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Comparative Study on Solvent Casting Techniques for Migraine Drug Mouth Dissolving Films

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Abstract: *Mouth Dissolving Films are an innovative oral drug delivery system designed for rapid disintegration in saliva without water. Their importance is particularly high in migraine treatment due to rapid onset requirements and ease of administration, especially during acute episodes. This review focuses on solvent casting techniques employed for fabricating migraine drug MDFs, analyzing formulation parameters, polymer selection, processing methods, evaluation metrics, and comparative outcomes.*

Keywords: Mouth dissolving films; solvent casting technique; migraine drugs

I. INTRODUCTION

Migraine affects millions globally and requires fast-acting formulations to alleviate acute pain. Traditional tablets often delay onset due to gastric transit time. Mouth dissolving films enhance patient compliance and drug bioavailability through oral mucosal absorption (Khan et al., 2018). Solvent casting remains the most prevalent technique because of its simplicity and scalability (Sharma & Jain, 2020). This paper compares different solvent casting methods for migraine drug MDFs.

MOUTH DISSOLVING FILMS: OVERVIEW

MDFs are thin polymeric strips that rapidly disintegrate on the tongue. They offer:

- Rapid onset of action
- Improved patient compliance
- Elimination of water requirement
- Better stability than liquid forms

Common migraine medications used in MDFs include triptans such as Sumatriptan, Rizatriptan, and Zolmitriptan.

SOLVENT CASTING TECHNIQUE

The solvent casting technique is a foundational and widely adopted method for the development and preparation of thin, polymer-based oral drug delivery films, particularly mouth-dissolving films (MDFs) which are gaining importance due to patient-friendly, fast-acting therapeutic applications. The method begins with dissolving the selected polymer in an appropriate solvent, most commonly water or hydro-alcoholic systems, forming a homogeneous polymeric solution. This step is followed by incorporating the drug of interest alongside additional excipients such as plasticizers, saliva-stimulating agents, sweeteners, flavoring substances, and stabilizers. Plasticizers, including glycerin, sorbitol, and propylene glycol, are integral to modifying mechanical elasticity and flexibility of the film by reducing the intermolecular forces between polymer chains. The polymer–plasticizer interaction, which impacts film flexibility, can be mathematically expressed using the Fox Equation for predicting glass transition temperature:

$$T_{g(film)} = \frac{w_1 T_{g1} + w_2 T_{g2}}{w_1 + w_2}$$

Where T_g is the final glass transition temperature of the film, and w_1, w_2 are the proportional weights of the polymer and plasticizer. After proper dissolution and blending of all components, the solution is subjected to degassing, a process commonly assisted through ultrasonication to remove entrapped air bubbles which could negatively influence film uniformity. Ultrasonic energy delivered in this step is expressed by the relation:

$$E = P \times t$$

Where E is total applied energy, P the power of the ultrasonic source, and t the duration of exposure. Once degassing is completed, the solution is poured into molds or casting trays, assisted by calibrated spreaders to achieve uniform thickness. The casting process is performed on a flat, non-stick surface such as glass plates, coated metal surfaces, or Teflon-coated trays. The thickness desired can be controlled based on the volume of casting solution, polymer viscosity, and leveling speed.

Drying is a crucial step in solvent casting, determining final film properties such as tensile strength, shrinkage, solvent residue, and micro structural uniformity. Drying can be executed under ambient conditions or in controlled environments with specific temperatures and humidity levels. In many studies, controlled drying at 40–60°C has been reported to enhance physicochemical quality of films due to reduced crystallization and improved plasticization. A mathematical relation that helps evaluate the rate of solvent evaporation is based on the diffusion principle:

$$J = -D\frac{dC}{dx}$$

Where J is diffusion flux, D is solvent diffusion coefficient, and dC/dx represents concentration gradient over distance. This gradient determines how quickly solvent migrates from the polymer matrix during drying. Fast evaporation may lead to structural defects such as pores, cracks, and surface roughness, whereas slow drying increases solvent retention and can affect drug stability. Therefore, the casting process often integrates staged drying, where the initial film is dried at low temperatures to avoid bubble formation, followed by higher temperatures to remove remaining solvent traces.

The solvent casting method offers substantial benefits such as scalability, low production cost, suitability for thermo labile drugs, and ease of incorporation of hydrophilic active compounds. It is highly effective in preparing mouth-dissolving films intended for fast disintegration in the oral cavity (typically within 30–60 seconds), allowing the drug to release rapidly and bypass first-pass metabolism through oral mucosa absorption. The technique also allows precise dose accuracy because drugs are uniformly distributed within the film matrix. Uniformity of dosage within casted film strips is a critical parameter, expressed by the drug content uniformity formula:

$$\%\text{Drug Content} = \frac{\text{Observed Drug Amount}}{\text{Theoretical Drug Amount}} \times 100$$

High percent values ensure therapeutic effectiveness, especially in dosage-sensitive conditions such as migraine.

Another essential parameter in solvent-cast films is tensile strength, which defines the film's ability to withstand stress. It can be expressed mathematically as:

$$TS = \frac{F}{A}$$

Where F is the force applied at breakage and A is the cross-sectional area of the film strip. Ideal films must possess tensile strength high enough for packaging and handling but possess low enough elasticity to avoid brittleness. Folding endurance, another mechanical parameter, is evaluated manually and represents the number of folds a film withstands before breaking. Film thickness, which ranges typically between 0.3 mm to 1.0 mm, is measured by micrometer and determines disintegration time and mechanical endurance. Moisture content of films is also essential, measured using Karl Fischer titration or gravimetric methods since high water content leads to microbial growth and risk of degradation, while extremely low moisture can result in cracking.

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One of the distinguishing features of solvent casting is its ability to allow multi-layered film fabrication, where different layers can encapsulate incompatible drugs or add mucoadhesive features. Solvent-cast multi-layer films are especially useful in migraine treatment formulations when combining immediate-release and sustained-release drugs. The formulation factors influencing solvent cast films include type of polymer, polymer concentration, solvent nature, plasticizer ratio, and drying temperature. For instance, hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), pullulan, sodium alginate, and polyvinyl alcohol (PVA) are common due to their rapid hydration capacity. The viscosity of polymer solution, another critical aspect, can be described by the Stokes-Einstein Relation:

$$\eta = \frac{kT}{6\pi rD}$$

where η is viscosity, k is Boltzmann constant, T is temperature, r is hydrodynamic radius, and D is diffusion coefficient. Higher solution viscosity results in thicker films, slower drying, and potentially prolonged disintegration time.

Despite its advantages, solvent casting has certain limitations. One significant drawback is the need for solvent evaporation, which may leave traces of organic solvents in the final product if not properly dried. This poses safety concerns especially when ethanol or acetone-based systems are used. Another limitation is its inefficiency with highly water-insoluble drugs, which require anodizing techniques or dispersing agents in order to distribute uniformly within the polymeric system. To overcome these limitations, modifications such as ultrasonication-assisted dispersion, nanocrystal-loaded casting, and use of surfactants (e.g., Tween 80) are increasingly integrated. Furthermore, controlled humidity drying chambers have been introduced to improve moisture control, preventing film brittleness and microbial exposure.

Overall, solvent casting remains a vital technology in the pharmaceutical field, especially for the development of patient-friendly fast-dissolving delivery systems that can improve drug bioavailability and compliance. It's simple, adaptable, and cost-effective nature ensures widespread industrial acceptance. The incorporation of optimization techniques such as Response Surface Methodology (RSM) allows formulators to adjust polymer-to-plasticizer ratios and drying conditions to achieve desired physicochemical behavior. As formulation science continues advancing, solvent casting is expected to integrate newer polymers such as bioadhesive biopolymers and super-disintegrates, making films dissolve even faster and offering targeted release for drugs requiring immediate systemic onset such as migraine medication.

PRINCIPLE

Solvent casting involves dissolving drug and polymers in volatile solvents, casting the solution on a surface, and allowing solvent evaporation to form films.

BASIC STEPS:

Dissolve polymer in solvent (e.g., water, ethanol).
Add plasticizers (e.g., glycerol).
Pour into casting mold.
Dry to remove solvent.
Cut films to size.

COMMON POLYMERS

Hydroxypropyl methylcellulose (HPMC)
Polyvinyl alcohol (PVA)
Sodium alginate
Pullulan

PLASTICIZERS

Plasticizers like glycerin or propylene glycol improve flexibility.

GLASS TRANSITION TEMPERATURE FORMULA:

$$T_{g(film)} = \frac{w_1 T_{g1} + w_2 T_{g2}}{w_1 + w_2}$$

Where T_g is the glass transition temperature and www is weight fraction of components (Fox equation) essential for film flexibility (Fox, 1956).

COMPARATIVE TECHNIQUES

Comparative techniques in the fabrication of migraine drug mouth-dissolving films (MDFs) play a crucial role in determining the efficiency, uniformity, and performance of these pharmaceutical dosage forms. The most commonly adopted process is the traditional solvent casting method, which involves dissolving the film-forming polymer in a suitable aqueous or organic solvent, adding plasticizers and drug solution, pouring the mixture into a casting mold, and allowing solvent evaporation to produce a thin film. While this method offers simplicity, cost-effectiveness, and compatibility with heat-sensitive triptan drugs such as Sumatriptan and Rizatriptan, its major challenges lie in uneven film thickness, prolonged drying time, and the possibility of residual solvent retention. In contrast, controlled drying solvent casting introduces refined environmental conditions, such as regulated humidity (40–50%) and drying temperature (30–40°C), to prevent film cracking or folding. Studies suggest that controlled drying results in improved mechanical strength, smoother surface formation, and higher uniformity of drug distribution, thus resulting in better therapeutic consistency. This improvement is particularly important for migraine films, which need rapid dissolution within 30–60 seconds to provide immediate relief during severe episodes.

Another modern technique is solvent casting assisted with ultrasonication, where ultrasonic waves are applied to the polymer–drug mixture prior to casting. This process reduces particle aggregation, ensuring enhanced drug uniformity and improved dissolution kinetics. Ultrasonication also eliminates entrapped air bubbles commonly observed defects in manually cast films thus creating a more homogeneous matrix. The efficiency of ultrasonication can be explained by the cavitation principle, in which high-frequency sound waves cause micro-bubble collapse, dispersing particles uniformly at the molecular level. As a result, MDFs produced through ultrasonication show faster in vitro drug release rates, ideal for drugs like Zolmitriptan that require rapid mucosal uptake. Moreover, solvent casting with polymer blend technology offers another comparative approach, where polymers like HPMC, PVA, and pullulan are combined to tailor film characteristics. This method allows customization of tensile strength, folding endurance, and dissolution profile through modulation of polymer ratios. For instance, pullulan improves film clarity and dissolvability, whereas HPMC enhances structural integrity and tensile behavior, making blends more adaptable depending on the migraine drug's physicochemical properties.

A more industrial-oriented comparative method is the hot melt extrusion (HME) technique, which eliminates solvents altogether. Although less commonly applied in migraine MDFs, HME offers rapid, continuous manufacturing, making it suitable for large-scale production. However, its major drawback is thermal stress on active pharmaceutical ingredients, rendering it unsuitable for heat-labile drugs frequently used in migraine therapy.

Comparative evaluation across these techniques reveals that while traditional casting remains prevalent due to simplicity, newer variations such as controlled drying and ultrasonication significantly enhance film performance markers, including disintegration time, drug content uniformity, tensile strength, and mucosal absorption capacity. Ultimately, the choice of casting technique depends on target drug properties, intended clinical outcomes, production scale, and regulatory requirements, making comparative study essential for optimizing future migraine mouth-dissolving film development.

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TRADITIONAL SOLVENT CASTING
Most widely used.
Suitable for heat-sensitive drugs.
Requires careful control of drying to avoid cracks.

ADVANTAGES:
Good drug uniformity
Simple equipment

LIMITATIONS:
Long drying time
Potential solvent residue

MODIFIED SOLVENT CASTING WITH CONTROLLED DRYING
Uses controlled temperature and humidity.
Better film homogeneity.

ASSESSMENT:

Parameter	Traditional	Controlled Drying
Film uniformity	Moderate	High
Drying time	Long	Reduced
Mechanical strength	Variable	Improved
Solvent residue	Higher	Lower

SOLVENT CASTING WITH ULTRASONICATION
Ultrasonication reduces particle aggregation.
Promotes uniform drug dispersion.

ULTRASONIC CAVITATION ENERGY:

$$E = P \times t$$

Where E = energy, P = power, t = time.

1. Evaluation Parameters
Film quality is assessed using:

2. Thickness
Measured by micrometer at different points (≤ 0.3–1.0 mm desirable).

3. Uniformity of Weight
Ensures consistent dosing.

4. Tensile Strength (TS)

$$TS = \frac{F}{A}$$

Where F is force at break, A is cross-sectional area.

5. Disintegration Time
Ideal MDFs disintegrate within 30–60 seconds (FDA guideline).

6. Drug Content Uniformity
Accessed via HPLC:

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$$\text{Drug Content (\%)} = \frac{\text{Amount measured}}{\text{Theoretical amount}} \times 100$$

7. In Vitro Release
Comparison of % drug released over time to evaluate onset potential.

MIGRAINE DRUGS IN MDFS
A. Sumatriptan
Fast action beneficial for acute episodes.
High solubility challenges require polymer optimization.
B. Rizatriptan
Lower dose requirement favors MDF due to minimal bulk.
Good mucosal absorption enhances onset.
C. Zolmitriptan
Balanced lipophilicity aids permeation.

DISCUSSION
Controlled drying improves uniformity and mechanical properties (Rahman et al., 2021).
Ultrasonication enhances dispersion, improving dissolution profiles (Gupta & Patel, 2019).
Polymer concentration and plasticizer ratios greatly influence disintegration time and tensile strength (Kumar et al., 2022).

KEY CONSIDERATIONS
Drug-polymer compatibility (via FTIR/DSC studies).
Solvent choice affects drying time and residual solvent.

II. CONCLUSION

Solvent casting remains the cornerstone technique for migraine drug MDFs. Modified approaches like controlled drying and ultrasonication yield films with improved mechanical and dissolution profiles. Future research must converge rapid manufacturing, solvent-free techniques, and scalable industrial processes.

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