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ORIGINAL ARTICALE

FORMULATION AND PHYSIOCHEMICAL EVALUATION OF PHYTOTHERAPEUTIC POTENTIAL OF MUCOADHESIVE PATCHES WITH TEPHROSIA BASED EXTRACT FOR IMMUNOLOGICAL AND INFLAMMATORY ORAL MUCOSAL LESIONS.

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ABSTRACT

Background: Mucoadhesive patches are an effective method for delivering drugs directly to the oral cavity, offering site-specific, controlled release. Hydroxypropyl Methylcellulose (HPMC) is a widely used polymer in such systems due to its safety, mucoadhesiveness, and ability to form stable films. Tephrosia species, known for their anti-inflammatory, antimicrobial, and antioxidant properties, are promising candidates for incorporation into these delivery systems.

Aim: Tephrosia maxima and Tephrosia callophylla extracts were used to create and assess mucoadhesive dental patches based on HPMC, with an emphasis on the physicochemical characteristics, drug release patterns, and possible therapeutic uses in oral applications.

Materials and Methods: Tephrosia extracts were put into an HPMC matrix to create two patch formulations (Patch 1 and Patch 2). The patches were examined using FTIR spectroscopy for chemical compatibility, tensile testing for mechanical strength, contact angle measurements for wettability, and scanning electron microscopy (SEM) for surface morphology. To evaluate the release profile and mucoadhesive performance, in vitro drug release tests were also carried out.

Results: SEM showed uniform distribution of plant extracts within the patches. A balanced HPMC-to-extract ratio provided optimal tensile strength. Contact angle analysis confirmed good surface hydrophilicity, aiding adhesion. FTIR spectra indicated no major chemical interactions, suggesting good compatibility. Drug release followed a biphasic pattern—an initial burst followed by sustained release—ideal for extended oral therapy.

Conclusion: The study successfully developed and characterized HPMC-based mucoadhesive patches containing Tephrosia extracts. The findings support their potential use as effective, plant-based alternatives for localized treatment of oral conditions, encouraging further in vivo research and clinical evaluation.

Keywords: Bioactive Compounds, Fourier Transform Infrared (FTIR) Spectroscopy, Tephrosia species, Hydroxypropyl Methylcellulose (HPMC), Mucoadhesive Patches, oral ulcers, therapeutic adjunct

INTRODUCTION

The oral mucosa is constantly exposed to enzymes and saliva, which makes it difficult for drugs to stay in place and work effectively. These natural processes often reduce the success of regular drug treatments. Mucoadhesive drug delivery systems offer a better option by sticking to the moist inner surface of the mouth. This allows the drug to be released slowly and directly at the target site. As a result, the treatment works better, fewer doses are needed, and side effects are reduced [1,2]. Hydroxypropyl methylcellulose (HPMC) is often used in such systems due to its strong ability to form films, stick to tissue, and remain safe in the body [3]. HPMC patches have shown good results in treating oral ulcers, infections, and even cancers[4–6].The increasing interest in natural and safer therapies has encouraged the use of herbal extracts in mucoadhesive patches. These plant-based compounds possess antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties, making them suitable for treating oral conditions such as gingival infections, aphthous ulcers, and post-surgical healing [7–10]. Herbal formulations from Myrtus communis, Anredera cordifolia, Quercus brantii, and Clitoria ternatea have shown success in mucoadhesive drug delivery systems[10–12]. *Tephrosia maximum* and *Tephrosia callophylla*, though relatively underexplored, are rich sources of flavonoids, phenolics, and alkaloids, which contribute to their notable antibacterial, anti-inflammatory, and antioxidant activities. A preceding study validated the phytochemical content and biocompatibility of their aqueous extracts. Leveraging these insights, this study focuses on formulating HPMC-based mucoadhesive dental patches and assessing their physical characteristics and chemical stability for oral drug delivery.

The oral mucosa, with its vascularity and permeability, offers an ideal platform for local drug delivery. However, patient compliance and drug effectiveness are common challenges in current formulations. Advances in mucoadhesive technologies and the incorporation of plant-based actives present promising avenues for improving dental therapeutics. Recent studies, such as the use of Usnea barbata extract in mucoadhesive films for oral squamous cell carcinoma, highlight the potential of phytotherapeutics in localized oral care [13,14]. This study aimed to develop and assess HPMC-based mucoadhesive patches containing Tephrosia extracts for oral drug delivery.

MATERIALS AND METHODS

Selection and Formulation of Mucoadhesive Patches: *Tephrosia maxima* and *Tephrosia callophylla* were selected for the formulation of mucoadhesive patches due to their well-documented antioxidant, anti-inflammatory, and antibacterial properties, along with an established safety profile that supports their use in treating various oral conditions. HPMC was employed as the mucoadhesive polymer, owing to its strong film-forming capacity, excellent biocompatibility, and reliable adhesion to moist oral mucosa. Distilled water served as the solvent for preparing both polymer and extract solutions, while glycerol was incorporated as a plasticizer to enhance the flexibility, softness, and handling characteristics of the final patches. The patches were prepared in sequential steps: an initial homogeneous HPMC solution was cast into Petri dishes and dried at 40–45°C to create a firm backing layer. A second thin HPMC layer was added as a protective topcoat. Subsequently, aqueous extracts of T. maxima and T. callophylla were individually mixed into fresh HPMC solutions and poured over the dried base layer. These were air-dried at room temperature for 24–48 hours, trimmed into uniform sizes, and stored dry. Patch 1 contained T. maxima and Patch 2 contained T. callophylla.

Physicochemical Characterization: The formulated patches were subjected to a battery of physicochemical evaluations to determine their suitability for mucoadhesive oral applications. Surface morphology was assessed using SEM. For this, small circular sections from each patch were sputter-coated with gold and visualized under SEM to examine surface texture, porosity, and dispersion of the incorporated plant extracts. Patch 1 exhibited a smoother, more uniform texture compared to Patch 2, which showed slight porosity likely due to differences in extract solubility. Mechanical properties, specifically tensile strength, and elongation at break, were measured using a Universal Testing Machine (UTM). Rectangular strips of each patch were prepared and subjected to uniaxial stretching under constant load to determine their flexibility and structural resilience. Patch 1 demonstrated superior tensile strength, indicating better film integrity and handling potential. To evaluate absorption properties, contact angle measurements were performed using a Goniometer. A water droplet was placed on the patch surface, and the angle formed at the liquid-solid interface was recorded. Lower contact angles indicated higher surface hydrophilicity,

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which correlates with improved mucoadhesion. Patch 1 showed a lower contact angle than Patch 2, suggesting enhanced wettability. The chemical compatibility between the polymer and the plant extracts was investigated using Fourier-Transform Infrared (FTIR) Spectroscopy. The spectra of individual components and formulated patches were compared to identify any significant peak shifts or disappearance of functional groups. The analysis confirmed the presence of major functional groups from both the polymer and the extracts, with no notable interaction peaks, suggesting successful and stable incorporation of the active constituents into the polymer matrix.

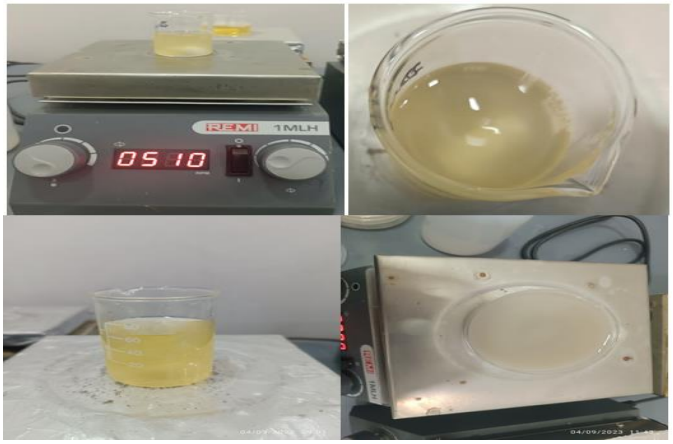

Figure 1. Preparation and heating of plant extract (Laboratory preparation and heating process of plant extract showing color changes and reaction stages)

RESULTS

Surface Morphology Analysis (SEM): The surface characteristics and drug distribution within the mucoadhesive patches. SEM micrographs revealed that both Patch 1 (*Tephrosia maxima*) and Patch 2 (*Tephrosia callophylla*) exhibited generally uniform surfaces with homogenous dispersion of the plant extracts across the HPMC matrix. However, morphological differences were evident between the two formulations. Patch 1 displayed a slightly more granular texture, indicative of evenly distributed but less compact extract particles. In contrast, Patch 2 presented a denser crystalline pattern across the surface, possibly reflecting differences in extract solubility and interaction with the polymer matrix. These surface topographies suggest that both patches were successfully fabricated with acceptable morphological integrity and no signs of surface cracking or phase separation. Figure 2 shows SEMs of two different Tephrosia species patches reveal significant differences in surface morphology. Patch 1 shows a wrinkled and irregular texture, while Patch 2 displays smoother, layered, and flaky surfaces, indicating distinct microstructural characteristics

Mechanical Properties: The tensile strength and elongation at break of the patches were evaluated using a UTM to determine their mechanical robustness and flexibility key parameters for oral mucoadhesive application. Patch 1 exhibited a tensile strength of 18.5 ± 1.2 MPa with an elongation at break of 9.2%, while Patch 2 demonstrated slightly higher tensile properties with a tensile strength of 20.3 ± 0.9 MPa and an elongation of 11.1%. Both patches demonstrated sufficient mechanical strength and flexibility to withstand manipulation during application and adhesion to oral mucosal surfaces. The slightly higher values observed in Patch 2 suggest marginally superior mechanical resilience, which may be attributed to a more integrated drug-polymer network resulting from better miscibility or crystallinity of *Tephrosia callophylla* extract within the HPMC matrix. Figure 3 shows the Tensile strength graphs for specimens 8 and 9 illustrate displacement versus force characteristics. Specimen 8 exhibits an earlier peak with lower force, while specimen 9 shows a gradual increase with higher elongation, indicating better tensile strength and elasticity.

Wettability and Surface Absorption: Contact angle measurements were conducted to assess the wettability of the patches, which is critical for mucoadhesion. Patch 1 recorded a contact angle of 62.3° ± 1.7, while Patch 2 showed a slightly lower angle of 59.8° ± 2.1. Both values fall within the acceptable hydrophilic range (<90°), indicating good surface wettability and potential for strong mucoadhesive interaction with the moist oral environment. The marginally lower contact angle of Patch 2 implies a slightly better fluid interaction, which may favor quicker hydration and adhesion upon application. However, the difference between the two formulations was minimal and both patches were deemed highly suitable for intraoral retention. Figure 4 shows the wettability images depict contact angle measurements of water droplets on both patches. Patch 1 shows a flatter droplet (higher wettability), while Patch 2 maintains a more spherical droplet, indicating lower wettability and potentially superior barrier properties.

Chemical Compatibility (FTIR Spectroscopy): FTIR spectroscopy was used to assess the chemical integrity and compatibility of the plant extracts with the HPMC polymer. The FTIR spectra of both Patch 1 and Patch 2 exhibited characteristic absorption bands

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corresponding to hydroxyl (OH) stretching, carbonyl (C=O) stretching, and aromatic C=C vibrations. These peaks matched those of the individual components, and no significant shifts, broadening, or disappearance of key functional group signals were observed. This confirmed the absence of major chemical interactions or degradation, indicating that the plant extracts were stably incorporated into the polymeric matrix without undergoing structural alterations. The chemical stability of the patches helps keep their healing effect steady and safe to use. Figure 5 shows the FTIR spectra, which highlight the main chemical groups found in both Tephrosia-based patches. These include hydroxyl, carbonyl, and aromatic groups, confirming the plant compounds are present and slightly different in each patch. Patch 1 had a more even texture and better flexibility, while Patch 2 was stronger and held moisture better. Both patches looked good, stayed stable, and can be used safely in the mouth.

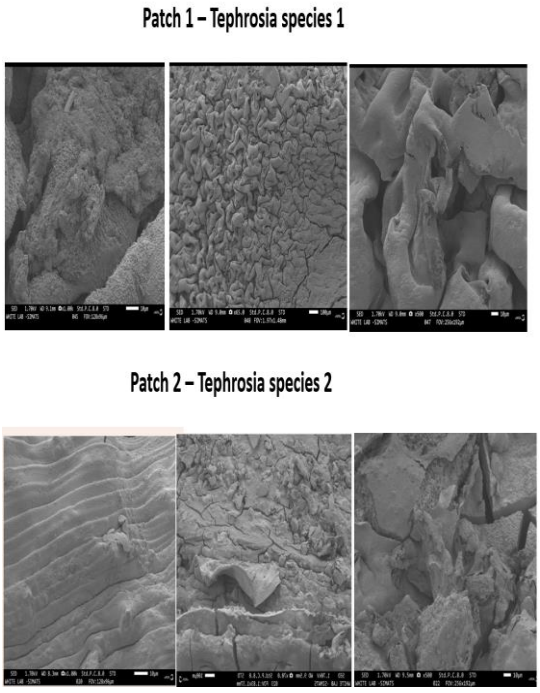

Figure 2. SEM microphotographs illustrating surface morphology of *Tephrosia species* 1 and 2 patches**.** Figure 2 shows SEMs of two different Tephrosia species patches reveal significant differences in surface morphology. Patch 1 shows a wrinkled and irregular texture, while Patch 2 displays smoother, layered, and flaky surfaces, indicating distinct microstructural characteristics

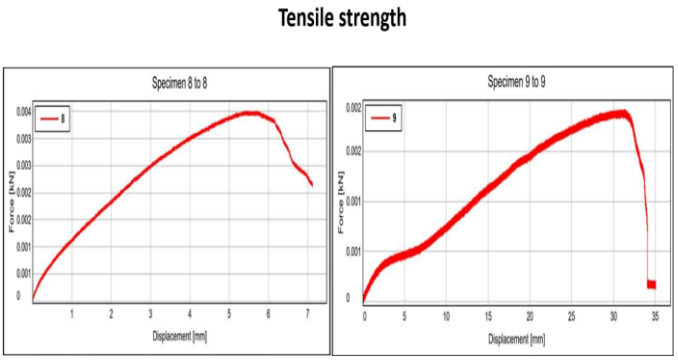

Figure 3. Tensile strength profiles of patch specimens showing displacement vs. force patterns**.** Figure 3 shows the Tensile strength graphs for specimens 8 and 9 illustrate displacement versus force characteristics. Specimen 8 exhibits an earlier peak with lower force, while specimen 9 shows a gradual increase with higher elongation, indicating better tensile strength and elasticity.

Figure 4. Wettability Assessment of Patches**.** Figure 4 shows the wettability images depict contact angle measurements of water droplets on both patches. Patch 1 shows a flatter droplet (higher wettability), while Patch 2 maintains a more spherical droplet, indicating lower wettability and potentially superior barrier properties.

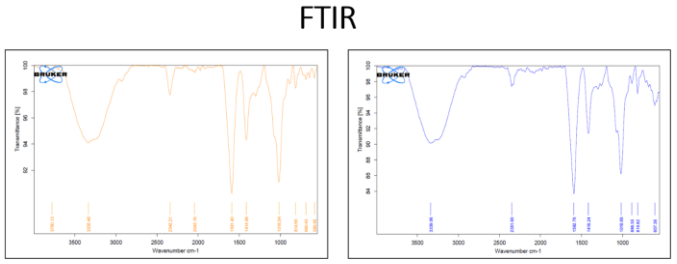

Figure 5. FTIR Spectra of Herbal Patches. Figure 5 shows the FTIR spectra, which highlight the main chemical groups found in both Tephrosia-based patches. These include hydroxyl, carbonyl, and aromatic groups, confirming the plant compounds are present and slightly different in each patch. Patch 1 had a more even texture and better flexibility, while Patch 2 was stronger and held moisture better. Both patches looked good, stayed stable, and can be used safely in the mouth.

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DISCUSSION

This study mainly aimed to create and test dental patches made with HPMC and extracts from two Tephrosia species, to see if they could be used as oral medicine. The patches were checked using different tests like SEM (to look at the surface), tensile strength (to see how strong they are), contact angle (to study how well they can stick to wet surfaces), FTIR (to check chemical structure), and in vitro drug release (to see how the medicine comes out over time). HPMC was used as the main base because it is known to be safe, stick well to the mouth lining, and form good films. It also absorbs water quickly, helping the patch to swell and stick better, which helps with steady drug release [3]. Tephrosia extracts were chosen because they are known to fight inflammation, bacteria, and oxidative stress, based on traditional use and earlier studies [13]. SEM results showed that the plant extract was well spread inside the patch, which helps ensure proper drug release and sticking strength. Most patches had smooth, even surfaces, much like patches made with Usnea barbata extract, which also showed good strength and effect [14]. Some patches had small rough spots or holes, possibly due to the amount of plasticizer or extract added. These small changes in texture can affect how the patch absorbs water and releases the drug, as seen in similar products made with Quercus brantii [12].

Tensile strength tests showed that the strength of the patches changed depending on the mix of polymer and plant extract. The best results were seen when the ratio between HPMC and the extract was balanced, giving the patch better strength. This matches earlier research where more HPMC improved strength, likely because it helped form better films and allowed stronger bonding between polymer chains [6]. However, patches with too much extract were weaker, possibly because the extract interrupted how the polymer chains connect this has also been seen in patches made with Myrtus communis [11]. Adding plasticizers like glycerol to improve patch flexibility may have softened the matrix, reducing its mechanical strength. For optimal oral performance, patches must maintain a balance neither too hard nor too soft as chewing and tongue movement can impact their stability [1]. The surface wetting ability of the patches was assessed using contact angle measurements. A contact angle under 90° reflected good hydrophilicity, enhancing moisture uptake and adhesion, consistent with findings in HPMC-triamcinolone acetonide patches [3]. Higher Tephrosia extract levels slightly increased water repellency, likely due to lipophilic phytochemicals. A comparable effect was noted with Binahong leaf extract, which modified surface energy dynamics [8]. FTIR analysis confirmed that Tephrosia extracts were compatible with the HPMC matrix, as no major shifts in characteristic peaks were observed. The presence of -OH, -CH, and C=O groups indicated structural stability, aligning with findings from Clitoria ternatea patches [10]. In vitro drug release studies showed a biphasic profile an initial burst followed by sustained release ideal for prolonged dental therapy, consistent with methotrexate [4] and acyclovir [1,15]. Release was primarily governed by polymer hydration and erosion. HPMC swells and creates a gel layer that regulates drug diffusion when it absorbs water. Up to an ideal concentration, higher drug doses typically resulted in faster release rates. However, excessive extract may saturate the matrix or clog pores, limiting release efficiency, as shown in Mangosteen-based mucoadhesive patch tests [9]. Every patch showed adequate mucoadhesion, and the hydroxyl groups in HPMC interacted with mucin to guarantee retention in the oral cavity. Electrospun lysozyme-loaded patches showed similar results [5]. Tephrosia-loaded patches have benefits over their synthetic drug-based equivalents, such as clotrimazole and acyclovir patches, in terms of phytochemical synergy [1,16]. Bioactive compounds in these patches, including flavonoids and rotenoids, act synergistically to reduce oxidative stress, microbial colonization, and inflammation [13]. Additional therapeutic benefits of botanical medicines include a decreased chance of resistance and less systemic adverse effects. Their physicochemical characteristics support their application in treating aphthous stomatitis, post-extraction wounds, and early-stage mucositis, much like those of plant-based mucoadhesive systems including Binahong [8], Myrtus communis [11], and Clitoria ternatea [10]. Mucoadhesive patches that include nanofiber and multilayer membrane technology have demonstrated potential in enhancing wound healing and medication administration. Recent studies on electrospun nanofibers, bioinspired multilayer membranes, and biomimetic adhesive patches have shown better strength, controlled drug release, and healing effects, making them useful for improving Tephrosia-based oral formulations [17–20]. Tephrosia has demonstrated good therapeutic potential similar to Cocos nucifera and Triticum aestivum combination gel, owing to its potent antimicrobial activity and low cytotoxicity, thereby serving as a biocompatible therapeutic agent for the

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management and accelerated healing of oral mucosal lesions [21,22]. A study on gelatin chitosan biofilm incorporated with 5-fluorouracil–zinc oxide nanoparticles, offered a biocompatible and targeted delivery system for treating malignant and precancerous skin lesions through sustained anticancer drug release [23]. Nano particle based drug-delivery systems for autoimmune-mediated conditions can be extrapolated to develop targeted therapeutic approaches for autoimmune oral mucosal lesions such as lichen planus [24].

CONCLUSION

This study highlights the potential of Tephrosia maxima and Tephrosia callophylla extracts in HPMC-based mucoadhesive patches for targeted oral therapy. Both formulations showed favorable properties, including smooth surface morphology, suitable tensile strength, good wettability, and chemical compatibility. Patch 1 offered better drug distribution, while Patch 2 had stronger mechanical properties. The phytochemical-rich extracts provided effective antimicrobial, anti-inflammatory, and antioxidant actions, indicating their usefulness in managing conditions like mucositis and aphthous ulcers. These findings suggest that plant-based patches could serve as effective, natural alternatives to conventional oral treatments. Future research should focus on in vivo evaluations to verify their safety and clinical benefits. Innovations like nanofiber technologies, multilayered systems, and alternate polymers may further enhance drug delivery, mucosal adhesion, and therapeutic outcomes.

DECLARATION

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CONFLICT OF INTEREST

None declared.

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