

FORMULATION AND DEVELOPMENT OF AYURVEDIC LOZENGES FOR MOUTH ULCER AND HEALTHIER DIGESTION

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Abstract- Mouth ulcers, also known as canker sores, are small, painful lesions present in the buccal cavity with a reddish border that appears to be white or yellow in the middle. The area across the ulcer gets enlarged. It can be caused by various factors such as stress, hormonal changes, consuming highly acidic foods, and some dental procedures such as dental fillings. In this article, the major aim is to formulate oral ayurvedic lozenges that are beneficial for local delivery of drugs in the oral cavity. The rate of dissolution and disintegration time of lozenges are high, which leads to rapid on-set action. This lozenge is prepared from an herbal infusion made from Tulsi leaf, guava leaf, aloe vera gel, liquorice and spices like clove and turmeric, which are added to a mixture of dextrose and honey to make lozenges and later coated with amla powder to maintain moisture. This ingredient has antiulcer, anti-inflammatory, antioxidant, antibacterial, analgesic, soothing, and wound healing properties that help reduce pain, inflammation, and bacterial growth and repair damaged tissue. This formulation has the fewest side effects compared to synthetic formulations and has many other beneficial factors that help to maintain a healthier digestion process.

Keywords: Mouth ulcer, Ayurvedic lozenges, Canker sores, Herbal infused lozenges, Healthier digestion.

INTRODUCTION

A mouth ulcer occurs due to the loss of the upper mucosal lining in the buccal cavity, which leads to irritation, discomfort, and pain while eating and swallowing. There are various factors that cause mouth ulcers, such as viruses, fungi, hormonal changes, stress, aggressive cleaning of teeth, dental procedures, etc. Mouth ulcers are usually found in a rounded form with redness around them, which is associated with inflammation. The healing period depends on the seriousness of the ulcer. If the ulcer has a diameter of approximately 2 mm to 8 mm, it takes around 10 to 14 days to heal, as it is considered a minor ulcer. On the other hand, if the diameter of the ulcer ranges around 1 cm or more, it is termed a "major ulcer," which has undefined boundaries and takes weeks to a month to heal.^[1] The mouth ulcer occurs mainly in the inner part of the buccal area; it has been generally seen around the tongue, behind the lips, in the inner lining of the cheek, etc. Initially, burning sensations are associated with inflammation and irritation around the epithelial lining where the ulcer is formed, which causes difficulties while chewing and maintaining oral hygiene. There are various allopathic medicaments like antibiotics, mouthwashes, and topical agents that help to relieve pain and discomfort caused by ulcers. Mouthwashes that have chlorhexidine as an active ingredient help to treat ulcers, but using mouthwash containing chlorhexidine for a longer duration of time causes staining of teeth. On the other hand, topical corticosteroids are also used to treat ulcers by reducing inflammation and discomfort, but prolonged use of topical corticosteroids leads to risks of adrenal suppression and systemic absorption of corticosteroids that can further cause various other adverse effects in the body.^[2] To limit the various side effects caused by allopathic formulations for mouth ulcers, ayurvedic lozenges are prepared, which are made up of herbal infusions, spices, and other supportive ingredients. Making infusions from fresh herbs boosts the potency and efficacy of lozenges by concentrating the active compound and essential oil. The lozenges directly disintegrate in the buccal cavity and help achieve rapid on-site action. There have been several natural sweetening ingredients, such as dextrose, that enhance the taste of lozenges and act as binder, which helps to achieve patient compliance. Herbal infusions and honey that are used in the formulation of lozenges have various properties that decrease pain and inflammation. They also have certain other benefits for our digestive system, which assist in the wellness of digestion. The properties of the ingredients that have been used for formulating the lozenges are discussed below.

Tulsi leaf (*Ocimum sanctum*)

Effect on Mouth Ulcer:

It has been used for health purposes since ancient times. Tulsi leaf has analgesic and anti-cancer properties. Tulsi leaf contains eugenol, which has analgesic properties and is thus useful in mucosal ulcer pain. It also possesses high antimicrobial and antifungal properties, which help prevent further mouth damage.^[3]

Role In Digestive Health:

Tulsi is traditionally used for pain in the stomach, gastric cramps, and vomiting.^[4] It also helps to decrease digestive discomfort and assist in maintaining a proper digestion process.

Guava leaf (*Psidium guajava*)

Effect on Mouth Ulcer:

Psidium guajava contains alkaloids, glycosides, flavonoids, tannins, and saponins. It has active properties of antioxidant, anti-

inflammatory, and antifungal activity, which help in pain relief caused by mouth ulcers.^[5] It has anti-ulcer properties, thus providing effectiveness in treating mouth ulcers.^[6]

Role In Digestive Health:

Guava leaf has been found to contain antibacterial properties in an antimicrobial susceptibility test, which helps with stomach issues caused by bacteria. Different mechanisms are involved in the inhibition of microorganisms in stomach issues.^[7]

Liquorice (*Glycyrrhiza glabra*)

Effect On Mouth Ulcer:

Liquorice contains mainly two components, which are the glycone part and the aglycone part responsible for the effect shown. It comprises anti-allergic, anti-inflammatory, and antioxidant properties. Liquorice is the dried root of *Glycyrrhiza glabra* Linn, which is useful in treating canker sores.^[8]

Role In Digestive Health:

Liquorice is used to treat canker sores, and it is also known for its benefits in the digestive system. Liquorice's anti-inflammatory properties improve digestion, which in turn regulates the immune system and metabolism in the body. It is said to help with heartburn and other GI tract issues.

Clove (*Syzygium aromaticum*)

Effect on Mouth Ulcer:

It has been used for a long time as a spice, and it also has various beneficial health properties. Clove is a strong antioxidant and antimicrobial agent. Clove oil is widely used for the treatment of ulcers as it is active against bacteria and fungi. It contains anti-inflammatory, analgesic, and antipyretic properties due to the presence of eugenol.

Role In Digestive Health:

Cloves contain eugenol, which has analgesic properties and helps with stomach ache. Clove is used to cure various health issues, such as intestinal parasites and diarrhoea. Clove also provides relief from nausea, vomiting, and gas.^[9]

Turmeric (*Curcuma longa*)

Effect on Mouth Ulcer:

Turmeric, also known as curcumin, has healing properties and has been used for ages for health benefits. Turmeric has anti-bacterial properties and can be used in the treatment of mouth ulcers. It is taken from the *Curcuma longa* plant. It also contains anti-inflammatory properties and can be helpful in treating gastric ulcers. It is found to increase cellular proliferation and thus show wound healing properties.^[10]

Role In Digestive Health:

Curcumin showed effective cures for diseases of the GI tract. Curcumin contains anti-bacterial properties and showed an effect against gut bacteria. Turmeric improves gut health and provides healthier digestion.^[11]

Honey

Effect On Mouth Ulcer:

Honey has been known for a long time for its benefits in wound healing and also has the ability to cure mouth ulcers and treat chronic wounds. Honey is also used in the treatment of burns.^[12] Honey has anti-inflammatory, anti-bacterial, and anti-oxidant properties, which are major reasons for treating mouth sores. Honey has the ability to decrease oxidative reactions and thus also reduce inflammation at the site of ulcers.^[13]

Role In Digestive Health:

Honey has high antibacterial activity and thus helps remove gut bacteria and improve gut health. Honey is a naturally sweet substance that contains carbohydrates and improves the digestive system.

Aloe vera (*Aloe barbadensis miller*)

Effect On Mouth Ulcer:

Aloe vera, a naturally obtained substance, has been found to contain antibacterial, anti-inflammatory, antioxidant, antifungal, and immunity-boosting properties. It has been widely used in the treatment of various oral diseases like mouth ulcers and burning mouth syndrome. Aloe vera tends to increase epithelial cell migration, which may be the primary reason for its wound healing action. It also causes an increase in wound closure rate and relieves pain.^[14]

Role In Digestive Health:

Aloe vera, used traditionally for its health benefits, is found naturally. It was a common herbal medicine. Aloe vera showed effective anti-oxidant properties during digestion. The phenolics that get released during digestion reduce oxidative reactions and help gut health.^[15]

Amla (*Phyllanthus emblica*)

Effect On Mouth Ulcers:

Amla comes under the family Phyllanthaceae, also known as the Indian gooseberry. It is most useful in treating inflammation. Amla powder has anti-inflammatory, anti-bacterial, and anti-oxidant activities that are helpful in the treatment of canker sores. Tannins and phenolics present in it help in the management of mouth ulcers due to their antioxidant properties. It shows more effect on oral ulcers when used with honey and cures mouth sores.^[16]

Role In Digestive Health:

Amla contains a high amount of vitamin C, which helps improve immunity in the body. Fibres present in amla help with better digestion and regulate bowel movements.

MATERIAL AND METHODS

The ingredients that were required for the formulation, such as guava leaves, Tulsi leaves, and aloe vera leaf, were freshly plucked from Vadodara district. Fresh herbs are believed to be more powerful than dried herbs since they have larger concentrations of their active components as well as essential oils. Ingredients such as cloves, turmeric, liquorice, honey, amla powder, and coconut oil were brought from local stores. The lozenges were formulated by measuring the recommended amount of ingredients on digital weighing balance while avoiding any possible errors. Initially, the infusion was prepared by weighing and gently washing the leaves of guava and Tulsi, which were added to the beaker containing distilled water. Clove, turmeric, liquorice, and the gel of aloe vera leaf were then mixed in the beaker and kept over the hot plate. The hot plate was used to extract all the active compounds and oils from the ingredients by gently heating them to make a more potent herbal infusion that has high efficacy for treating the canker sores. The boiling and high flame heating were avoided to ensure any loss of active compounds or essential oils. The mixtures were kept over a hot plate for 20 minutes at 55 °C to form a concentrated infusion. After the infusion was prepared, it was filtered and added to another beaker. After that, honey and dextrose were added, and it was gently heated on a hot plate to achieve the required viscosity for formulating the lozenges. During this period of time, coconut oil was applied to the lozenges to avoid the stickiness of the lozenges with mould. After reaching the desired consistency, the mixture was poured into a lozenge mould in which the amla powder was spread to make it more effective, and the upper surface was also covered with amla powder after it was kept for cooling at normal room temperature. It was packed in aluminium foil and stored in a tight container to avoid moisture. The composition of herbal infusion for ayurvedic lozenges is shown in Table 1.

Table 1: Composition of Herbal Infusion

Sr No.	Herbal Infusion Ingredient	Weight (For 50ml)
1.	Tulsi leaves	0.5gm
2.	Guava leaves	0.5gm
3.	Clove	0.5gm
4.	Turmeric	0.25gm
5.	Aloe vera gel	1gm
6.	Liquorice	2gm
7.	Distilled water	50ml

After the herbal infusion becomes half or comes at 25ml, it is transferred to another beaker in which 20gm of dextrose and 5gm of honey are present. The herbal infusion is mixed with honey and dextrose and then added to the lozenge mould in which Q.S amount of amla powder is spread before and after adding the mixture of ayurvedic lozenge.

RESULTS AND DISCUSSION

The formulation, dimensions, and organoleptic evaluation of ayurvedic lozenges were carried out successfully, and the outcome of the evaluation parameters was as follows:

Dimension: Diameter of lozenges = 1.8cm, Height of lozenges = 1.5cm

Table 2: Organoleptic Evaluation

Sr No.	Organoleptic Test	Result
1.	Taste	Sweet
2.	Colour	Brownish
3.	Texture	Smooth
4.	Shape	Rounded

It was found that the formulated ayurvedic lozenges had passed all the organoleptic evaluation test based on standard guidelines. The ayurvedic lozenges have a direct local effect in the oral cavity, which leads to rapid on-set action due to which the healing time of mouth ulcers increases. While turmeric and amla create the desired immune-modulatory activity, honey's acidity, hygroscopicity, and ability to increase epithelialization speed up the healing process. The other botanical ingredients, such as Psidium guajava leaves, clove, liquorice, aloe vera, and Tulsi, enhance the therapeutic effect. The ingredients used in the ayurvedic lozenges can help maintain digestive wellness. It was also found that amla powder absorbed moisture from the air for certain periods of time, but to increase the shelf life, proper packaging and storage are required. As a result, ayurvedic lozenges can be an effective and affordable treatment for lowering discomfort, pain, inflammation, and the size of mouth ulcers, as well as for maintaining healthier digestion.

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REFERENCES:

1. Archna Agnihotri, Antervir Kaur, Rosy Arora, Oral Ulceration and Indian Herb, Dental Journal of Advance Studies 8(04) 2020:1-9.

2. E. A. Field & R. B. Allan, oral ulceration – aetiopathogenesis, clinical diagnosis and management in the gastrointestinal clinic, *Aliment Pharmacol Ther*, 2003 15;18(10):949-962.
3. Akhil Anand Chaurasia, Tulsi-a promising herb in dentistry, *Journal of Oral Medicine, Oral Surgery, Oral Pathology and Oral Radiology*;2015;1(1):21-2.
4. Dr. Sudhir Kumar Mishra, Principal, S.S. College, Jehanabad, A Review Paper on Tulsi Plant (*Ocimum sanctum L.*) *Journal of Emerging Technologies and Innovative Research*. 2022 JETIR January 2022, Volume 9, Issue 1:515-524.
5. Jisha Gopi and Umesh Kumar Sharma. Development and evaluation of in situ gel of Guava Leaf's for the management of mouth ulcer, *Journal of Emerging Technologies and Innovative Research*. JETIR June 2019, Volume 6, Issue 6:58-59.
6. Vrushali Patil, Utkarsha Leaf's Patil, Formulation and evaluation of guava leaf extract gel for mouth ulcer management, *Indian Journal of Pharmacy and Pharmacology*. Volume-10, issue-01:247-251.
7. Bipul Biswas, Kimberly Rogers, Fredrick McLaughlin, Dwayne Daniels and Anand Yadav. Antimicrobial Activities of Leaf Extracts of Guava (*Psidium guajava L.*) on Two Gram-Negative and Gram-Positive Bacteria. *International journal of microbiology*. Volume2013 | Article ID 746165:1-7.
8. Mr. Mhaske Saurav Dilip Rao, Prof. Jagdish Sable Vilas, Miss Holkar Priyanka Uddhav,
9. Miss. Gulve Akshada Subhash, Mr. Tarade Akash Santosh. Formulation and evaluation of oral antiulcer gel from liquorice extract, *Journal of Emerging Technologies and Innovative Research*. JETIR June 2022, Volume 9, Issue 6: 297-310.
10. Mayank Agrawal, Sonam Agrawal, Dr Radhika Rastogi, Dr Pallavi Singh, Dr Adyanthaya BR, Dr Gupta H. L, A review on uses of clove in oral and general health, *Indian Journal of Research in Pharmacy and Biotechnology*. July-August 2014:1321-1323.
11. Yogesh S. Thorat, Asha M. Sarvagod, Shital V. Kulkarni, Avinash H. Hosmani. Treatment Of Mouth Ulcer by Curcumin Loaded Hosmane Mucoadhesive Gel: A Technical Note, *International journal of pharmacy and pharmaceutical sciences*. Vol 7, Issue 10:399-402.
12. Christine T. Peterson, Alexandra R. Vaughn, Vandana Sharma, Deepak Chopra, Paul J. Mills, Scott N. Peterson and Raja K. Sivamani. Effects of Turmeric and Curcumin Dietary Supplementation on Human Gut Microbiota: A Double-Blind, Randomized, Placebo-Controlled Pilot Study. *Journal of Evidence-Based integrative Medicine*. Volume 23, January-December 2018:1-8.
13. Nergiz Yılmaz, Özlem Nisbet, Cevat Nisbet, Gözlem Ceylan, Fatih Hoşgör and Ö. Doğu Dede.
14. Biochemical Evaluation of the Therapeutic Effectiveness of Honey in Oral Mucosal Ulcers. *Journal of the association of basic medical sciences*. 2009 November;9(4):290–295.
15. Maddison Hunter, Jane Kellett, Nathan M. D'Cunha, Kellie Toohey, Andrew McKune1 and Nenad Naumovski. The Effect of Honey as a Treatment for Oral Ulcerative Lesions: A Systematic Review Exploratory Research and Hypothesis in *Medicine* 2020;5(1):27-37.
16. Giroh, Versha R.; Hebbale, Manjula; Mhapuskar, Amit; Hiremutt, Darshan; Agarwal, Priya.
17. Efficacy of aloe vera and triamcinolone acetonide 0.1% in recurrent aphthous stomatitis. *Journal of Indian Academy of Oral Medicine and Radiology* 31(1), Jan–Mar 2019:45-50.
18. Ruth B. Cuvas-Limon, Pedro Ferreira-Santos, Mario Cruz, José A. Teixeira, Ruth Belmares and Clarisse Nobre. Effect of Gastrointestinal Digestion on the Bio accessibility of Phenolic Compounds and Antioxidant Activity of Fermented Aloe vera Juices. *Antioxidant Capacity of Bioactive Plant Compounds for Therapeutic Purpose*. 2022, 11(12):1-20.
19. Chaitali U Bio accessibility Vishnu Hombre. Oral health benefits of *Phyllanthus embolic*: A narrative review. *SRM journal of research in dental sciences* 2022; 13(1):22-24.