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Review Article

Formulation And Evaluation of Mouth Ulcer Gel

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ABSTRACT

Mouth ulcers, also known as aphthous ulcers, are among of the most frequent oral mucosal lesions that cause pain, discomfort, and trouble eating and speaking. The development of effective topical formulations for their treatment remained a primary focus of pharmaceutical research. Mouth ulcer gels are a handy and effective way to apply therapeutic ingredients directly to the afflicted area, which leads to localized action, longer contact duration, and faster healing. This review focuses on the formulation and evaluation of mouth ulcer gels, with an emphasis on active pharmaceutical ingredients like antiseptics, anti-inflammatory drugs, and analgesics. The selection of appropriate polymers, gelling agents, humidifying agents, and preservatives is critical in obtaining desired consistency, bioadhesion, and drug release. pH, viscosity, ability to spread, distribution of drug content, and in vitro diffusion are all mentioned as important factors in product performance evaluation. Improvements in natural and herbal-based formulations have also been addressed owing to their biocompatibility and low side effects. Overall, the review tries to provide an in-depth knowledge of the design considerations and evaluation procedures for optimizing mouth ulcer gels in order to increase their curative effectiveness and patient compliance.

INTRODUCTION

Mouth ulcers, also known as ulcers of aphthous pus or canker sores, are some of the most serious oral mucosal illnesses, characterized by painful lesions that prevent eating, speaking, and swallowing. They can be caused by a variety of

conditions, including stress, nutritional defects, hormonal changes, mechanical harm, or infection.(1) The primary goals of mouth ulcer therapy are to relieve discomfort, reduce inflammation, and speed up the healing process. Smilo Gel is a topical substance developed to safely cure mouth ulcers. It contains active substances such as choline salicylate, lidocaine,

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benzalkonium chloride, tannic acid, and menthol among others, which all contribute to its analgesic, anti-microbial, anti-inflammatory, and relaxing benefits. The gel creates a protective layer over the ulcer surface, avoiding irritation and speeds up healing. (2) his review study tries to provide a complete overview of Smilo Gel, comprising its formulation, way of action, evaluation standards, medicinal potential, and stability. It also underlines the positive aspects of Smilo Gel over typical mouth ulcer treatments, offering insights into its role as an efficient, patient-friendly topical therapy for oral mucosal ulceration. (3)

Mouth ulcer - Oral ulcers Ulcers happen by molecular necrosis and damage the epithelium's integrity. Ulcers are most commonly found in the mouth, and patients commonly seek medical or dental attention for them. Typical signs include discomfort, a burning sensation, and/or redness.(4) They can appear anywhere in the mouth cavity, but if they do so in the moving area, they may cause irritation. Mouth ulcers are quite prevalent and can be linked to a variety of conditions and procedures, but they rarely have serious underlying causes. Common causes of mouth ulcers include dietary problems such as iron

deficiency, vitamin deficiencies, particularly B12 and C, poor oral hygiene, infection, stress, indigestion, mechanical damage, food allergies, hormonal problems, diseases of the skin, and so on. Mouth ulcers, also known as aphthous ulcers, can cause discomfort while drinking, chewing, or cleansing your teeth. (5)

Types of Mouth Ulcers

Mouth ulcers can be defined as mild, large, or herpetiform based upon their size and quantity. The biggest types of ulcers in oral cavity are

Minor ulcers range in size from 2 to 8mm and generally heal between 10 days to 2 weeks.

Major ulcers are broader and deeper, typically with a raised or rough border. This form of ulcer can take many weeks for treatment and may leave a scar on the mouth.

Herpetiform ulcers can be made up of dozens of tiny infections the size of a pin head.(6)

Classification of gels - Gels are classified relative to their colloidal phases, solvent format, physical nature, and rheological properties, among other characteristics.(7)

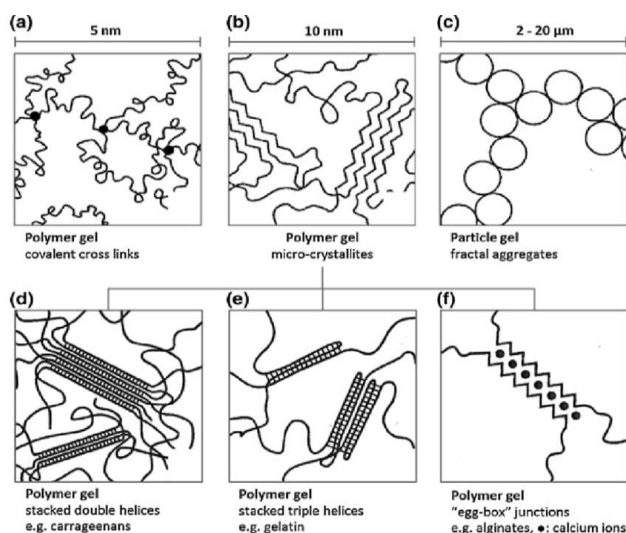


Fig- 1 Structure of gel

1) Based on colloidal phases They are classified into:

a) Inorganic (Two phase system)

b) organic (Single phase system)

a) Inorganic (Two phase system) When the particle size of the dispersed form is quite large, a system consists of floccules of small particles rather than bigger molecule, and the dimensional framework of the gel is formed throughout. (8)

b) Organic (Single phase system) They make up of large molecule of organic matter that split in a continuous phase that occurs on twisted strings.

2)Based on the nature of solvent used:

a) Hydrogels (water based) Water operates as a continuous liquid phase in hydrogels, for example. Consider poloxamer gel, gelatin, cellulose its derivatives, and bentonite basalt.(9)

b) Organic Gels (with a non-aqueous solvent) In their ongoing phase, they utilize a non-aqueous solvent. Examples include metallic stearate distribution in oils and low molecules of polyethylene that has been dissolved in mineral oil and subsequently chilled.(10)

c)Xerogels Solid gels that have decreased solvent content are referred to as xerogels. They form as the solvent goes away, leaving the gel structure behind when it comes into collision with the extra fluid. Some examples are tragacanth ribbons, acacia tears, dry cellulose, and polystyrene.(11)

3)Based on rheological properties: Usually, gels exhibit non-Newtonian flow. They are classified into:

a) Plastic gel yield value of the gels at which the elastic gel deforms and start to flow is expressed

by the rheogram plot. For example, Bingham bodies and suspended aluminum hydroxide suspensions demonstrate plastic flow.(12)

b) Pseudo plastic gel viscosity of that kind of gel decreasing as you increase the shear rate, however there is no yield value. For example, tragacanth, sodium alginate.

c) Thixotropic gels the connections amongst the particles in these kinds of gel are relatively fragile and easily weakened by shaking.

4) Based on physical properties

Elastic gels occur at the junction, with relatively weak interactions such as hydrogen bonds and dipole attraction maintaining the fibrous molecules together. These include alginates, guar gum, and agar gels.(13)

b) Rigid gels These are gel polymers in which the framework is bound to it by a primary secondary bond. For example, in silica gel, silica acid molecules are tied together by Si-O-Si-O bonds, generating a polymer structure having a network of pores.

5) Bases or gel forming polymers:

a) Natural polymers These polymers can be produced by bacteria and viruses and occur naturally. a number of polysaccharides including agar, tragacanth, pectin, and gum, as well as proteins such as collagen and gelatin.(14)

b) Semi synthetic polymers These polymers are usually manufactured through chemical modification to organic polymers. As a case study, consider carboxymethyl cellulose, methylcellulose, and hydroxyethyl cellulose.

c)Synthetic polymers Synthetic polymers are those made up in vitro. Examples are



polyacrylamide, polyvinyl alcohol, poloxamer, carbomercarbopol 940, and carbopol 934.(15)

Factors responsible for the mouth ulcers

- Toothpastes and mouthwashes that contain
- sodium lauryl sulfate
- Emotional stress / Psychic stress
- Hormonal changes
- Nutritional deficiencies
- Mechanical trauma
- Viral infections
- Allergies and sensitivities
- Genetics
- Infectious agents (both bacterial and viral)
- Medical conditions
- Irregular brushing or use of harsh mouthwashes
- Tobacco chewing or smoking
- Viral infections such as **Herpes simplex virus (HSV)**
- Bacterial or fungal infections of the oral cavity
- Consumption of **spicy, acidic, or salty foods**
- Sensitivity to certain ingredients like **sodium lauryl sulfate (SLS)** in toothpaste(16)



Fig. 2 – Mouth ulcer

A mouth ulcer is a sore on the soft tissue lining of the inner cheeks, tongue, gums, lips, or tongue. They can be very painful and usually yellow or red. Mouth ulcers are sometimes known as aphthous ulcers or canker sores. Mouth ulcers are easy to identify. Sores can occur on the lips, gums, tongue, inner cheeks, and roof of the mouth. Mouth ulcers usually have white, yellow, or grey in the middle, with red around the outer edges. You could get multiple ulceration. Other symptoms may include:

- Swelling below the ulcer.
- Increased soreness during brushing your teeth.
- Pain worsens upon eating spicy, salty, or sour foods.(17)

Causes

There is a lack of cause for mouth ulcers. But a variety of elements can cause the occurrence of these sores:

- Dental work, such as fixing spaces, can cause minor tissue damages.
- Inadvertently biting your cheek or tongue.
- Allergic reaction to certain bacteria.
- Wearing orthodontic braces or retainers.
- Vitamin insufficiency.

- Use harsh or abrasive toothpaste.
- Eating acidic foods include oranges, pineapples, and strawberries.
- Period-related hormonal changes.
- Stress.
- Lack of sleep.(18)

Drug Name:

Povidone-Iodine (PVP-I)

◆ Chemical Name:

Polyvinylpyrrolidone-iodine complex

◆ Category:

- Povidone-iodine works as an antiseptic and disinfectant by carefully removing free iodine through tissues.
- Free iodine enters microbial cells, damaging proteins, nucleotides, and fatty acids, eventually causing cell death.
- Effective against bacteria (including Gram-positive or Gram-negative), fungi, and viruses.
- Protozoa and spores.(19)

Uses of Gels-

1. As methods of delivery for orally supplied drugs.
2. Topical medications injected directly to the skin, respiratory tract, or eyes.
3. Long-acting pharmaceuticals injected intramuscularly or implanted in the body.
4. As tablet granulation binders, suspension protective colloids, and additives in

5. oral liquid and suppository bases.
6. Cosmetics that consist of shampoos, flavors, dentifrices, and skin and hair hygiene preparations.
7. Lubricant for catheters.(20)

Evaluation of mouth ulcer gel

1.Physical Appearance and Colors.

- Objective: Check gel quality, shades, and clarity.
- The gel should be smooth, smooth, and free of lumps and air bubbles, with a uniform hue and appearance. (21)

2. pH Measurement

- Objective: Optimize health with the oral cavity.
- To measure pH, take a digital pH meter at room temperature.
- The acceptable pH range is 6.5 to 7.5, which corresponds to the mouth's PH (22)

3. Viscosity.

- Objective: Analyse the gel's consistency and ability to spread.
- Performed using a Brookfield viscometer at a specified temperature.
- Optimal viscosity increases sticking to mucosa and ease of application.(23)

4.Spreadability

- Objective: To evaluate the ease of spreading of gel on application.
- Method: A small quantity of gel is placed between two glass slides
- Good spreadability ensures uniform application and patient comfort.(24)



5.Extrudability

- Objective: To evaluate the ease of spreading of gel on application.
- Method: A small quantity of gel is placed between two glass slides
- Good spreadability ensures uniform application and patient comfort.

6.Adhesion (Mucoadhesive Strength)

- Objective: To assess the ability of the gel to adhere to the mucosal surface.
- Method: Measured using a texture analyzer or modified balance method with mucosal tissue.
- Significance: High adhesion ensures prolonged retention and drug action.

7.Drug Content Uniformity

- Objective: To confirm uniform distribution of the active drug (Povidone-Iodine) throughout the gel.
- Method: Dissolve a specific quantity of gel in suitable solvent, filter, and analyze spectrophotometrically at the drug's λ_{max} .
- Acceptance Criteria: 95–105% of the labeled claim.

8.In Vitro Diffusion Study

- Objective: To study the rate and extent of drug release.
- Method: Performed using a Franz diffusion cell with dialysis membrane in phosphate buffer (pH 6.8).
- Significance: Determines the sustained release behavior and therapeutic potential.

9.Stability Study

- Objective: To assess the stability of gel under different storage conditions.
- Method: Stored at room temperature and accelerated conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$, $75\% \text{ RH} \pm 5\%$) for a specific period.
- Observation: Evaluated for changes in appearance, pH, viscosity, and drug content over time.

10.Antimicrobial Activity

- Objective: To evaluate the effectiveness of the gel against oral pathogens.
- Method: Performed using agar well diffusion method against organisms like *Streptococcus mutans* and *Candida albicans*.
- Significance: Confirms the antiseptic efficacy of Povidone-Iodine and synergistic ingredients.(25)

DISCUSSION

Mouth ulcers are a usual oral disorder that results in pain, discomfort, and trouble eating or speaking. Conventional therapies for mouth ulcers, such as antiseptic mouthwashes, corticosteroid ointments, or oral tablets, often give just short-term relief and may cause local irritation. In this context, Smilo Gel is a prospective topical medicine that encourages patient compliance along with rapid pain relief.

The formulation of Smilo Gel is meant to include different therapeutic activities in a single topical layer. The key active ingredient, choline salicylate, has beneficial anti-inflammatory and analgesic properties by decreasing prostaglandin synthesis, which reduces pain and swelling. Lidocaine has a powerful local anesthetic effect, allowing

immediate pain relief Benzalkonium chloride is an antiseptic that protects afterwards bacterial infections Increased testing, including clinical trials and stability studies, is required for assessing its long-term safety, bioadhesive characteristics, and therapeutic efficacy. Standardization of formulation details, pH stability, and microbiological testing can improve reliability and financial viability Inally, the debate emphasizes that Smilo Gel is a reliable and patient-friendly formulation for the treatment of mouth ulcers, providing fast relief while supporting healing using a well-balanced combination of active substances.

CONCLUSION

The review concludes that a mouth ulcer gel involving Povidone-Iodine, Zinc Oxide, Camphor, Carbopol, Glycerine, and Propylene Glycol serves as an effective, safe, and stable formulation for managing oral ulcers. The synergistic blend of disinfectant, healing, and soothing components speeds up wound healing, minimizes secondary infection, and promotes patient comfort. Excipient selection ensures desirable physical characteristics like as consistency, pH, and bioadhesion, which are needed for local drug delivery in the oral cavity. Thus, this gel formulation offers an appealing therapeutic alternative for recurring aphthous stomatitis and other oral mucosal diseases.

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