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Formulation and Evaluation of Aqueous Gel of Custard Apple Leaves in the Treatment of Mouth Ulcer

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ABSTRACT

The main objective behind this formulation of herbal Custard Apple Leaves gel was to overcome the pain & discomfort by the mouth ulcers. As we know there are different types of mouth ulcers that cause inflammation & pain. The most common oral ulcers are Local trauma & Aphthous Stomatitis. Now a day's lots of herbal medicines are important stay of primary healthcare because of good response & highly efficient treatment with less amount of side effects. The formulated gel contains main ingredients is Custard Apple Leaves Powder & Carbopol 940 as gelling agent & Propylene glycol as co-solvent. The other ingredients as Haldi & Lavang act as antiseptic & antifungal agents. The formulated gel was evaluated for different parameters like physicochemical parameters (pH, viscosity, spreadability, etc.), zone of inhibition, etc. The formulated gel was made transparent homogeneous mixture with pH ranges between 6-7.5. This herbal gel was stable at room temperature which is protected from any of microorganisms & thus it is safer for use for mouth ulcers. An ulcer is a break in the skin or mucous membrane with loss of surface tissue and the disintegration and necrosis of epithelial tissue. A mucosal ulcer is an ulcer that specifically occurs on a mucous membrane.An ulcer is a tissue defect that has penetrated the epithelial-connective tissue border, with its base at a deep level in the submucosa, or even within the muscle or periosteum.

Keywords: Oral ulcer, Custard Apple leaves, Haldi, Lavang, Carbopol 940 & Gel.

INTRODUCTION

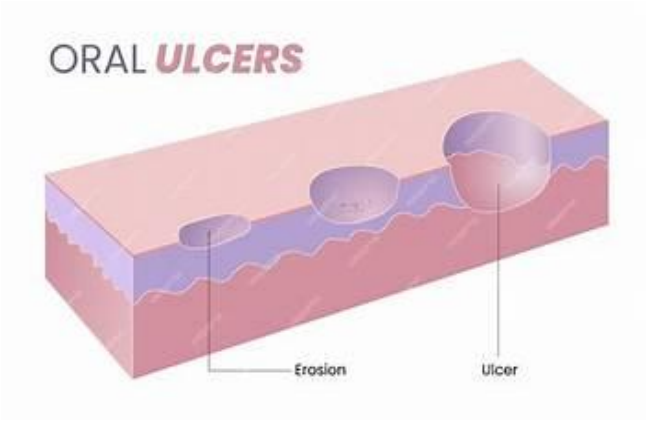

Fig. 1: Diagrammatic representation of mucosal erosion (left), excoriation (Centre), and ulceration (right)

Mouth Ulcer A mouth ulcer (also termed an oral ulcer or a mucosal ulcer) is an ulcer that occurs on the mucous membrane of the oral cavity. They are painful round or oval sores that form in the mouth, mainly on the inside of the cheeks or lips.

Mouth ulcers, also known as aphthous ulcers, can be painful while eating, drinking or brushing teeth. Common causes of mouth ulcers include nutritional deficiencies such as iron, vitamins especially B12 and C, poor oral hygiene, infections, stress, indigestion, mechanical injury, food allergies, hormonal imbalance, skin disease etc.[1] 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 color and usually looks like a depression in mouth that is the mucous membrane.[2]

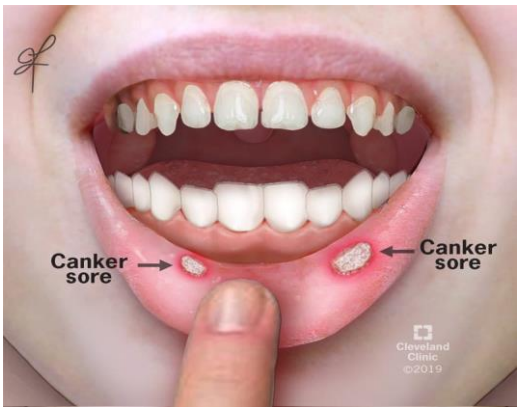

Fig 2: Mouth ulcers are often white or yellow in the middle with red around the edges.

Types of Mouth Ulcer

On the basis of ulcer size and number

1. Minor ulcers: These are around 2-8mm in diameter and they usually clear up in 10 days to 2 weeks.

2. Major ulcers: These are bigger and deeper, often with a raised or irregular border.

3. Herpetiform ulcers: This type of ulcer is a cluster of dozens of smaller sores about the size of pinhead's order.

4. Ulcerative Conditions: Mouth ulcers are very common and are mainly due to trauma such as from ill-fitting dentures, fractured teeth, or fillings.[1]

5. Factors responsible for the mouth ulcers

6. Toothpastes and mouthwashes that contain sodium lauryl sulfate

7. Emotional stress / Psychic stress

8. Hormonal changes

9. Nutritional deficiencies

10. Mechanical trauma

11. Viral infections

12. Allergies and sensitivities

13. Genetics

14. Infectious agents (both bacterial and viral)

Medical conditions.[1]

PATHOPHYSIOLOGY:

Simple mechanisms which predispose the mouth to trauma and ulceration are xerostomia (dry mouth – as saliva usually lubricates the mucous membrane and controls bacterial levels) and epithelial atrophy, making the lining more fragile and easily breached.[5]

Similarly, cutaneous (skin) conditions can also involve the mouth and sometimes only the mouth, sparing the skin. The different environmental conditions (saliva, thinner mucosa, trauma from teeth and food) mean that some cutaneous disorders which produce characteristic lesions on the skin produce only nonspecific lesions in the mouth.[6]

AVOIDANCE FROM MOUTH ULCERS INCORPORATE TAKING AFTER POINTS: -

- Brush your teeth twice day by day and floss once every day for ideal verbal health.
- Use a soft-bristled toothbrush to dodge tissue irritation
- Eat a healthy diet rich in fresh fruits and vegetables.
- Visit your dentist regularly for checkups and cleanings Visit.[7]

TREATMENTS FOR MOUTH ULCERS: -

• Antiseptic gels or mouth rinses like Orajel™ or Anbesol®.

• Steroid treatments like triamcinolone.

• Immunosuppressant (in severe cases).

• Drink a bounty of water.

• Practice great verbal cleanliness to keep your mouth as clean as possible.

• Make a blend of break even with parts hydrogen peroxide and water and flush your mouth twice a day.

• Avoid hot and spicy foods until the ulcer heals.[7]

PLAN OF WORK

1. Selection of materials for experiments: -

- Custard apple leaves
- Carbopol940
- Triethanolamine
- Methyl parabens
- Sodium benzoate

2. Selection of equipment's used for experiments

- Weighing balance
- Hot air oven
- Magnetic stirrer

- PH meter
- Sieving

3. Formulation of aqueous gel involves two steps: -

- Formulation of fine powder particles of custard apple leaves
- Formulation of aqueous gel with the addition of API

4.Evalution test: -

- Measurement of Ph
- Texture
- Homogeneity
- Clarity
- Washability
- Stability study
- Spreadability[16]

MATERIALS USED IN FORMULATION

Table.1: Materials used in formulation.

SR.NO	INGREDIENTS	CATEGORY
1	CUSTARD APPLE LEAVES	ANTIBACTERIAL, ANTIDIABETIC, ANTIOXIDANT
2	CARBOPOL-940	POLYMER
3	TRIETHANOLAMINE	BUFFER, SURFACTANT
4	SODIUM BENZOATE	PRESERVATIVE
5	METHYL PARABEN	PRESERVATIVE

1. FORMULATION OF POWDER OF HERBAL DRUG: -

• In the formulation of aqueous gel custard apple leaves were used as an active medicament ingredient. Custard apple leaves show properties such as antioxidant,antimicrobial, lipid-lowering, and hepatoprotective functions.[23]

• Steps carried out during formulation of powder: -

Cleaning the fresh green leaves of custard apple with the help of water and dry it properly.
For complete drying place it in the oval for 6 hours at temperature 35 to 50 degree Celsius.
After complete drying, crush it with the help of a motel & pestle and make a fine powder of leaves.
Now, the powder is prepared. Allow it to pass from sieve number 80 so that very fine particles can be used for experiment.

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These fine powders should be free from moisture, so place them in the oven for complete loss of moisture.

2.FORMULATION OF AQUEOUS GEL

Quantities of the ingredients

Table.2: Ingredient used in the experiment.

SR.NO	NAME OF INGREDIENTS	F1	F2	F3
1	LEAVES POWDER	0.5g	0.5g	0.5g
2	CARBOPOL-940	0.5g	0.5g	0.5g
3	TRIETHANOLAMINE	1ml	1ml	1ml
4	METHYL PARABEN	0.2g	0.5g	0.2g
5	SODIUM BENNZOATE	0.5g	0.5g	0.5g
6	WATER	50ml	100ml	150ml

Fig.3: Chemicals used in the formulation.

RESULT OF EXPERIMENT

• The results show that all the prepared gel formulations have good homogeneity and gelling properties.

• The pH of all gel formulations was in the range compatible with the normal pH rang.
• The study of Spreadability shows that with increasing the viscosity of formulation Spread ability decreases and vice versa.

• The gelling & bioadhesive strength of all the batches was found in the suitable range.

• One-month stability study was done with an open and closed container and it showed that the open container containing gel was not stable and the closed container gel was stable.

• Formulated gel containing open container when exposed to ambient room temperature then syneresis was observed which means liquid exudates separating.

• There was statistically significant marked improvement of pain symptoms as early as three days post-treatment among patients who were administered.

CONCLUSION OF THE EXPERIMENT

• Developed a new herbal gel formulation that is suitable for mouth ulcer treatment.

• From all the above three groups of formulation, F2 shows all the necessary parameters required to form a gel.

• F3 have a low viscosity and hence appear like a solution.

• As they appear like a solution, they don't have the necessary gel strength and hence get wiped off after applying on the skin.

• The pH of gel formulations was in the range compatible with normal pH range of the skin.

• 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 liquid exudates separating.

• This instability in the open container suggests that the gel is sensitive to environmental conditions, leading to liquid exudates and gel shrinking.

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