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# FORMULATION AND EVALUATION OF MUCOADHESIVE HERBAL ORAL GEL CONTAINING *SCUTELLARIA BAICALENSIS* EXTRACT FOR THE TREATMENT OF ORAL INFLAMMATORY CONDITIONS

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**ABSTRACT**

The present study aimed to formulate and evaluate a mucoadhesive herbal oral gel containing *Scutellaria baicalensis* extract for the treatment of oral inflammatory conditions. The plant extract, rich in flavonoids such as baicalin and baicalein, exhibits significant anti-inflammatory, antimicrobial, and antioxidant properties. Herbal gel formulations (F1-F6) were prepared using Carbopol 940 as a gelling agent with varying concentrations to optimise physicochemical and release characteristics. The formulations were evaluated for pH, viscosity, spreadability, drug content, *in-vitro* diffusion, antimicrobial activity, anti-inflammatory activity, and mucoadhesive strength. Results indicated that all formulations showed acceptable physicochemical properties. Among them, formulation F4 demonstrated an optimal balance of viscosity, spreadability, and sustained drug release. *In-vitro* diffusion studies revealed controlled drug release following Higuchi kinetics, indicating a diffusion-controlled mechanism. The formulation also exhibited significant antibacterial activity against *E. coli* and notable anti-inflammatory activity. The developed herbal gel showed promising potential as an effective localised drug delivery system for oral conditions.

**Keywords**: *Scutellaria baicalensis*, herbal gel, mucoadhesive, oral drug delivery, Carbopol, *in-vitro* diffusion.

## INTRODUCTION

Oral diseases such as gingivitis, periodontitis, and oral ulcers are highly prevalent and significantly affect quality of life[1]. Conventional treatments often lead to adverse effects and antimicrobial resistance with prolonged use [2]. Herbal medicines offer a safer alternative due to their multi-target therapeutic action[3].

*Scutellaria baicalensis*, a medicinal plant rich in flavonoids, possesses anti-inflammatory, antimicrobial, and antioxidant properties, making it a promising candidate for oral therapy[4]. However, its effective delivery requires a suitable formulation that can prolong residence time in the oral cavity[5]. Phytochemical investigations have revealed that *Scutellaria baicalensis* contains a variety of biologically active compounds, including flavonoids, phenolic acids, and glycosides. Among these compounds, flavonoids such as baicalin, baicalein, and wogonin are considered the primary active constituents responsible for the plant's pharmacological activities[6]. These compounds have been widely studied for their therapeutic potential in various disease conditions. Baicalin is one of the major flavonoid glycosides present in *Scutellaria baicalensis* and has demonstrated a wide range of biological activities, including anti-inflammatory, antioxidant, and antimicrobial effects. Studies have shown that baicalin can inhibit the production of pro-inflammatory cytokines and reduce inflammatory responses in various experimental models[7].

This property makes it a promising candidate for treating inflammatory disorders affecting the oral cavity. Baicalein, another important flavonoid present in the plant, has been reported to possess strong antioxidant activity; it can scavenge free radicals and protect cells from oxidative damage caused by reactive oxygen species[8]. Oxidative stress plays a significant role in the pathogenesis of many inflammatory diseases, including those affecting the oral mucosa; therefore, the antioxidant properties of baicalein may help protect and heal oral tissues. Wogonin is another bioactive flavonoid found in *Scutellaria baicalensis* that exhibits potent anti-inflammatory and immunomodulatory activities. Research studies have demonstrated that wogonin can inhibit the activation of inflammatory signalling pathways such as the nuclear factor-kappa B (NF-κB) pathway, which plays a critical role in the regulation of inflammatory responses[9,10]. By suppressing these pathways, wogonin may help reduce inflammation and tissue damage associated with oral diseases.

In addition to their anti-inflammatory effects, the flavonoids present in *Scutellaria baicalensis* have also demonstrated significant antimicrobial activity against a variety of pathogenic microorganisms. Flavonoids are known to disrupt microbial cell membranes, inhibit nucleic acid synthesis, and interfere with bacterial metabolic processes[11]. Such mechanisms contribute to inhibiting microbial growth and preventing infections. Several studies have reported the antimicrobial activity of *Scutellaria baicalensis* extracts against bacteria and fungi associated with oral infections. The plant-derived flavonoids exhibit inhibitory effects against various microorganisms implicated in dental plaque formation and oral inflammatory conditions [12,13]. These findings suggest that the plant extract may be beneficial in the treatment of oral microbial infections.

Another important pharmacological property of *Scutellaria baicalensis* is its ability to promote wound healing and tissue regeneration. Experimental studies have shown that the flavonoids present in the plant can stimulate cellular processes involved in tissue repair, including fibroblast proliferation and collagen synthesis[14]. These effects are particularly valuable in the management of oral ulcers and other mucosal lesions. The anti-inflammatory activity of *Scutellaria baicalensis* is further supported by studies showing its ability to inhibit the production of inflammatory mediators, including prostaglandins and cytokines. These mediators play a central role in the development of inflammatory responses and tissue damage in various diseases[15]. By modulating these pathways, the plant extract may contribute to reducing inflammation and promoting tissue healing. Furthermore, the immunomodulatory properties of *Scutellaria baicalensis* have been reported in several studies; the plant extract can regulate immune responses by influencing immune cell activity and cytokine production, an effect that may enhance the body's defence mechanisms against infections and support the resolution of inflammatory conditions [16].

The safety profile of *Scutellaria baicalensis* has also been evaluated in various studies. Toxicological investigations indicate that the plant extract has relatively low toxicity when used within the recommended therapeutic limits [17]. Regulatory and safety-monitoring frameworks for botanical and herbal medicinal products, such as those issued by the OECD[26], the European Medicines Agency[27], and the World Health Organization[28], provide additional guidance on the quality and safety assessment of plant-derived actives. This favourable safety profile supports the potential use of *Scutellaria baicalensis* extract in pharmaceutical formulations intended for topical or oral applications. Mucoadhesive oral gels provide localised drug delivery with improved retention and sustained release[18]. Therefore, the present study focuses on developing and evaluating an oral herbal gel containing *Scutellaria baicalensis* extract.

## MATERIALS AND METHODS

### Materials And Formulation Table

*Scutellaria baicalensis* extract was used as the active ingredient. Carbopol 940 was used as the gelling agent owing to its well-established mucoadhesive and rheological behaviour in topical and mucosal gel systems [22,25]. Glycerin, propylene glycol, sorbitol, sodium benzoate, peppermint oil, and triethanolamine were used as humectant, solvent/penetration enhancer, sweetening agent, preservative, flavouring agent, and pH adjuster respectively; the concentrations of these excipients were selected in accordance with standard pharmaceutical excipient references[21]. Distilled water was used as the vehicle. The composition of the six formulations (F1-F6) is summarised in Table 1.

**Table 1: Formulation Table**

| Ingredient | F1 | F2 | F3 | F4 | F5 | F6 | Function |
|---|---|---|---|---|---|---|---|
| *Scutellaria baicalensis* extract* | 2.5 g | 2.5 g | 2.5 g | 2.5 g | 2.5 g | 2.5 g | Active ingredient |
| Carbopol 940 | 0.25 g | 0.50 g | 0.75 g | 1.00 g | 1.25 g | 1.50 g | Gelling agent |
| Glycerin | 5 ml | 5 ml | 5 ml | 5 ml | 5 ml | 5 ml | Humectant |
| Propylene glycol | 3 ml | 3 ml | 3 ml | 3 ml | 3 ml | 3 ml | Solvent/penetration enhancer |
| Sorbitol | 4 g | 4 g | 4 g | 4 g | 4 g | 4 g | Sweetening agent |
| Sodium benzoate | 0.10 g | 0.10 g | 0.10 g | 0.10 g | 0.10 g | 0.10 g | Preservative |
| Peppermint oil | 0.05 ml | 0.05 ml | 0.05 ml | 0.05 ml | 0.05 ml | 0.05 ml | Flavouring agent |
| Triethanolamine | q.s. | q.s. | q.s. | q.s. | q.s. | q.s. | pH adjuster (gel neutraliser) |
| Distilled water | q.s. to 50 g | q.s. to 50 g | q.s. to 50 g | q.s. to 50 g | q.s. to 50 g | q.s. to 50 g | Vehicle |

**Scutellaria baicalensis* extract (Latin binomial of the plant source).

### Formulation Of Gel

Six formulations (F1-F6) were prepared using varying concentrations of Carbopol 940 following a quality-by-design approach to formulation development[19,20]. The polymer was dispersed in water and allowed to hydrate, following which the plant extract and other excipients were incorporated with continuous stirring. The pH was adjusted using triethanolamine to obtain the desired gel consistency (Table 1). The resulting hydrogel matrix provided a three-dimensional polymeric network suited for sustained release and mucosal retention [23,24].

### Evaluation Parameters

The formulated gels were evaluated for physical appearance, pH, viscosity, spreadability, washability, extrudability, drug content, *in-vitro* diffusion, release kinetics, antibacterial activity, anti-inflammatory activity, and mucoadhesive strength. Physical appearance, pH, viscosity, spreadability, washability, extrudability, and drug content were determined using standard pharmacopoeial procedures without modification, as previously described[21,24,25]. The *in-vitro* diffusion, antibacterial, anti-inflammatory, and mucoadhesive strength studies were carried out using the detailed procedures described below, along with the corresponding pre-formulation characterisation of the extract.

**Table 2: Solubility Profile**

| Solvent | Solubility |
|---|---|
| Water | Slightly soluble |
| Methanol | Soluble |
| Ethanol | Soluble |
| Phosphate buffer (pH 6.8) | Moderately soluble |

**Table 3: Calibration Data**

| Concentration (µg/mL) | Absorbance |
|---|---|
| 0 | 0 |
| 2 | 0.182 |
| 4 | 0.356 |
| 6 | 0.521 |
| 8 | 0.698 |
| 10 | 0.865 |

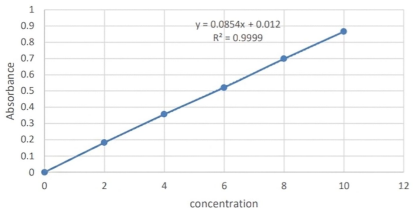


**Figure 1: Calibration Curve**

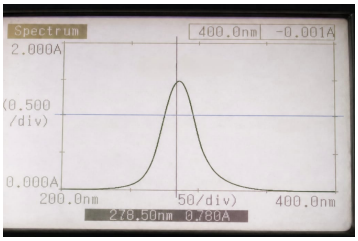


**Figure 2: UV Spectroscopy Study**

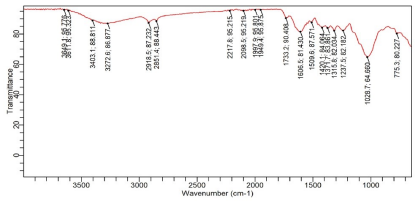


**Figure 3: FTIR Spectrum of Pure Extract (Drug)**

**Table 4: FTIR Interpretation of Pure Extract (Drug)**

| Functional Group | Standard Frequency ($cm^{-1}$) | Observed Frequency ($cm^{-1}$) |
|---|---|---|
| O-H stretching (free) | 3600-3650 | 3649, 3611 |
| O-H stretching (H-bonded phenols) | 3200-3400 | 3403, 3272 |
| C-H stretching (alkane) | 2850-2950 | 2918, 2851 |
| C=O stretching (carbonyl) | 1700-1750 | 1733 |
| C=C stretching (aromatic) | 1500-1600 | 1606, 1509 |
| O-H bending (phenols) | 1350-1450 | 1420 |
| C-H bending | 1350-1380 | 1371 |
| C-O stretching (phenols/ethers) | 1200-1320 | 1315, 1237 |
| C-O-C stretching (glycosidic) | 1000-1100 | 1028 |
| Aromatic C-H bending | 700-900 | 775 |

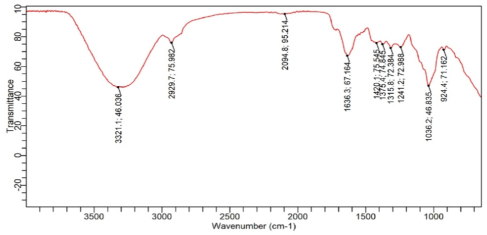


**Figure 4: FTIR Spectrum of Drug + Excipients**

**Table 5: FTIR Interpretation of Drug + Excipients**

| Functional Group | Standard Frequency ($cm^{-1}$) | Observed Frequency ($cm^{-1}$) |
|---|---|---|
| O-H stretching (broad, H-bonded) | 3200-3600 | 3321 |
| C-H stretching (alkane) | 2850-2950 | 2929 |
| C=O stretching / C=C (aromatic) | 1600-1700 | 1636 |
| $COO^-$ stretching (Carbopol) | 1400-1550 | 1420-1450 |
| C-H bending | 1350-1380 | 1375 |
| C-O stretching (phenols/alcohols) | 1200-1300 | 1315, 1241 |
| C-O-C stretching | 1000-1100 | 1036 |
| Aromatic C-H bending | 700-900 | 924 |
| Combination/overtones (weak) | ~2000-2100 | 2094 |

**Table 6: Physical Appearance of Formulations**

| Formulation | Colour | Odour | Appearance | Texture |
|---|---|---|---|---|
| F1 | Brown | Pleasant (peppermint) | Smooth | Soft |
| F2 | Brown | Pleasant | Smooth | Soft |
| F3 | Brown | Pleasant | Smooth | Soft |
| F4 | Brown | Pleasant | Smooth | Viscous |
| F5 | Brown | Pleasant | Smooth | Viscous |
| F6 | Brown | Pleasant | Smooth | Highly viscous |

**Table 7: pH of Formulations**

| Formulation | pH |
|---|---|
| F1 | 6.3 |
| F2 | 6.4 |
| F3 | 6.5 |
| F4 | 6.6 |
| F5 | 6.7 |
| F6 | 6.8 |

**Table 8: Viscosity of Formulations**

| Formulation | Viscosity (cps) |
|---|---|
| F1 | 4520 |
| F2 | 11,850 |
| F3 | 27,640 |
| F4 | 51,320 |
| F5 | 85,750 |
| F6 | 128,600 |

**Table 9: Spreadability of Formulations**

| Formulation | Spreadability (g·cm/sec) |
|---|---|
| F1 | 23.4 |
| F2 | 17.6 |
| F3 | 12.8 |
| F4 | 9.6 |
| F5 | 6.4 |
| F6 | 4.2 |

**Table 10: Extrudability of Gel Formulations**

| Batch | Evaluation |
|---|---|
| F1 | Good |
| F2 | Very good |
| F3 | Excellent |
| F4 | Excellent |
| F5 | Very good |
| F6 | Good |

**Table 11: Drug Content of Formulations**

| Formulation | Drug Content (%) |
|---|---|
| F1 | 94.8 |
| F2 | 95.9 |
| F3 | 96.7 |
| F4 | 97.5 |
| F5 | 98.3 |
| F6 | 99.0 |

**Table 12: Results for *In-Vitro* Drug Release**

| Time (min) | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 8 | 10 | 12 | 15 | 20 | 9 |
| 30 | 14 | 18 | 22 | 28 | 35 | 16 |
| 45 | 22 | 28 | 32 | 40 | 50 | 25 |
| 60 | 30 | 36 | 42 | 52 | 65 | 34 |
| 75 | 38 | 45 | 52 | 65 | 78 | 44 |
| 90 | 46 | 54 | 60 | 75 | 88 | 54 |
| 105 | 53 | 62 | 68 | 83 | 95 | 62 |
| 120 | 66 | 76 | 82 | 96 | 100 | 73 |

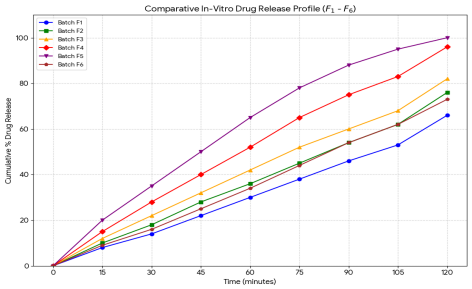


**Figure 5: *In-Vitro* Release Profile**

**Table 13: Zero-Order Kinetics Data**

| Time (min) | Cumulative % Drug Release (Q) |
|---|---|
| 0 | 0 |
| 15 | 15 |
| 30 | 28 |
| 45 | 40 |
| 60 | 52 |
| 75 | 65 |
| 90 | 75 |
| 105 | 83 |
| 120 | 96 |

**Zero-Order Regression: $R^2$ = 0.9958 | Slope (K0): 0.7856**

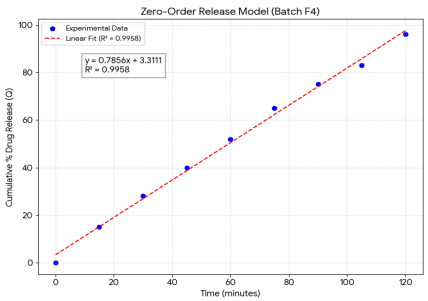


**Figure 6: Zero-Order Kinetics**

**Table 14: First-Order Kinetics Data**

| Time (min) | % Drug Remaining (100-Q) | Log % Drug Remaining |
|---|---|---|
| 0 | 100 | 2.000 |
| 15 | 85 | 1.929 |
| 30 | 72 | 1.857 |
| 45 | 60 | 1.778 |
| 60 | 48 | 1.681 |
| 75 | 35 | 1.544 |
| 90 | 25 | 1.398 |
| 105 | 17 | 1.230 |
| 120 | 4 | 0.602 |

**First-Order Regression: $R^2 = 0.8496$ | Slope (K1): -0.0098**

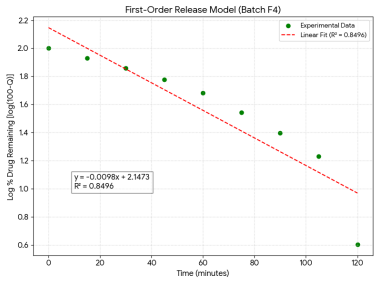


**Figure 7: First-Order Kinetics**

**Table 15: Higuchi Model Data**

| Square Root of Time | Cumulative % Drug Release (Q) |
|---|---|
| 0.000 | 0 |
| 3.873 | 15 |
| 5.477 | 28 |
| 6.708 | 40 |
| 7.746 | 52 |
| 8.660 | 65 |
| 9.487 | 75 |
| 10.247 | 83 |
| 10.954 | 96 |

**Higuchi Regression: $R^2 = 0.9414$ | Slope (KH): 9.313**

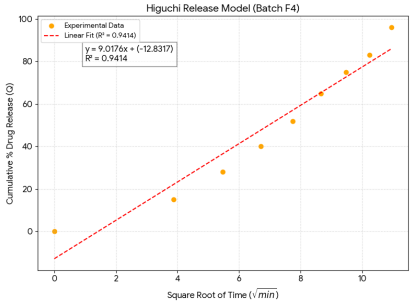


**Figure 8: Higuchi Model**

**Table 16: Korsmeyer-Peppas Model Data**

| Log Time (log t) | Log % Drug Release (log Q) |
|---|---|
| 1.176 | 1.176 |
| 1.477 | 1.447 |
| 1.653 | 1.602 |
| 1.778 | 1.716 |
| 1.875 | 1.813 |
| 1.954 | 1.875 |
| 2.021 | 1.919 |
| 2.079 | 1.982 |

**Peppas Regression: $R^2 = 0.9997$ | Release Exponent (n): 0.905**

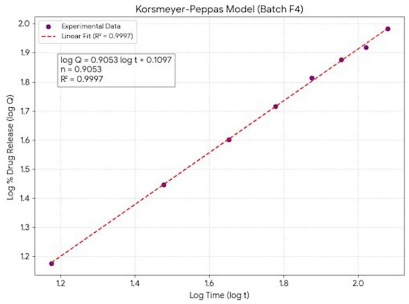


**Figure 9: Korsmeyer-Peppas Model**

**Table 17: Master Kinetic Summary Table (F1-F6)**

| Batch | Zero Order ($R^2$) | First Order ($R^2$) | Higuchi ($R^2$) | Peppas ($R^2$) | n Value |
|---|---|---|---|---|---|
| F1 | 0.9949 | 0.9506 | 0.8896 | 0.9953 | 1.015 |
| F2 | 0.9970 | 0.9375 | 0.9069 | 0.9988 | 0.948 |
| F3 | 0.9973 | 0.9354 | 0.9273 | 0.9996 | 0.901 |
| F4 | 0.9958 | 0.8496 | 0.9414 | 0.9997 | 0.905 |
| F5 | 0.9724 | 0.9340 | 0.9662 | 0.9992 | 0.848 |
| F6 | 0.9982 | 0.9542 | 0.8967 | 0.9961 | 1.014 |

**Table 18: Model Fitting and Mechanism Summary for Batches F1-F6**

| Batch | Best Fit Model | Highest $R^2$ | n Value | Inferred Release Mechanism |
|---|---|---|---|---|
| F1 | Korsmeyer-Peppas | 0.9953 | 1.015 | Super Case II Transport (Swelling/Erosion) |
| F2 | Korsmeyer-Peppas | 0.9988 | 0.948 | Super Case II Transport (Swelling/Erosion) |
| F3 | Korsmeyer-Peppas | 0.9996 | 0.901 | Super Case II Transport (Swelling/Erosion) |
| F4 | Korsmeyer-Peppas | 0.9997 | 0.905 | Super Case II Transport (Optimised) |
| F5 | Korsmeyer-Peppas | 0.9992 | 0.848 | Anomalous Transport (Diffusion + Swelling) |
| F6 | Zero-Order | 0.9982 | 1.014 | Super Case II Transport (Swelling/Erosion) |

**Table 19: Antibacterial Activity of Test Compound Against *E. coli***

| Sample | Zone of Inhibition (mm) |
|---|---|
| Control | 00 |
| Standard (Streptomycin) | 30 |
| *Scutellaria baicalensis* extract herbal gel | 24 |

**Figure 10: Antibacterial Activity of Test Compound Against *E. coli***

**Table 20: *In-Vitro* Anti-Inflammatory Activity by Protein Denaturation Method**

| Sample code | Concentrations (µg/ml) | Absorbance at 660 nm | | | | % of Inhibition | $IC_{50}$ (µg/ml) |
|---|---|---|---|---|---|---|---|
| | | Test 1 | Test 2 | Test 3 | Mean | | |
| Control | | 1.54 | 1.54 | 1.54 | 1.54 | – | – |
| Standard (Diclofenac Sodium) | 20 | 1.40 | 1.37 | 1.39 | 1.39 | 9.74% | 72.21 |
| | 40 | 1.20 | 1.20 | 1.22 | 1.21 | 21.43% | |
| | 60 | 0.91 | 0.89 | 0.93 | 0.91 | 40.91% | |
| | 80 | 0.67 | 0.65 | 0.63 | 0.65 | 57.79% | |
| | 100 | 0.21 | 0.18 | 0.23 | 0.21 | 86.36% | |
| *Scutellaria baicalensis* extract herbal gel | 20 | 1.42 | 1.45 | 1.49 | 1.45 | 5.84% | 93.51 |
| | 40 | 1.31 | 1.36 | 1.39 | 1.35 | 12.34% | |
| | 60 | 1.02 | 1.05 | 1.08 | 1.05 | 31.82% | |
| | 80 | 0.86 | 0.81 | 0.87 | 0.85 | 44.81% | |
| | 100 | 0.69 | 0.62 | 0.71 | 0.67 | 56.49% | |

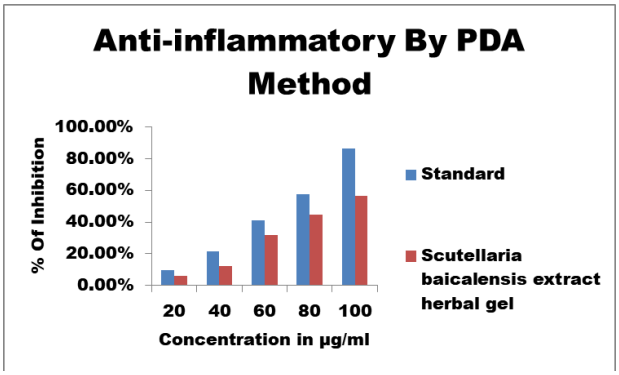


**Figure 11: Anti-Inflammatory Activity by Protein Denaturation Assay**


**Figure 12: Images of Anti-Inflammatory Activity by Protein Denaturation Assay**

**Table 21: Report of Mucoadhesive Strength Test**

| Formulation | Peak Detachment Force (N) | Work of Adhesion (N·mm) | Detachment Distance (mm) |
|---|---|---|---|
| Herbal Gel (F4) | 0.182 ± 0.01 | 5.21 ± 0.30 | 1.25 ± 0.05 |

## OBSERVATION AND RESULTS

### Pre-Formulation Studies

**Organoleptic Evaluation**
The organoleptic properties of the drug (*Scutellaria baicalensis* extract) were evaluated through visual inspection and sensory analysis. The extract was an amorphous powder, brownish yellow in colour, with a characteristic herbal odour.

**Solubility Studies**
The solubility of *Scutellaria baicalensis* extract was determined in various solvents to select a suitable solvent system for formulation and analysis (Table 2). The extract was slightly soluble in water, soluble in methanol and ethanol, and moderately soluble in phosphate buffer (pH 6.8).

**Calibration Curve by UV Spectroscopy**
A calibration curve was constructed using standard solutions of the extract in methanol at λmax 278 nm (Table 3, Figures 1 and 2). The absorbance increased proportionally with concentration over the range of 0-10 µg/mL, confirming linearity in accordance with the Beer-Lambert law.

**pH Determination of Drug**
The pH of the drug solution was 6.1 ± 0.2, which is near-neutral, indicating that the drug is suitable for oral administration without causing mucosal irritation.

**FTIR Study of Drug**
FTIR spectroscopy was performed to identify the functional groups present in the drug and to assess compatibility between the drug and excipients. FTIR spectra were recorded for the pure extract (Figure 3) and for the physical mixture of drug and excipients (Figure 4).

The FTIR studies of both the pure extract and the drug-excipient mixture confirmed the presence of characteristic functional groups of phenolic and flavonoid compounds (Tables 4 and 5). The absence of significant peak shifts indicates compatibility between the drug and excipients, supporting the stability of the developed herbal gel.

**Total Ash Value**
The total ash content of the extract was 18.50%, within acceptable limits for herbal extracts and indicating minimal inorganic contamination.

**Loss On Drying**
The loss on drying (LOD) was 11.50%, a low value indicating good stability and a reduced likelihood of microbial growth due to limited moisture content.

**Identification Test of Active Chemical Constituents**
Phytochemical identification tests were carried out to confirm the presence of the principal active constituents. In the Shinoda test, the extract showed a positive result, with the development of a pink/red colour indicating the presence of flavonoids. The lead acetate test also gave a positive result, confirming the presence of flavonoids in the extract. In the alkaline reagent test, the disappearance of the yellow colour on dilution further confirmed the presence of flavonoids. Collectively, these tests confirmed the presence of flavonoids, including baicalin and baicalein, thereby validating the drug's identity.

**Bulk Density**
The bulk density of the extract was found to be in the range of 0.45-0.55 g/mL, indicating acceptable flow and packing characteristics for further processing.

**Evaluation Of Herbal Gel Formulations (F1-F6)**
The prepared herbal gel formulations (F1-F6) were evaluated for various physicochemical and biological parameters to assess their suitability for oral application.

**Physical Appearance**
All formulations were smooth, homogeneous, and free from lumps (Table 6). The colour variation was attributable to the extract concentration, and peppermint oil effectively masked the herbal odour, thereby improving patient acceptability.

**Determination of pH**
All formulations had pH values within the acceptable range (6-7), suitable for the oral mucosa and unlikely to cause irritation (Table 7).

**Viscosity Measurement**
Viscosity increased progressively from F1 to F6 as Carbopol 940 concentration increased (Table 8). Higher viscosity improved retention time but tended to reduce spreadability.

**Spreadability**
Spreadability decreased with increasing viscosity; nonetheless, all formulations showed acceptable spreadability for topical oral application (Table 9).

**Washability**
All formulations were easily washable with water. Good washability indicates ease of removal from the oral cavity, which enhances patient compliance.

**Extrudability Test**
Extrudability determines how easily the gel can be expelled from the collapsible tube and directly affects patient compliance and ease of application (Table 10).

**Drug Content Determination**
Drug content was within the acceptable limits (95-100%) for formulations F2-F6, indicating uniform distribution of the extract in the gel (Table 11).

***In-Vitro* Diffusion Study**
The *in-vitro* drug release studies of the six formulations (F1-F6) were conducted over a period of 120 minutes (Table 12, Figure 5). The cumulative percentage drug release at 2 hours was 66%, 76%, 82%, 96%, 100%, and 73% for F1, F2, F3, F4, F5, and F6, respectively.

The release profile graph (Figure 5) shows that F5 reached the fastest release, achieving 100% within the 120-minute window, whereas F1 showed the slowest release, reaching only 66% and indicating a more retarded drug delivery. F4, the optimised batch, showed a linear and consistent release reaching 96%, making it the most balanced formulation for sustained delivery. All batches

showed a steady increase in release, with the rate progressively increasing from F1 to F5 before declining again in F6.

***In-Vitro* Release Kinetics**

The release data were fitted to zero-order, first-order, Higuchi, and Korsmeyer-Peppas kinetic models (Tables 13-16, Figures 6-9). For the optimised batch F4, the zero-order model provided the best linear fit ($R^2 = 0.9958$, K0 = 0.7856), whereas the first-order model yielded a comparatively poorer fit ($R^2 = 0.8496$, K1 = -0.0098). The Higuchi plot showed a high degree of linearity ($R^2 = 0.9414$, KH = 9.313), and the Korsmeyer-Peppas model gave the best overall fit ($R^2 = 0.9997$) with a release exponent (n) of 0.905.

The release data were fitted to zero-order, first-order, Higuchi, and Korsmeyer-Peppas kinetic models for all batches (Tables 17 and 18). The optimised batch F4 showed the best fit with the zero-order kinetic model ($R^2 = 0.9958$), indicating that the drug was released at a constant rate independent of its concentration. Analysis using the Korsmeyer-Peppas equation yielded a release exponent (n) of 0.905 for F4, consistent with a Super Case II transport mechanism governed by synchronised swelling and relaxation of the polymer matrix. Across batches F1-F5, the Korsmeyer-Peppas model consistently yielded the highest $R^2$, as expected given its flexible power-law form; batch F5 was a notable exception, with its n value dropping to 0.848, indicating a shift toward a more diffusion-dominated (Fickian) release. Batch F4 fitted both the zero-order and Korsmeyer-Peppas models exceptionally well ($R^2 = 0.9958$ and 0.9997, respectively), consistent with an optimised controlled-release system in which polymer relaxation (n = 0.905) proceeds at a rate that keeps drug release essentially constant. Batch F6, in contrast, fitted the zero-order model marginally better than the Peppas model ($R^2 = 0.9982$), consistent with the very rigid, steadily releasing gel network formed at this higher polymer concentration. Overall, the variation in release rates across F1-F6 can be attributed to differences in Carbopol 940 concentration, with F4 providing the most favourable balance of release extent and rate consistency for the intended therapeutic effect.

***In-Vitro* Antimicrobial Study (Optimised Batch F4)**

The antibacterial activity of the optimised batch (F4) was assessed by the agar well diffusion method against *E. coli* (ATCC 25922), with streptomycin as the standard and an untreated well as the control (Table 19, Figure 10). The gel exhibited a mm24 of zone of inhibition, compared with 30 mm for standard streptomycin and no inhibition for the control, indicating good antibacterial activity relative to the standard.

***In-Vitro* Anti-Inflammatory Study (F4)**

The *in vitro* anti-inflammatory activity of F4 was evaluated using the protein denaturation method. The reaction mixture (10 mL) consisted of 0.4 mL of egg albumin (from fresh hen's egg), 5.6 mL of phosphate-buffered saline (pH 6.4), and 100 µL of test sample at different concentrations (20, 40, 60, 80, and 100 µg/mL); an equal volume of double-distilled water served as the control. The mixtures were incubated at 37 ± 2°C for 15 minutes and then heated at 70°C for 5 minutes. After cooling, absorbance was measured at 660 nm using the vehicle as blank. Diclofenac sodium was used as the reference drug and treated similarly. The percentage inhibition of protein denaturation was calculated as % Inhibition = (C - T)/C × 100, where T is the absorbance of the test sample and C is the absorbance of the control (Table 20).

The protein denaturation assay showed a concentration-dependent increase in percentage inhibition for both the standard drug and the *Scutellaria baicalensis* herbal gel extract over the concentration range of 20-100 µg/mL. At lower concentrations (20-40 µg/mL), only mild inhibition of protein denaturation was observed, with a gradual and significant increase occurring at higher concentrations. The standard drug showed the highest activity, achieving nearly 85-90% inhibition at 100 µg/mL, whereas the herbal gel exhibited moderate to strong activity, with about 55-60% inhibition at the same concentration. Although the activity of the herbal formulation was lower than that of the standard, it effectively stabilised protein against denaturation, indicating notable anti-inflammatory potential in a dose-dependent manner (Figures 11 and 12).

**Mucoadhesive Strength Test (F4)**

The mucoadhesive strength of the herbal gel was determined using a tensile strength method with a texture analyser. Fresh buccal mucosa was excised and washed with phosphate buffer (pH 6.8), and the mucosal tissue was fixed onto the lower platform of the instrument using adhesive tape. A known quantity of herbal gel (1 g) was placed on the mucosal surface, and the upper probe of the texture analyser was lowered to make contact with the gel and held under a constant force (0.5 N) for 60 seconds to ensure proper adhesion. After the contact time, the probe was withdrawn at a controlled speed (0.5 mm/s), and the maximum force required to detach the gel from the mucosal surface was recorded as the mucoadhesive strength (Table 21).

The tensile strength analysis of the optimised herbal gel formulation demonstrated a peak detachment force of 0.182 ± 0.01 N, indicating moderate mucoadhesive strength and adequate adhesion to the mucosal surface. The work of adhesion (5.21 ± 0.30 N·mm) reflects the total energy required to detach the gel, suggesting a stable and sustained interaction between the gel matrix and the mucin layer, while the detachment distance (1.25 ± 0.05 mm) indicates good elasticity and cohesive properties of the formulation during separation (Table 21).

**DISCUSSION**

Among all the prepared formulations (F1-F6), batch F4 was selected as the optimised formulation based on its overall physicochemical and biological performance. The optimised batch was selected by comparing physical appearance, pH, viscosity, spreadability, drug content, *in vitro* diffusion, release kinetics, antimicrobial activity, anti-inflammatory activity, and mucoadhesive strength across all six batches. F4 exhibited moderate viscosity, ensuring easy application and adequate retention on the oral mucosa, and showed good spreadability, allowing uniform distribution over the affected area. Its pH was within the physiological range, making it safe for oral use, and it showed uniform drug distribution, indicating formulation stability and consistency. F4 also exhibited controlled and sustained drug release of approximately 96% over two hours, which is ideal for prolonged therapeutic action, together with effective inhibition of oral pathogens and appreciable anti-inflammatory activity attributable to its flavonoid content, and it demonstrated sufficient mucoadhesion to ensure prolonged residence time at the site of action.

The *in vitro* drug-release behaviour of all formulations (F1-F6) was concentration-dependent, with release increasing progressively from F1 to F5, with F5 exhibiting the highest release (100% at 120 minutes). A decrease in drug release was observed for F6 (73% at 120 minutes), which may be attributed to the formation of a more viscous and dense gel network at the higher polymer concentration used in this batch; the resulting increase in viscosity reduces the mobility of drug molecules and increases the diffusional path length, thereby retarding drug release. This pattern indicates the presence of an optimal polymer concentration beyond which drug diffusion is hindered, and

although F5 showed the highest overall release, formulation optimisation was based on overall performance rather than release extent alone. F5 was not selected as the optimum batch because its very high release would not support a sustained therapeutic effect, its high viscosity resulted in poor spreadability, and these characteristics would be expected to reduce patient compliance. F4, by contrast, showed a more favourable balance, with controlled release of 96% at 120 minutes, good viscosity, good spreadability, and suitability for application to the oral mucosa. Although F5 showed the maximum drug release, its higher viscosity and reduced spreadability may affect patient compliance and application characteristics; F4, in contrast, demonstrated a balanced profile with adequate drug release, suitable viscosity, and good spreadability, and was therefore considered the optimised formulation for further study.

Drug release from the formulation appears to be governed jointly by the swelling behaviour and viscosity of Carbopol 940, as well as by the cosolvent system used. At lower polymer concentrations, polymer swelling dominates and increases drug release, whereas at higher concentrations, increased viscosity retards release, producing an optimum between F4 and F5; this behaviour is consistent with a non-linear, non-Fickian diffusion process. At the highest polymer concentration (F6), the gel's viscosity increases markedly, leading to the formation of a dense, rigid network that restricts drug movement. The drug release behaviour is therefore best explained by a balance between swelling-induced enhancement of diffusion and viscosity-induced retardation of release, with release from the optimised batch F4 following predominantly zero-order kinetics with a Korsmeyer-Peppas release exponent consistent with Super Case II transport, indicating controlled release governed by polymer swelling and relaxation rather than simple drug diffusion.

## CONCLUSION

The present research successfully developed and evaluated a mucoadhesive herbal gel formulation containing *Scutellaria baicalensis* extract for oral application. Pre-formulation studies confirmed the extract's suitability for formulation development, and the prepared gel formulations (F1-F6) exhibited acceptable physicochemical properties, including appropriate pH, viscosity, spreadability, and drug content. Among all formulations, F4 was identified as the optimised batch for its balanced characteristics: controlled, sustained drug release over two hours, making it suitable for prolonged therapeutic action. The optimised formulation also demonstrated significant antimicrobial and anti-inflammatory activities, indicating its effectiveness in managing oral inflammatory conditions, while adequate mucoadhesive strength ensured prolonged retention at the site of application and enhanced therapeutic efficiency. It can therefore be concluded that the developed herbal gel formulation is a promising candidate for oral drug delivery, offering improved efficacy, patient compliance, and sustained drug release.

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