ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26feb537

Orodispersible Herbal Films for Fever: A Review on Tulsi (*Ocimum sanctum*) and Guduchi (*Tinospora cordifolia*)

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Publication Date: 2026/02/20

Abstract: Fever is a prevalent clinical sign of infection and inflammation, driven by endogenous pyrogens and the synthesis of prostaglandin E2 (PGE2) in the hypothalamus. While conventional antipyretics, such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs), are commonly utilized, their extended use can result in adverse effects including hepatotoxicity, nephrotoxicity, and gastrointestinal irritation. In contrast, herbal medicines are gaining popularity due to their multi-target pharmacological properties and enhanced safety profiles. Notably, Tulsi (*Ocimum sanctum* Linn.) and Guduchi (*Tinospora cordifolia* (Willd.) Miers) are well-known Ayurvedic herbs traditionally recognized as "Jwarahara" agents for managing fever. The antipyretic effects of these herbs are mainly linked to their bioactive components, which include eugenol, ursolic acid, rosmarinic acid, diterpenoid lactones, alkaloids, and immunomodulatory polysaccharides. These constituents demonstrate anti-inflammatory, antioxidant, antimicrobial, and immune-regulatory activities. However, traditional herbal dosage forms such as syrups, tablets, and decoctions often face challenges, including delayed onset of action, taste preferences, and poor compliance, particularly among pediatric and geriatric patients. Orodispersible films (ODFs) represent an innovative drug delivery system that rapidly disintegrates in the oral cavity without water, providing benefits such as swift onset, enhanced patient compliance, precise dosing, and convenience. This review explores the pharmacological foundations of Tulsi and Guduchi as herbal antipyretic agents, formulation strategies for integrating these extracts into ODFs, evaluation parameters to ensure quality and efficacy, and future possibilities including nano-enabled films, advanced manufacturing techniques, standardization methods, and clinical validation. Herbal antipyretic ODFs present a promising avenue for merging traditional herbal treatments with modern pharmaceutical advancements for effective and patient-friendly fever management.

Keywords: *Orodispersible Films; Oral Thin Films; Herbal Antipyretic; Fever; Tulsi; Ocimum Sanctum; Guduchi; Tinospora Cordifolia; Fast Dissolving Films; Phytoconstituents; Solvent Casting; Patient Compliance.*

How to Cite: T. D. Farande; A. Purohit (2026) Orodispersible Herbal Films for Fever: A Review on Tulsi (Ocimum sanctum) and Guduchi (Tinospora cordifolia). *International Journal of Innovative Science and Research Technology*, 11(2), 1011-1022. https://doi.org/10.38124/ijisrt/26feb537

I. INTRODUCTION

Fever (pyrexia) is a prevalent clinical symptom of infection and inflammation, marked by an increase in body temperature due to the release of endogenous pyrogens and inflammatory mediators. The hypothalamus plays a key role in regulating fever by synthesizing prostaglandin E2 (PGE2), which raises the body's temperature set point. Fever is commonly associated with viral, bacterial, and parasitic infections, making its management vital for symptomatic relief and complication prevention, particularly in pediatric and geriatric populations. While traditional antipyretic medications like paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) are frequently used, their extended use may lead to adverse effects such as gastrointestinal irritation, renal toxicity, and hepatotoxicity, highlighting the need for safer therapeutic alternatives [1,2].

Herbal medicines are gaining popularity due to their multi-targeted pharmacological effects and relatively fewer side effects. Among herbal antipyretics, *Ocimum sanctum* Linn. (Tulsi) is a well-regarded medicinal plant utilized in Ayurveda and traditional medicine for treating fever, respiratory issues, inflammation, and immune support. The antipyretic and anti-inflammatory properties of Tulsi are attributed to its phytochemical constituents, including eugenol, ursolic acid, flavonoids, and phenolic compounds, which demonstrate antioxidant and immunomodulatory activities. Numerous experimental studies have confirmed its antipyretic, analgesic, and anti-inflammatory effects, reinforcing its traditional application in fever management [3,4].

Similarly, *Tinospora cordifolia* (Guduchi/Giloy), part of the Menispermaceae family, is another esteemed medicinal herb known as "Amrita" in Ayurveda for its rejuvenating and

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26feb537

immune-enhancing properties. Guduchi is traditionally regarded as a "Jwarahara" (fever reducer) and has been scientifically shown to possess antipyretic, anti-inflammatory, antioxidant, and immunomodulatory effects. Research on animal models has validated the significant antipyretic and analgesic properties of *T. cordifolia*, supporting its use in treating febrile conditions [5,6].

Despite the promising pharmacological potential of herbal extracts like Tulsi and Guduchi, their conventional oral dosage forms—such as tablets, capsules, and syrups—present certain limitations, including delayed onset of action, swallowing difficulties, and lower compliance, particularly among pediatric, geriatric, and dysphagic patients. Recently, fast-dissolving drug delivery systems have emerged as a patient-friendly solution to address these challenges. Among these, orodispersible films (ODFs) are thin polymeric films that quickly disintegrate or dissolve upon contact with saliva, releasing the active ingredient without requiring water. The benefits of orodispersible films include rapid onset of action, enhanced bioavailability, improved patient compliance, ease of administration, and suitability for acute conditions like fever [7–9].

Incorporating herbal extracts into orodispersible films offers a novel approach that merges traditional medicine with advanced drug delivery technology. Formulating Tulsi and Guduchi extracts into ODFs can provide rapid antipyretic action, improved stability of phytoconstituents, and convenient administration. This method is especially advantageous in fever management, where prompt relief and improved patient acceptability are essential. Thus, developing herbal antipyretic orodispersible films containing Tulsi and Guduchi extracts presents a promising alternative to conventional antipyretic therapies. This review will explore the pharmacological basis of Tulsi and Guduchi as antipyretic agents, formulation considerations for herbal ODFs, evaluation parameters, and the future research landscape in this area [7–9].

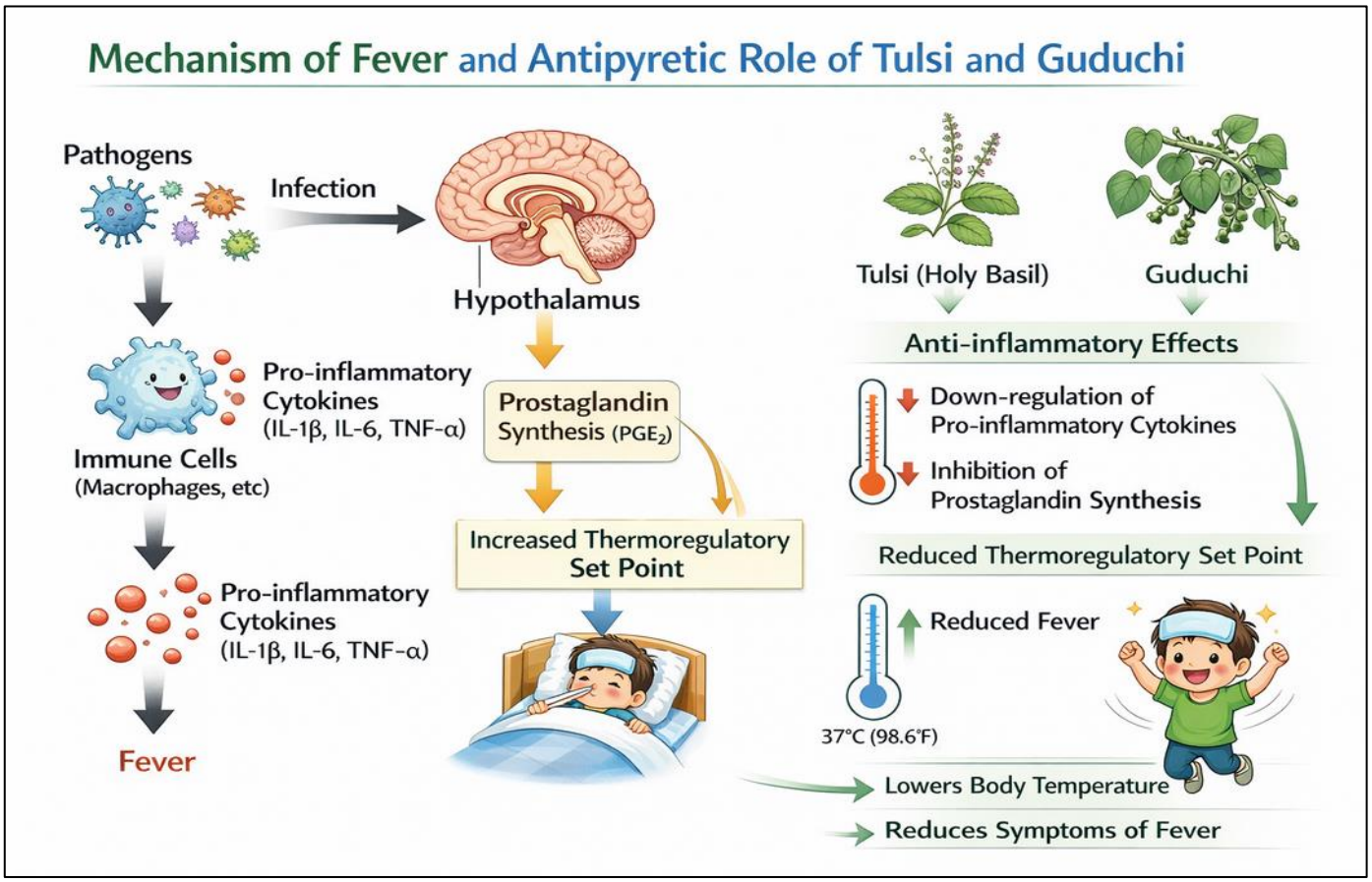

Fig 1 Mechanism of Fever and Antipyretic Action of Tulsi & Guduchi.

II. DISCOVERY AND DEVELOPMENT OF ORODISPERSIBLE FILMS (ODFS)

Orodispersible films (ODFs), also referred to as oral thin films or orally dissolving films, are an advanced oral drug delivery system designed to rapidly disintegrate or dissolve in the oral cavity without the requirement of water. The concept of film-based oral dosage forms has its foundation in early polymeric film technologies. Initial research on water-soluble polymer films dates back to the mid-20th century, where thin films made from hydrophilic polymers were developed as dissolvable strips, providing a basis for future pharmaceutical applications [10]. Further progress in film technology was observed during the 1960s, when drug-impregnated paper and gelatin-based films were explored, which contributed significantly to the development of medicated oral film dosage forms [11].

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The major commercial breakthrough in oral thin film technology occurred much later with the introduction of Listerine® PocketPaks in 2001, which demonstrated the feasibility, patient convenience, and market acceptance of rapidly dissolving oral strips [12]. Following this success, drug-loaded orodispersible films gained strong pharmaceutical interest, leading to the development of medicated oral films for both over-the-counter and prescription products. Additionally, regulatory recognition and inclusion of orodispersible films in official pharmaceutical guidelines further supported their establishment as a promising drug delivery platform [12]. Today, ODFs are widely investigated for delivering synthetic drugs as well as herbal extracts due to their rapid onset of action, improved patient compliance, portability, and suitability for pediatric and geriatric patients [12].

A. *Orodispersible Films (ODFs)*

Orodispersible films (ODFs) are slender, flexible, polymer-based oral dosage forms designed to swiftly disintegrate or dissolve in the mouth within a short time, typically in under a minute, without the need for water. This innovative dosage form has captured significant attention for its ability to enhance drug delivery efficiency and improve patient compliance. ODFs generally consist of a hydrophilic polymer matrix that includes the active ingredient, plasticizer, sweeteners, flavoring agents, and other additives to ensure rapid disintegration and pleasant organoleptic properties. Thanks to their large surface area and quick wetting in saliva, ODFs can dissolve faster than traditional tablets, leading to improved therapeutic responses in acute conditions [13,14].

B. *Significance of Orodispersible Films*

The significance of ODFs lies in their capability to address the limitations of conventional oral dosage forms like tablets and syrups. ODFs are particularly advantageous for pediatric, geriatric, bedridden, and dysphagic patients who may struggle to swallow tablets or capsules. Unlike liquid formulations, which can suffer from inaccurate dosing, poor portability, and stability issues, ODFs offer precise unit doses and are easy to carry and administer. Moreover, ODFs can be taken without water, making them especially convenient during situations involving fever, nausea, vomiting, or emergencies where water access may be limited [15,16].

C. *Ideal Characteristics of Orodispersible Films*

An ideal ODF should exhibit several key pharmaceutical characteristics to ensure patient acceptability and formulation success:

- *Mechanical Strength and Flexibility:*
  Must withstand handling, packaging, and transportation.

- *Rapid Disintegration:*
  Should dissolve quickly in saliva, leaving no residue and providing a smooth mouthfeel.

- *Uniform Thickness and Drug Content:*
  Essential for accurate dose delivery.

- *Taste Masking:*
  Important since the dosage form dissolves directly in the mouth; an unpleasant taste can hinder compliance.

- *Neutral Surface pH:*
  Should be close to neutral to avoid irritating the oral mucosa.

- *Moisture Stability:*
  Critical, as most film-forming polymers are hydrophilic and can easily absorb moisture, which may impact disintegration time and drug release [17,18].

D. *Advantages of Orodispersible Films*

ODFs present numerous advantages over traditional dosage forms:

- *Rapid Disintegration and Fast Drug Release:*
  Facilitates quicker onset of action.

- *Reduced Risk of Choking:*
  A significant concern for children and elderly patients.

- *Portability and Convenience:*
  Ideal for outpatient use.

- *Accurate Dosing:*
  ODFs eliminate dosing errors associated with measuring devices used in syrups.

- *Enhanced Bioavailability:*
  Certain drugs may be partially absorbed through the buccal mucosa, potentially bypassing hepatic first-pass metabolism. These benefits make ODFs a favored dosage form for medications requiring immediate symptomatic relief, such as antipyretics, analgesics, and antiemetics [19,20].

E. *Limitations of Orodispersible Films*

Despite their potential advantages, ODFs also face limitations:

- *Limited Drug-Loading Capacity:*
  The thin structure restricts the incorporation of high-dose drugs.

- *Formulation Complexity:*
  Particularly challenging for bitter drugs and herbal extracts due to taste masking difficulties.

- *Moisture Sensitivity:*
  The hydrophilic polymers can lead to stickiness, brittleness, or microbial contamination, necessitating specialized packaging.

- *Uniform Distribution Challenges:*
  Achieving consistent distribution of herbal extracts is difficult due to variability in phytochemical composition, solubility, and stability, which may impact therapeutic outcomes [21–23].

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F. Pharmaceutical Significance

From a formulation perspective, ODFs represent an advanced oral drug delivery system due to their flexible design and patient-centered approach. They provide a suitable platform for delivering low-dose drugs and herbal extracts with rapid onset. Manufacturing methods such as solvent casting, hot-melt extrusion, and printing technologies enable controlled thickness, uniformity, and dosing precision. Additionally, ODFs have attracted industrial interest for their potential in continuous manufacturing and improved product performance, making them a vital area of pharmaceutical research, especially for integrating herbal medicines into contemporary dosage forms [24,25].

G. Clinical Significance

Clinically, ODFs are highly relevant as they enhance adherence and reduce medication refusal among pediatric and geriatric patients. Their quick disintegration guarantees rapid drug availability, which is particularly beneficial in acute conditions like fever, pain, allergies, and nausea. In fever management, the ability to administer medication without water is especially useful when patients are weak, dehydrated, or vomiting. ODFs also provide greater convenience in emergency scenarios, community healthcare, and home-based treatment. For these reasons, ODFs are recognized as an effective and patient-friendly dosage form with increasing clinical significance in modern therapy [26,27].

➢ *Tulsi (Ocimum sanctum Linn. / Ocimum tenuiflorum)*

Fig 2 Tulsi (Ociumum sanctum Linn./Ocimum tenuiflorum)

- *Botanical Description*

Tulsi (*Ocimum sanctum* Linn., synonym *Ocimum tenuiflorum*) is a renowned aromatic medicinal plant belonging to the Lamiaceae family. It is commonly found across India and cultivated in tropical regions. This erect, branched herb or shrub generally reaches a height of 30–60 cm and features opposite, ovate, serrated leaves along with purple or white flowers arranged in racemes. Traditionally, Tulsi is revered as a crucial medicinal herb for treating fever, cough, cold, and inflammatory disorders. It is extensively documented in Ayurveda as a "Rasayana" plant, recognized for its potential to modulate the immune system [28].

- *Parts Used*

The leaves are the most commonly utilized component for medicinal and pharmaceutical purposes due to their rich concentration of essential oils and polyphenols. While seeds and aerial parts are also used, leaf extracts have the strongest scientific validation for their antipyretic and anti-inflammatory properties [29].

- *Bioactive Constituents*

Tulsi is abundant in phytoconstituents that contribute to its therapeutic effects. Key reported bioactive compounds include:

✓ Phenolic compounds: eugenol, methyl eugenol
✓ Phenolic acids: rosmarinic acid
✓ Terpenoids: linalool, β-caryophyllene
✓ Triterpenoids: ursolic acid
✓ Flavonoids: apigenin, luteolin
✓ Tannins and saponins

These compounds endow Tulsi with potent antioxidant, anti-inflammatory, antimicrobial, and immunomodulatory effects, reinforcing its role as an antipyretic agent in cases of fever [30].

- *Mechanism of Antipyretic Action*

Fever arises from the release of pyrogen-induced cytokines (IL-1β, IL-6, TNF-α), leading to an increase in prostaglandin E2 (PGE2) synthesis in the hypothalamus. Tulsi exhibits its antipyretic activity primarily by suppressing inflammatory mediators and inhibiting the cyclooxygenase pathways responsible for prostaglandin synthesis. Eugenol and rosmarinic acid have been shown to diminish oxidative stress and inflammatory signaling, aiding in the normalization of elevated body temperature and systemic inflammation [31].

- *Clinical Evidence and Therapeutic Efficacy*

Research involving human subjects and systematic reviews indicates that Tulsi enhances immune status and provides symptomatic relief in respiratory infections, which are often linked to fever. The evidence suggests that Tulsi improves inflammatory and metabolic parameters, supporting its traditional use as a medicinal plant that enhances immunity. These findings emphasize its relevance as a supportive herbal antipyretic agent [32].

- *Justification for Use in Antipyretic Therapy*

Tulsi is therapeutically justified for managing fever as it offers multiple supportive actions: antipyretic, antimicrobial, anti-inflammatory, and antioxidant effects. This wide-ranging efficacy is crucial since fever is frequently associated with infections and systemic inflammation. Consequently, Tulsi is well-suited for modern herbal formulations aimed at treating fever-related conditions [33].

- *Suitability in Orodispersible Film (ODF) Formulation*

Tulsi extract is ideally suited for ODF formulations because of its effectiveness in low doses, the need for rapid onset in febrile conditions, and its patient-friendly nature.

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26feb537

ODFs can enhance compliance in pediatric patients, overcome swallowing difficulties, and facilitate quick release of Tulsi phytoconstituents in the mouth. However, its bitterness and aromatic volatility necessitate effective taste masking and moisture-protective packaging to maintain stability [34].

➢ *Guduchi (Tinospora cordifolia (Willd.) Miers)*

Fig 3 Guduchi (Tinospora cordifolia(Willd)Miers)

- *Botanical Description*

Guduchi (*Tinospora cordifolia*) is a large, deciduous climbing shrub that belongs to the **Menispermaceae** family. It features long, twining stems with aerial roots, heart-shaped leaves, small greenish-yellow flowers, and red drupes. Widely distributed across India, Guduchi is highly esteemed in Ayurveda as a "Rasayana" drug due to its rejuvenating, antipyretic, and immunomodulatory properties [35].

- *Parts Used*

The stem is the most commonly utilized medicinal part, rich in alkaloids, diterpenoid lactones, and immunomodulatory polysaccharides. While the leaves are used traditionally, the stem extract remains the most scientifically validated for its antipyretic and immune-enhancing effects [36].

- *Bioactive Constituents*

Guduchi is composed of several pharmacologically active compounds, including:

✓ Diterpenoid lactones: tinosporide, cordifolide, cordifol
✓ Alkaloids: magnoflorine, berberine
✓ Glycosides: tinocordiside
✓ Steroids: β-sitosterol
✓ Polysaccharides: immunomodulatory polysaccharide fractions

These constituents contribute to Guduchi's significant antipyretic, antioxidant, immunomodulatory, and anti-inflammatory activities [37].

- *Mechanism of Antipyretic Action*

Guduchi exhibits antipyretic effects through immune modulation and the suppression of inflammatory mediators. It reduces fever by lowering pro-inflammatory cytokine expression and oxidative stress while enhancing immune cell activation. The polysaccharides in Guduchi boost macrophage and phagocytic activity, which aids in eliminating microbial pyrogens responsible for fever due to infection [38].

- *Clinical Evidence and Therapeutic Efficacy*

Clinical and experimental studies have established Guduchi's effectiveness in enhancing immune function and alleviating inflammatory burdens in chronic infections and febrile conditions. It has been extensively researched for its immunostimulatory and anti-inflammatory benefits, supporting its therapeutic potential in managing fever and systemic inflammatory disorders [39].

- *Justification for Use in Antipyretic Therapy*

Guduchi is a well-justified herbal option for treating fever due to its dual functionality: alleviating fever symptoms and reinforcing immune defense. Unlike conventional antipyretics that primarily target prostaglandin pathways, Guduchi offers broader therapeutic benefits, including antioxidant protection and immune recovery, making it ideal for recurrent fever and infections [40].

- *Suitability in Orodispersible Film (ODF) Formulation*

Guduchi is suitable for ODF dosage forms due to its bitter taste (which can deter compliance with syrups or decoctions), the requirement for frequent dosing, and its usefulness for pediatric and geriatric patients. Incorporating Guduchi extract into polymeric films allows for precise dosing, rapid release, and improved stability compared to liquid herbal preparations. However, formulation challenges include bitterness, high extract load, and hygroscopicity, necessitating careful polymer selection and taste-masking techniques [41].

III. FORMULATION APPROACHES FOR HERBAL ANTIPYRETIC ORODISPERSIBLE FILMS (ODFS)

Herbal orodispersible films (ODFs) are thin, polymer-based oral strips that dissolve quickly in saliva, facilitating the rapid release of herbal actives without requiring water. They are especially advantageous for antipyretic treatment due to their quick onset of action, enhanced patient compliance, and suitability for both pediatric and geriatric patients [42,43].

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26feb537

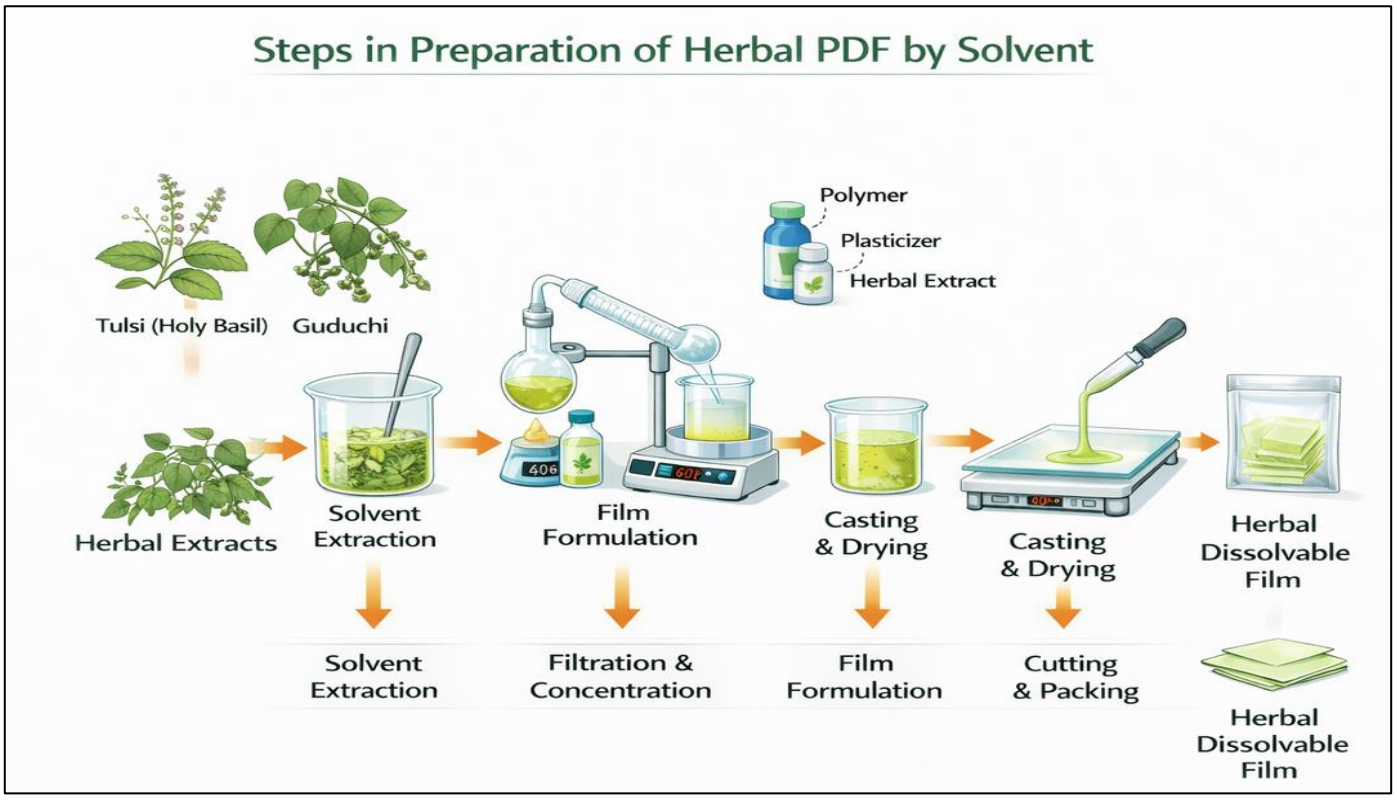

Fig 4 Solvent Casting Method for Preparation of Herbal ODF (Tulsi + Guduchi).

A. Selection of Film-Forming Polymers

Film-forming polymers serve as the foundation of ODF formulation, providing mechanical strength, flexibility, and rapid disintegration. Commonly used polymers include hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), polyvinyl alcohol (PVA), pullulan, sodium alginate, gelatin, and pectin.

The choice of polymer significantly influences tensile strength, drug release rate, disintegration time, and stability of the final product [42,43]. For herbal extracts like Tulsi and Guduchi, hydrophilic polymers such as HPMC and pullulan are generally favored, as they promote uniform extract dispersion and quick hydration in saliva [43].

B. Use of Plasticizers

Plasticizers are incorporated to enhance film flexibility and reduce brittleness. Common plasticizers for ODFs include glycerol, polyethylene glycol (PEG-400), propylene glycol, and sorbitol.

These agents help decrease polymer chain rigidity, thereby improving folding endurance and handling characteristics [42]. However, an excess of plasticizer may lead to increased tackiness and moisture absorption, potentially causing stability concerns during storage [43].

C. Incorporation of Herbal Extracts

Incorporating herbal extracts presents formulation challenges, such as high bitterness, poor solubility, hygroscopicity, and chemical instability. Thus, the incorporation process must be optimized to ensure uniformity and compatibility with the polymer matrix. Careful control of extract load is essential to prevent a reduction in mechanical strength while maintaining rapid disintegration [43].

Successful plant extract-based ODFs have been developed by selecting appropriate polymer ratios and drying conditions that preserve phytochemical activity [46].

D. Taste Masking and Palatability Enhancement

Taste masking is crucial, as ODFs dissolve in the oral cavity. Herbal extracts like Guduchi can be quite bitter, necessitating the addition of sweeteners (such as sucralose, aspartame, or stevia), flavors (like mint, orange, or lemon), and cooling agents.

Complexation with cyclodextrins and the use of polymer blends have also been reported as effective methods for improving taste [42,43]. Palatability is particularly important for pediatric applications and directly affects patient compliance in fever management [42].

E. Saliva Stimulating Agents

Saliva stimulants such as citric acid, malic acid, and tartaric acid are utilized to boost saliva production and hasten film disintegration. These agents also enhance taste and mouthfeel, increasing acceptability [42].

F. Manufacturing Methods

The most commonly employed method for ODF preparation is solvent casting, which involves dissolving polymers in water or a hydroalcoholic solvent, mixing in the herbal extract, casting the mixture, and then drying it. This method is favored for its simplicity, uniformity, and compatibility with herbal extracts [42].

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Additionally, modern manufacturing techniques like hot-melt extrusion, electrospinning, and printing technologies are being explored to enhance dose precision and scalability of ODF production [43,45].

G. Evaluation and Optimization Parameters

When evaluating herbal antipyretic ODFs, the following parameters should be considered:

- Thickness uniformity
- Weight variation
- Folding endurance
- Tensile strength
- Surface pH
- Disintegration time
- Drug content uniformity
- Moisture absorption and stability studies

These evaluations are essential to ensure film quality, patient safety, rapid performance, and long-term stability of herbal formulations [42,43].

IV. EVALUATION PARAMETERS FOR HERBAL ANTIPYRETIC ORODISPERSIBLE FILMS (ODFS)

The assessment of herbal antipyretic ODFs is crucial to ensure uniformity, rapid disintegration, mechanical strength, stability, and therapeutic efficacy. Given that herbal extracts like Tulsi and Guduchi can influence film characteristics due to their phytochemical makeup, thorough evaluation is vital for standardization and quality assurance [47].

A. Physical Evaluation Parameters

- *Appearance and Organoleptic Properties*

Films should be assessed for color, transparency, surface smoothness, texture, odor, and taste. Herbal extracts can impart distinct odors and bitterness; thus, organoleptic evaluation is essential for patient acceptability, particularly in managing fever in pediatric patients [48].

- *Thickness Uniformity*

The thickness of the film is gauged using a micrometer screw gauge at various points to confirm the even distribution of the extract and ensure consistent dosing. Uniform thickness is necessary for predictable disintegration and drug release [49].

- *Weight Variation*

Each film is weighed and compared with the average weight to evaluate consistency. Weight variation signifies uniform casting and the even distribution of herbal extract within the polymeric matrix [50].

B. Mechanical Evaluation Parameters

- *Folding Endurance*

Folding endurance is assessed by repeatedly folding the film at the same point until it breaks. A high folding endurance indicates good flexibility and mechanical strength, ensuring safe handling during packaging and administration [47].

- *Tensile Strength*

Tensile strength measures the maximum stress the film can endure before rupture. This is critical to ensure that the herbal films remain intact during handling or transport. The concentration of polymers and plasticizers significantly affects tensile strength [51].

- *Percent Elongation*

Percent elongation evaluates the film's elasticity and flexibility. A higher value indicates greater flexibility, which is essential for the practical handling and packaging of ODFs [51].

C. Performance Evaluation Parameters

- *Surface pH*

Surface pH is determined by placing the film on moist agar gel or in contact with distilled water. Ideally, the surface pH should be close to neutral (6.5–7.5) to prevent irritation of the oral mucosa. Herbal extracts may influence surface pH; therefore, this test is crucial [48,52].

- *Disintegration Time*

Disintegration time is a key parameter for ODFs. It is measured by placing the film in a small volume of simulated saliva and recording the time taken for complete disintegration. A rapid disintegration time (<30–60 seconds) is preferred for quick fever relief [47,53].

- *In-vitro Dissolution Studies*

Dissolution testing is carried out using USP dissolution apparatus (commonly the paddle method) with simulated saliva or buffer. This assesses the release profile of herbal constituents and helps predict in vivo performance [49].

D. Content and Uniformity Parameters

- *Drug/Extract Content Uniformity*

Ensuring the uniformity of herbal extract in each film is vital for dose accuracy. Extract content is evaluated by dissolving a known area of the film and analyzing the phytochemical marker (e.g., eugenol for Tulsi or cordifolide for Guduchi) using UV/Vis spectrophotometry or HPLC [54].

- *Assay of Marker Compounds*

Quantifying marker compounds ensures batch-to-batch reproducibility and standardization of herbal antipyretic ODFs. HPLC or GC-MS methods are commonly preferred for precise estimation [54,55].

E. Moisture and Stability Evaluation

- *Moisture Content*

Moisture content impacts mechanical strength, microbial stability, and disintegration time. Films are dried and weighed to assess moisture loss. Herbal films tend to be hygroscopic, making moisture evaluation critical [50].

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➢ *Moisture Uptake (Hygroscopicity Study)*

Moisture uptake is assessed by exposing films to controlled humidity conditions. Excessive moisture uptake can lead to stickiness, microbial growth, and loss of mechanical integrity [52].

➢ *Stability Studies*

Stability testing follows ICH guidelines to evaluate physical changes (such as brittleness or discoloration) and the chemical degradation of herbal constituents. This is essential since phytochemicals may degrade due to exposure to light, heat, and humidity [56].

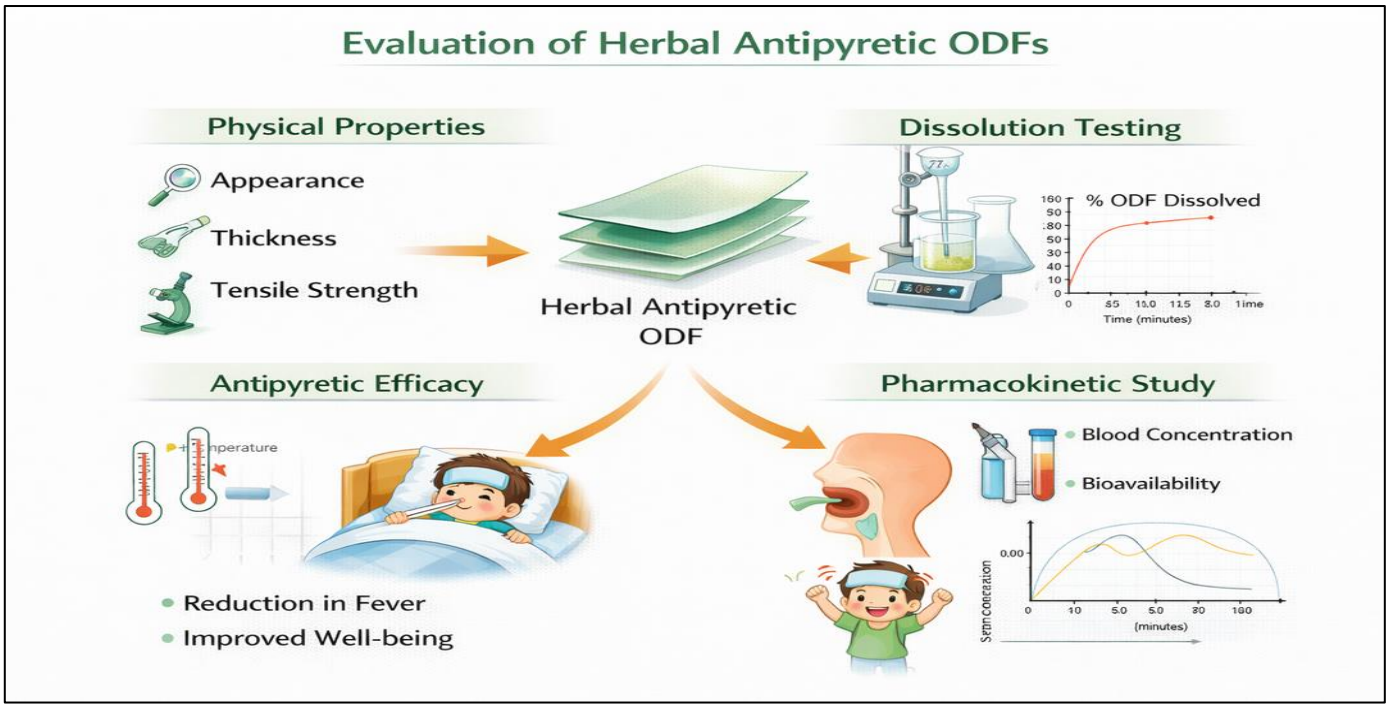

Fig 5 Evaluation Parameters of Herbal Antipyretic Orodispersible Films (ODFs).

F. Advanced Evaluation Parameters (Optional but Strong for Publication)

➢ *Scanning Electron Microscopy (SEM)*

SEM is utilized to analyze surface morphology and detect cracks, pores, and the uniformity of extract dispersion within the film matrix. It provides insights into structural integrity and compatibility between the polymer and herbal extract [57].

➢ *FTIR Compatibility Studies*

FTIR analysis confirms compatibility between the herbal extract and excipients by identifying functional group interactions. This is crucial for ensuring chemical stability and preventing degradation reactions [58].

➢ *Differential Scanning Calorimetry (DSC)*

DSC is employed to evaluate the thermal behavior, crystallinity, and stability of the extract within the polymer matrix. It aids in confirming amorphous dispersion and enhances predictability of drug release [58].

Table 1 Evaluation Parameters for Herbal Antipyretic Orodispersible Films

Parameter	Method	Importance
Thickness	micrometer	uniform dose distribution
Weight variation	weighing balance	batch uniformity
Folding endurance	repeated folding	flexibility and handling
Tensile strength	texture analyzer	mechanical integrity
Surface pH	pH meter/agar method	mucosal safety
Disintegration time	simulated saliva	rapid onset of action
Dissolution test	USP apparatus	release profile prediction
Content uniformity	UV/HPLC	dose accuracy
Moisture uptake	humidity chamber	stability evaluation
Stability studies	ICH guidelines	shelf-life determination
SEM	microscopy	surface morphology
FTIR	spectroscopy	drug–excipient compatibility
DSC	thermal analysis	stability and crystallinity

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26feb537

V. FUTURE PROSPECTS OF HERBAL ANTIPYRETIC ORODISPERSIBLE FILMS

Herbal antipyretic orodispersible films (ODFs) signify an exciting blend of traditional herbal medicine and contemporary drug delivery technology. As the focus on patient-centric and rapid-acting dosage forms intensifies, various future avenues can be explored to improve the effectiveness, scope, and applicability of this innovative herbal formulation method.

A. Enhanced Bioavailability and Targeted Action

While herbal extracts like Tulsi and Guduchi possess inherent therapeutic benefits, bioavailability challenges arise from poor solubility and first-pass metabolism. Future investigations may delve into nano-enabled ODF platforms (such as drug-loaded nanoparticles, nanoemulsions, and lipid carriers) incorporated into the film matrix to boost dissolution and mucosal absorption, which may enhance systemic absorption and antipyretic effectiveness [59,60].

B. Advanced Manufacturing Technologies

Innovative fabrication techniques like 3D printing and hot-melt extrusion offer precise control over film thickness, dose distribution, and multilayer structures. These methods can be utilized for herbal ODFs to achieve personalized dosing, multi-layer release profiles, and combination therapy formats (e.g., merging antipyretics with immunomodulators or analgesics) [61,62].

C. Standardization and Phytochemical Fingerprinting

A significant hurdle in herbal formulations is batch variability stemming from differences in plant sources, harvest times, and extraction processes. Future endeavors should focus on chemical standardization and fingerprinting through advanced analytical methods (HPLC, LC–MS) to ensure consistency, quality control, and regulatory compliance of herbal ODFs, especially as they are scaled for industrial manufacturing [63].

D. Clinical Evaluation and Evidence Generation

Currently, there is a lack of clinical data specifically addressing herbal ODF antipyretic systems, despite existing evidence for individual herbs like Tulsi and Guduchi. Future research should incorporate well-structured clinical trials to validate safety, efficacy, pharmacokinetics, and dose-response relationships of herbal ODFs in human populations, including vulnerable groups such as children and the elderly [64].

E. Integration with Digital Health and Patient Monitoring

The rise of wearable health devices and digital analytics offers a chance to connect the rapid symptomatic relief from ODF administration with real-time physiological monitoring (e.g., temperature, heart rate). This integration could facilitate personalized dosing recommendations and data-driven validation of antipyretic effects, enhancing the clinical relevance of herbal ODFs within modern therapeutic frameworks [65].

F. Expanded Phytotherapeutic Combinations

In addition to Tulsi and Guduchi, numerous other antipyretic and anti-inflammatory herbs (e.g., Ashwagandha, Neem, Holy Basil) could be investigated for synergistic combinations within ODF platforms. Systematic studies on herbal synergy and phytochemical interactions may produce formulations with improved efficacy, fewer side effects, and wider therapeutic applications [66].

G. Regulatory Pathways and Quality Assurance Frameworks

As herbal ODFs move toward commercialization, the development of clear regulatory frameworks tailored for hybrid products that integrate traditional extracts with modern delivery systems is vital. Research focusing on meeting pharmacopoeial standards, safety requirements, and compliance with regulatory authorities (e.g., FDA, EMA) will be essential for industrial uptake and global acceptance [67].

Table 2 Future Prospects of Herbal Antipyretic ODFs

Area	Future strategy	Benefit
Bioavailability	nanoemulsions, nanoparticles	improved absorption
Dose personalization	3D printing films	patient-specific dosing
Stability improvement	multilayer films	protects phytoconstituents
Standardization	LC-MS fingerprinting	batch consistency
Taste masking	cyclodextrin complexation	better acceptability
Clinical validation	randomized trials	regulatory acceptance
Regulatory pathway	GMP + WHO guidelines	global commercialization

VI. CONCLUSION

Herbal antipyretic orodispersible films (ODFs) stand out as a highly promising and patient-friendly drug delivery system, merging the therapeutic advantages of traditional medicinal plants with cutting-edge pharmaceutical technology. Tulsi (*Ocimum sanctum*) and Guduchi (*Tinospora cordifolia*) are well-recognized for their antipyretic, anti-inflammatory, antioxidant, antimicrobial, and immunomodulatory effects, primarily due to bioactive compounds such as eugenol, rosmarinic acid, diterpenoid lactones, alkaloids, and polysaccharides [68,69]. These pharmacological properties make them ideal herbal choices for fever management and supportive immune therapy.

ODFs offer numerous formulation benefits, including rapid disintegration, ease of administration without water, enhanced patient adherence, and suitability for both pediatric and geriatric populations. The integration of herbal extracts into ODFs presents a novel method for achieving quick

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26feb537

symptomatic relief while ensuring precise dosing and greater convenience compared to traditional decoctions and syrups. Nonetheless, challenges such as bitterness, extract variability, stability concerns, moisture sensitivity, and limitations in drug loading remain significant issues that necessitate optimization through careful polymer selection, taste-masking techniques, and standardization methods [70,71].

In summary, Tulsi–Guduchi-based antipyretic ODFs represent a forward-thinking and effective herbal dosage form with considerable clinical and commercial potential. Future research should prioritize phytochemical standardization, advanced formulation methods such as nano-enabled films, long-term stability assessments, and well-structured clinical trials to confirm safety, efficacy, and regulatory compliance. With appropriate pharmaceutical development and scientific validation, herbal ODFs could emerge as a modern, rapid-acting, and globally accepted therapeutic option for fever and related inflammatory conditions [72,73].

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