ambient room temperature then syneresis was observed it means the contraction of gel by separating out of liquid. Syneresis, it means the form of instability in aqueous gels.

9) Zone inhibition study:

table no . 3:zone inhibition study

S. aureus	C. albicans
20+_0.5	18+_0.6

fig.15.zone inhibition in prepared gel

fig.16.micobial assay of a .mexicana

The gel formulation shows antibacterial and antifungal activity against S. aureus and Candida albicans. Also A. Mexicana shows antimicrobial activity against S. aureus. S. aureus is the main microorganism to treat mouth ulcer and formulation it can also use to treat mouth ulcer treatment.

Result and discussion:

The prepared gel formulations were evaluated for parameters such as physical appearance, pH, homogeneity, spread ability and viscosity. The observation reveals that the gels were having smooth texture and were elegant in appearance. All the prepared gels showed good homogeneity with absence of lumps. The developed preparations were much clear and transparent. The viscosity of all the developed gels was found to be excellent and within the range.

Conclusion:

From the mentioned results, it was concluded that the prepared gel formulations are in good appearance with suitable pH range. Formulated gel have good homogeneity, proper gel strength & spread ability. The gel is neither too thick nor too thin. The all formulated gels are found to be stable in closed container as compared to open container. The formulation showed the antibacterial and antifungal activities against Staphylococcus aureus and Candida albicans.

Therefore, the study concluded that the natural remedies are more acceptable & they are safer with minimum side effects than synthetic preparations. Thus, the data presented in this study, it was concluded that the formulated gel of powdered possesses a significant therapeutically efficacious & have suitable vehicle for drug delivery. Thus, the formulated gel is suitable for treatment of mouth ulcer.

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