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Review Article

Design and Evaluation of Emulgels for Mouth Ulcer Treatment : A Systematic Review

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ABSTRACT

Mouth ulcers (aphthous stomatitis) are common and recurrent lesions of the oral mucosa, often associated with pain, infection and impaired oral function. Conventional dosage forms such as gels, mouthwashes, lozenges or sprays face challenges of retention, bio-adhesion, sustained release and patient compliance. The emulgel, a hybrid delivery system combining emulsion and gel technologies, offers advantages of both: enhanced solubilization of hydrophobic drugs, good spreadability, bioadhesive properties and sustained release. This review summarises the formulation strategies, evaluation parameters and therapeutic potential of emulgels—with a view to their application in mouth ulcer management. Key formulation variables (choice of oils, surfactants, gelling agents, penetration enhancers, mucoadhesive polymers), evaluation tests (physicochemical, rheological, spreadability, extrudability, bioadhesion, in-vitro/in-vivo release, mucosal safety), and specific adaptations for oral mucosa (salivary wash-off, pH, mucin layer) are discussed. The review also highlights current research gaps and future directions for product development.

INTRODUCTION

Recurrent aphthous stomatitis (RAS, mouth ulcers) affects a significant portion of the population, causing pain, delayed eating or speaking, and may be associated with microbial invasion and systemic conditions.^[6] Conventional

topical delivery forms for oral ulcer include gels, pastes, sprays and mouthwashes; however, they often suffer from rapid wash-off by saliva, short contact time, poor patient compliance and limited capacity to deliver hydrophobic actives.^[5]

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The emulgel formulation— essentially an emulsion (oil-in-water or water-in-oil) incorporated into a gel base — offers a promising strategy for topical and mucosal delivery. The gel matrix provides spreadability, bioadhesion and controlled release; the emulsion phase accommodates hydrophobic drugs and enhances penetration.^[1]

Given these advantages, applying an emulgel to the oral mucosa for mouth ulcer treatment makes mechanistic and practical sense. A few research reports have begun exploring such systems. For example, one study formulated an herbal-oil loaded emulgel for mouth ulcers and demonstrated good release profiles.^[5]

2. Emulgel: Concept and Advantages

2.1 Definition and rationale

The term “emulgel” is derived from emulsion + gel. In this system, an emulsion (either oil-in-water or water-in-oil) is incorporated into a gel base (via a gelling agent). The result is a semi-solid formulation that has the favorable attributes of both emulsion and gel.^[1]

The key rationale is:

- Many therapeutic actives are hydrophobic (poor solubility in aqueous gel bases) → emulsions help solubilise/dispense them.^[1]
- Gels offer advantages of spreadability, superficial retention, ease of application and improved patient acceptance compared to pastes/ointments.^[2]
- Combining the two phases yields a “dual-release control” system: the gel matrix and emulsion phase both contribute to release kinetics, allowing sustained delivery.^[10]

2.2 Advantages relevant for topical/mucosal delivery

According to the literature, the following advantages have been noted:

- Enhanced dissolution/ dispersion of hydrophobic drugs compared to conventional gel/cream.^[1]
- Better spreadability, non-greasy feel, patient comfort, and better organoleptic properties than traditional ointments.^[2]
- Potential for improved penetration (via oil phase/surfactants) and retention at site of application.^[6]
- Possibility of mucoadhesion (especially if mucoadhesive polymers are used) — important for oral cavity where wash-off by saliva is a problem. For example, in an oromucosal-targeted emulgel, gum polymers (tragacanth, xanthan) enhanced adhesion and retention.^[7]
- Potential for sustained release and prolonged contact time, thus reducing dosing frequency.^[4]

2.3 Limitations / considerations

- Formulation complexity (choice of correct emulsion phase, surfactants, gel base, stability) is greater than a simple gel.^[1]
- Risk of phase separation (emulsion destabilisation) if not properly optimised (emulsifier system, droplet size, gel compatibility).^[4]
- For mucosal/oral use: must consider taste, irritation potential, salivary wash-off, adhesion, biocompatibility.

- Regulatory/scale-up issues: uniformity, reproducibility, stability under storage conditions.
- emulgel study, clove oil, basil oil, curcumin and menthol were used.^[5]

3. Formulation Strategies for Emulgel

3.1 Selection of oil phase & surfactants

The oil phase acts as solubiliser of hydrophobic drug, enhances penetration. Oils used include light liquid paraffin, sesame oil, natural volatile oils (e.g., clove oil) etc. For example, in a study of aceclofenac emulgel, sesame oil and light liquid paraffin were compared.

Surfactants/co-surfactants stabilize the emulsion – selection of appropriate HLB value, droplet size is critical. Unfortunately, few mouth-ulcer specific reports detail this.

3.2 Gel base & gelling agents

Common gelling agents include Carbopol (940, 934), sodium-CMC, xanthan gum, tragacanth, gellan etc. For example, Nandgude et al. (2018) overviewed typical gel bases in emulgel systems.^[1]

Choice criteria for mucosal use:

- pH compatible with oral mucosa (~pH 6–7)
- Safe, non-irritant, non-toxic polymers
- Good bioadhesion, good spreadability, suitable viscosity (not too runny, not too stiff)

3.3 Incorporation of actives/ penetration enhancers

For mouth ulcers, actives may include anti-inflammatory agents, analgesics, antimicrobial/herbal extracts. Penetration enhancers (menthol, clove oil) may help mucosal penetration. For example, in a mouth-ulcer

3.4 Preparation method

Typical steps:

1. Prepare emulsion (oil phase + aqueous phase + surfactant/co-surfactant)
2. Prepare gel base (dissolve gelling agent, adjust pH)
3. Incorporate the emulsion into the gel base under stirring to form emulgel (commonly ratio ~1:1 emulsion:gel, though can vary)^[4]
4. Incorporate active drug and penetration enhancer.
5. Homogenise, check droplet size, viscosity, stability.

3.5 Optimization of formulation variables

Variables to be optimised include:

- Oil phase concentration and type
- Surfactant/co-surfactant ratio
- Gelling agent type and concentration
- Drug load
- Penetration enhancer type/concentration
- Mucoadhesive polymer content (if targeting mucosa)
- pH, viscosity, spreadability

For example, in a polyherbal emulgel study, a factorial design was used to influence viscosity and drug release by varying gelling agent type.^[9]

4. Evaluation Parameters

Evaluation of emulgels involves several tests to ensure quality, efficacy and safety. These tests must be adapted for oral mucosal delivery (e.g., salivary wash-off, mucoadhesion). The following list sets out major parameters.



4.1 Physicochemical tests

- Appearance (colour, homogeneity, presence of air bubbles)
- pH (should be compatible with oral mucosa; typical pH ~5.5-7.0)
- Viscosity and rheological behaviour (flow properties, thixotropy)
- Spreadability and extrudability (ease of application)
- Drug content (uniformity)
- Phase stability (checking emulsion separation, gel integrity on storage)

4.2 In-vitro drug release / permeation studies

- In-vitro release (e.g., Franz diffusion cell) to determine release kinetics of the active from emulgel. For example, in the mouth-ulcer emulgel study: ~79 % release of one constituent after 5 h.^[5]
- Ex-vivo permeation through mucosal tissue (in case of oromucosal delivery). For example, in the oromucosal emulgel for photosensitizer: porcine oromucosal epithelium used.^[7]

4.3 Mucoadhesion / Retention tests

For oral cavity application, mucoadhesive strength is critical to ensure formulation stays in contact with the ulcer surface despite saliva and movement. Some studies measure detachment force, work of adhesion.^[7]

4.4 Bioadhesion / Spreadability under simulated conditions

Testing ability to spread on mucosa, retention under simulated salivary flow, evaluation of texture.

4.5 Stability studies

Short-term stability (a few weeks) under different storage conditions (room, accelerated) to check for phase separation, change in pH, viscosity, drug content etc. For example, in the antifungal natural polymer emulgel study.

4.6 Safety / Irritation / Compatibility studies

For oral mucosal use, irritation to mucosa must be evaluated (e.g., 3D human oral epithelium model as in one emulgel study)^[7]

4.7 In vivo/clinical efficacy (when available)

Though limited for mucosal emulgels, some studies may include animal models or human trials for analgesic/anti-inflammatory efficacy (for skin/other sites) and could be adapted for mouth ulcer applications. For example, mefenamic acid emulgel showed analgesic/anti-inflammatory effect compared to marketed gel.^[7]

5. Specific Considerations for Mouth Ulcer (Oromucosal) Applications

Formulating an emulgel for mouth ulcer treatment demands additional special attention beyond standard topical skin emulgels. Key considerations include:

5.1 Oral environment

The oral cavity presents dynamic challenges: continuous saliva flow, muscle/tongue movement, mastication, pH (~5.75-7.05) and presence of mucin/biofilm surfaces. One study noted the buffer pH and fluid composition in the mouth.^[5] Hence the formulation must be designed for good retention/adherence, minimal flavour interference, appropriate viscosity (not too sticky/unpleasant).

5.2 Bio-adhesion and retention

To ensure prolonged contact with ulcer site, mucoadhesive polymers (tragacanth, xanthan, gellan) are beneficial. For instance, a study on oromucosal emulgel used tragacanth/xanthan and found improved retention and penetration.^[7]

5.3 Patient-comfort, taste & mouthfeel

Because it is applied intra-orally or to the mucosa, the emulgel must have acceptable taste, minimal irritation, non-toxic excipients, non-staining, non-burning sensation. Use of volatile oils (e.g., clove oil) may impart analgesic effect but need to be evaluated for taste. In one study for mouth ulcers the use of clove oil and menthol provided analgesic and cooling effect.^[5]

5.4 Active choice tailored to ulcers

Actives may include anti-inflammatory, analgesic, antimicrobial, antiseptic and healing promoters (e.g., herbal extracts like curcumin, basil oil, clove oil) — as used in the mouth-ulcer emulgel study.^[5]

5.5 Dosing form & application site

The ulcer site may be in cheek, tongue, floor of mouth etc — formulation must allow accurate placement, remain in situ, resist saliva. Use of a gel/emulgel rather than a wash might improve contact time.

5.6 Evaluation of specific performance endpoints

In addition to standard evaluations, mouth ulcer emulgel should be tested for:

- Retention time under simulated salivary flow
- Mouth rinse effect / stability in presence of saliva
- In-vivo assessment of pain relief, healing time, infection control

- Biocompatibility with oral mucosa (including taste, irritation, mucin interaction)

6. Recent Research Examples & Case Studies

- In one study, Surendra Ahirwar & Dharmendra Jain developed an emulgel containing curcumin, clove oil, basil oil and menthol for treatment of mouth ulcers. They prepared 5 formulations, evaluated viscosity, spreadability, extrudability, diffusion tests and short-term stability. The optimised formulation (E3G3S5T2) showed drug release of $\sim 79 \pm 3.2\%$ for clove, $\sim 72.22 \pm 3.1\%$ for basil oil and $\sim 72.07 \pm 4.8\%$ for curcumin over 5 h.^[5]
- A study on oromucosal emulgels using natural gums (tragacanth, xanthan, gellan) loaded with delta-aminolevulinic acid (ALA) for photodynamic therapy used mucoadhesion, penetration, safety on human oral epithelium model. The tragacanth/xanthan formulation had enhanced retention and penetration vs commercial gel.^[7]
- More general reviews discuss emulgel technology, including advantages, recent advances, preparation/characterisation—e.g., Nandgude (2018) “Emulgel: A Comprehensive Review for Topical Delivery of Hydrophobic Drugs”.^[1]
- There is also a formulation and evaluation of herbal gel (not emulgel) for mouth ulcers using extracts of *Aloe barbadensis*, *Ocimum tenuiflorum* and *Azadirachta indica*, indicating the feasible use of herbal gels in this indication.^[6]

7. Gaps, Challenges and Future Directions

7.1 Gaps in current research



- Limited number of studies specifically addressing emulgel for mouth ulcer / oromucosal application.
- Lack of extensive clinical trials comparing efficacy and safety of emulgel vs standard treatments in mouth ulcers.
- Limited data on long-term stability, salivary wash-off kinetics, patient-acceptance (taste/mouthfeel) and real-world adherence.
- Need for tailored mucoadhesive testing models (in vitro/in vivo) specific to oral cavity.
- Integration of novel actives (e.g., nano-carriers, bioadhesive nanoparticles) in emulgel targeted to oral mucosa remains under-explored.
- Taste-masking and patient-friendly features for oral cavity application.
- Stability studies under oral storage conditions (humidity, temperature cycles).
- Regulatory and commercialization aspects: scalability, packaging (syringe, tube, applicator), cost-effectiveness.

7.2 Future Directions

- Develop synergistic formulations combining analgesic + antimicrobial + healing promoters in emulgel form for mouth ulcer.
- Use of advanced mucoadhesive polymers (thiolated gums, lectin-based adhesives) to enhance retention at the ulcer site.
- Incorporation of nanotechnology: nano-emulsions, nano-particles within emulgel to improve penetration and controlled release.
- Clinical studies comparing emulgel formulation vs conventional gel/ointment/lozenge in mouth ulcer endpoints (pain relief onset, healing time, recurrence).
- Tailored evaluation methods: simulate salivary flow, tongue movement, chewing cycles to test retention and wash-off in vitro.

8. CONCLUSION

Emulgel is an attractive and under-utilised platform for the treatment of mouth ulcers, offering the combined benefits of gels and emulsions. With careful selection of oil phase, surfactant, gelling agent, penetration enhancer and mucoadhesive polymer, an emulgel can provide better drug solubilisation, spreadability, retention on the oral mucosa and sustained release — potentially improving pain relief, healing and patient comfort compared to conventional formulations. While preliminary studies are promising, significant research gaps remain — particularly large-scale clinical evaluation, real-world performance (salivary wash-off, taste, retention), and commercial translation. Researchers and formulators should focus on optimising mucosa-specific parameters, ensuring patient acceptance, and generating robust clinical evidence to support emulgel use in mouth ulcer management.

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