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Research Article

Formulation and Evaluation of Oro-Dental Gel

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ABSTRACT

The objective of the present work was to develop and evaluate an oro-dental gel for targeted management of oral pain and inflammation. Ketorolac tromethamine, a potent NSAID, was selected as the primary drug and combined with herbal actives Acacia catechu (Khadira) and clove oil to enhance therapeutic efficacy and patient compliance. Gels were prepared using suitable gelling agents and evaluated for physicochemical parameters including appearance, pH, homogeneity, spreadability, extrudability, swelling index, viscosity, drug content, and in vitro drug release. FTIR compatibility studies confirmed no significant drug–excipient interactions. The optimized formulation exhibited acceptable pH, good spreadability, and excellent extrudability, with sustained release following diffusion-controlled kinetics. The combination of synthetic and herbal components offered synergistic anti-inflammatory and analgesic activity while minimizing systemic side effects. The results suggest that the formulated oro-dental gel is a promising, patient-friendly dosage form for localized therapy in various oral inflammatory conditions.

INTRODUCTION

Oral diseases remain among the most prevalent health problems worldwide, disproportionately affecting socially and economically disadvantaged populations. Conditions such as oral ulcers, gingivitis, periodontitis, and dental pain cause significant discomfort, impair daily activities, and often require both systemic and topical interventions. While oral administration of analgesics and anti-inflammatory drugs is common, the onset of action is delayed, and systemic exposure can lead to undesirable adverse effects. [1,2,3]\

Topical drug delivery to the oral cavity offers distinct advantages, including site-specific action, bypassing first-pass metabolism, rapid onset of therapeutic effect, and reduced systemic toxicity. Gels are particularly advantageous as they are non-greasy, easy to apply, and capable of providing sustained drug release with good patient

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acceptability. [4,5,6] Ketorolac tromethamine, a potent NSAID with strong analgesic and anti-inflammatory properties, is widely used in the management of moderate to severe pain. Combining it with herbal agents such as *Acacia catechu* (Khadira) and clove oil can enhance therapeutic outcomes due to their astringent, antimicrobial, and antioxidant properties. This study was undertaken to formulate and evaluate an oro-dental gel incorporating both synthetic and herbal actives to achieve rapid and sustained relief from oral inflammatory conditions while improving patient compliance and minimizing systemic side effects. [7,8]

Oral diseases are highly prevalent worldwide and are more concentrated in socially disadvantaged populations, imposing significant economic and health burdens. The oral cavity, comprising the vestibule and oral cavity proper, contains teeth, gingiva, salivary glands, and associated structures that can be affected by various pathological conditions. Dental pain, one of the most common forms of facial pain, may arise from diseases of dental hard or soft tissues, gingivitis, periodontitis, or referred pain from other regions. Inflammation plays a central role in many oral disorders, and while oral drugs are widely used, they require systemic absorption before reaching the target site, leading to delayed action and potential side effects. Topical drug delivery offers advantages such as elimination of first-pass metabolism, rapid onset, localized action, and sustained release. Gels, due to their ease of application, non-greasy nature, and better patient acceptance, are ideal for such delivery. Ketorolac tromethamine, a potent NSAID, provides strong analgesic and anti-inflammatory effects, and when combined with herbal agents like *Acacia catechu* and clove oil, may offer synergistic benefits in managing oral pain and inflammation. This approach can improve therapeutic efficacy, enhance patient compliance, and reduce systemic adverse effects. [9,10,11]

1. GLOBAL BURDEN AND SIGNIFICANCE OF ORAL DISEASES

- Oral diseases represent a major public health problem, affecting billions of people worldwide.
- They are more prevalent among socially and economically disadvantaged populations due to limited access to oral healthcare and preventive measures.
- Common oral conditions include dental caries, gingivitis, periodontitis, oral ulcers, and orofacial pain, all of which can significantly impair mastication, speech, nutrition, and overall quality of life.
- The World Health Organization (WHO) reports that untreated dental caries in permanent teeth is the most common health condition globally.
- In developing countries, treatment costs and productivity losses associated with oral diseases create a substantial economic burden, often exceeding the available dental healthcare budget.
- Oral diseases also have systemic implications, being linked to cardiovascular disorders, diabetes, respiratory infections, and adverse pregnancy outcomes. [12,13]

2. ANATOMY OF THE ORAL CAVITY RELEVANT TO DRUG DELIVERY

- The oral cavity extends from the lips to the pharynx and is divided into:
  - Vestibule: The slit-like space between the lips/cheeks externally and the gums/teeth internally; communicates with the exterior through the oral fissure.
  - Oral cavity proper: Lies within the dental arches, bounded superiorly by the palate and

inferiorly by the tongue and sublingual mucosa.

- Salivary glands- parotid, submandibular, and sublingual- secrete saliva that continuously bathes the oral tissues, influencing drug dissolution and retention.
- Teeth are anchored in the alveolar bone of the maxilla and mandible, with a rich nerve and blood supply via branches of the trigeminal nerve and maxillary artery.
- Venous drainage occurs through pterygoid venous plexus pathways, and lymphatic drainage connects to cervical lymph nodes, making the oral cavity a unique environment for localized as well as systemic drug delivery.
- Constant mechanical movements (speech, chewing, swallowing) and salivary turnover present challenges to maintaining a drug at the site of action. [14,15]

3. CHARACTERISTICS OF HEALTHY TEETH AND GUMS [16,17,18]

Healthy gums are characterized by:

- Pink to coral-pink coloration.
- Firm, resilient texture with stippling ("orange-peel" appearance).
- Gingival margins closely adapted to tooth surfaces without signs of swelling or redness.
- No bleeding during daily oral hygiene practices.

Maintenance of oral health requires plaque control through brushing and interdental cleaning to prevent the onset of inflammatory conditions.

4. PAIN IN DENTISTRY [19,20]

- Definition: Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.
- In dental practice, pain can be:
  - Acute- sudden onset, short duration, often due to trauma or infection.
  - Chronic- prolonged duration, often due to persistent inflammation or nerve injury.
- Common causes of dental pain:
  - Dental caries affecting dentin or pulp.
  - Periodontal diseases.
  - Trauma to teeth or supporting structures.
  - Postoperative pain after dental procedures.
- Nociception in dental tissues: Mediated by Aδ fibers (sharp pain) and C fibers (dull, throbbing pain) originating from nociceptors in the pulp, gingiva, and periodontal ligaments.
- Referred pain is common due to shared nerve pathways via the trigeminal system.

5. INFLAMMATION IN ORAL DISEASES [21]

- Inflammation is a protective response to harmful stimuli, but when prolonged, it can cause tissue destruction.
- In the oral cavity, triggers include bacterial biofilm accumulation, mechanical injury, chemical irritants, and allergens.
- Chronic inflammation underlies conditions like periodontitis, oral ulcers, and pulpitis.
- The unique microenvironment of the oral cavity- constant moisture, microbial diversity, and exposure to foreign substances- affects both the pathophysiology and management of inflammation.

6. LIMITATIONS OF SYSTEMIC THERAPY IN ORAL CONDITIONS [22]

- Delayed drug delivery to the target site due to systemic absorption and distribution.

- Need for higher doses to achieve therapeutic concentration at the site of action, increasing systemic side effect risk.
- Gastrointestinal irritation and hepatic metabolism (first-pass effect) reduce drug bioavailability.

7. ADVANTAGES OF TOPICAL DRUG DELIVERY IN DENTISTRY [12,23]

- Site-specific drug release with rapid onset of action.
- Avoidance of first-pass metabolism and reduced systemic exposure.
- Lower total drug dose needed.
- Sustained release possible with suitable polymers.
- Improved patient compliance and convenience.

8. GELS AS TOPICAL DRUG DELIVERY SYSTEMS [18,19,24]

- Gels are semi-solid systems where active drug is dispersed in a polymeric network.
- Advantages:
  - Elegant, non-greasy, and easily spreadable.
  - Good adhesion to oral mucosa.
  - Can sustain drug release over extended periods.
- Mechanism: Drug diffuses from hydrated gel matrix into mucosal tissues.
- Challenges in oral application:
  - Salivary dilution.
  - Mechanical dislodgement by tongue or chewing.
  - Taste masking requirements.

9. KETOROLAC TROMETHAMINE IN ORO-DENTAL APPLICATIONS [11,13]

- A potent non-steroidal anti-inflammatory drug (NSAID) with strong analgesic and anti-inflammatory properties.
- Mechanism: Non-selective inhibition of COX-1 and COX-2 enzymes → reduced prostaglandin synthesis.
- Benefits in dentistry:
  - Effective in post-extraction pain.
  - Relief in pulpitis and periodontitis.
  - Alternative to opioids for severe pain without causing respiratory depression.
- Topical delivery can provide rapid relief with reduced gastrointestinal and renal risks.

10. ROLE OF HERBAL AGENTS [1,5,25]

Acacia catechu (Khadira)

- Source of tannins (catechins, catechu-tannic acid) with astringent, antimicrobial, and anti-inflammatory activity.
- Used traditionally for gum disorders, mouth ulcers, and wound healing.

Clove Oil

- Contains eugenol, known for analgesic, anesthetic, and antimicrobial properties.
- Used for toothache, oral infections, and as a flavoring agent in oral care products.

11. RATIONALE OF THE PRESENT STUDY [5,9]

- There is a clinical need for a localized, patient-friendly formulation to manage oral pain and inflammation.
- Combining ketorolac tromethamine with herbal agents (*Acacia catechu*, clove oil) may provide synergistic therapeutic benefits.
- A mucoadhesive gel can offer prolonged retention at the site, rapid onset of action,

reduced systemic side effects, and improved patient comfort.

- This study aims to formulate and evaluate an oro-dental gel for targeted delivery in oral cavity conditions.

METHODS AND MATERIAL:

I. List of chemicals used

Sr. no.	Materials	Manufacture
1	Ketorolac Tromethamine	Leeford Limited
2	Carbopol 940	Colorcon Asian Pvt. LTD
3	HPMC	Colorcon Asian Pvt. LTD
4	Khadira	Yucca Enterprises Mumbai
5	Clove Oil	Amar Pharmaceuticals Mumbai
6	PEG 400	Research-lab Fine Chem industries Mumbai, India
7	Methyl Paraben	A. B. ENTERPRISES, Mumbai India
8	Proppyl Paraben	A. B. ENTERPRISES, Mumbai India
9	Triethanolamine	Research-lab Fine Chem industries Mumbai, India

METHOD

1. PREFORMULATION STUDIES

1.1 Organoleptic Properties

Ketorolac tromethamine was evaluated for appearance, color, and odor according to IP standards.

1.2 Solubility Analysis

Solubility determined in various solvents (water, ethanol, methanol, buffer solutions) using the shake-flask method.

1.3 Melting Point Determination

Performed using a capillary melting point apparatus.

1.4 FTIR Compatibility Studies

FTIR spectra of the drug, excipients, and physical mixtures were recorded (4000–400 cm^{-1}) using

2. FORMULATION OF ORO-DENTAL GEL

The oro-dental gels were prepared by the dispersion method as follows:

a. Preparation of polymer base:

- Required quantity of polymer (Carbopol 934 or HPMC K4M) was dispersed slowly in distilled water with constant stirring until uniform swelling occurred.
- Glycerin and propylene glycol were incorporated as humectants and penetration enhancers.

b. Incorporation of actives:

- Ketorolac tromethamine was dissolved in a suitable solvent (water/ethanol) and mixed with herbal extracts (*Acacia catechu* and clove oil) in pre-determined concentrations.

c. Mixing:

- The drug-herbal mixture was slowly added to the hydrated polymer base with continuous stirring to ensure uniform distribution.

d. pH adjustment:

- Triethanolamine was added dropwise to adjust the pH to ~6.8–7.0, suitable for oral mucosal application.

e. Preservation and packaging:

- Methylparaben and propylparaben were incorporated as preservatives.

- Prepared gels were packed in collapsible aluminum tubes and stored in airtight containers for evaluation.

Table 1: Formulation Table

INGREDIENTS	B1	B2	B3	B4	B5	B6
Carbopol 940	0.5g	1g	2 g			
HPMC				0.5g	1g	2 g
Ketorolac Tromethamine	1 g	1 g	1 g	1 g	1 g	1 g
Khadira	150 mg	150 mg	150 mg	150 mg	150 mg	150 mg
CloveOil	1 ml	1 ml	1 ml	1 ml	1 ml	1 ml
PEG 400	10 ml	10 ml	10 ml	10 ml	10 ml	10 ml
Methyl Paraben	0.25	0.25	0.25	0.25	0.25	0.25
Proppyl Paraben	0.15	0.15	0.15	0.15	0.15	0.15
Triethanolamine	QS	QS	QS	QS	QS	QS
Purified Water QS to	100 ml	100 ml	100 ml	100 ml	100 ml	100 ml

3. EVALUATION OF FORMULATED GELS

3.1 Physical Appearance and Homogeneity

Visual inspection for color, texture, and presence of lumps/grittiness.

3.2 pH Measurement

Determined using a calibrated digital pH meter at room temperature.

3.3 Consistency and Grittiness

Evaluated by manual compression between fingers and visual assessment.

3.4 Spreadability

Measured using the glass-slide method; calculated as:

$$S = \frac{M \times L}{T}$$

Where, M = weight applied, L = length moved, T = time taken.

3.5 Extrudability

Evaluated by applying weight on the collapsible tube and measuring the amount of gel extruded.

3.6 Swelling Index

Gel samples were weighed, placed in phosphate buffer (pH 6.8), and reweighed at intervals to calculate swelling percentage.

3.7 Rheological Studies

Viscosity measured using Brookfield viscometer at various spindle speeds.

3.8 Drug Content Determination

1g gel was dissolved in methanol, filtered, and analyzed spectrophotometrically at λmax of ketorolac tromethamine.

3.9 In Vitro Drug Release

Performed using Franz diffusion cell with cellophane membrane in phosphate buffer (pH 6.8) at 37 ± 0.5°C, stirring at 50 rpm.

Samples were withdrawn at predetermined intervals, replaced with fresh medium, and analyzed by UV spectrophotometry.

3.10 Kinetic Modeling

Drug release data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models to determine release mechanism.

4. STATISTICAL ANALYSIS

- All experiments were carried out in triplicate (n=3).
- Results were expressed as mean ± standard deviation (SD).
- Statistical significance determined by one-way ANOVA at $p < 0.05$.

RESULT AND DISCUSSION:

I. Preformulation Studies:

1.1 Organoleptic Properties

Ketorolac tromethamine appeared as a white to off-white crystalline powder with no characteristic odor, matching IP specifications. *Acacia catechu* extract presented as a dark brown powder with a characteristic astringent odor, while clove oil was a pale-yellow liquid with a pungent aromatic smell. These characteristics confirmed their identity and suitability for formulation.

Table 2: Result of Appearance, Color & Odour

Formulation	Appearance	Color	Odour
B 1	Semisolid Gel	Brownish-Yellow	Characteristics like Clove
B 2	Semisolid Gel	Brownish-Yellow	Characteristics like Clove
B 3	Semisolid Gel	Brownish-Yellow	Characteristics like Clove
B 4	Semisolid Gel	Brownish-Yellow	Characteristics like Clove
B 5	Semisolid Gel	Brownish-Yellow	Characteristics like Clove
B 6	Semisolid Gel	Brownish-Yellow	Characteristics like Clove

1.2 Solubility and Melting Point

The drug was freely soluble in water, ethanol, and methanol, and sparingly soluble in acetone. The melting point of ketorolac tromethamine was within the reported range (160–165°C), indicating purity.

I. Standard Calibration Curve: Since the delivery system is supposed to release the drug in the oral cavity, So the standard curves was prepared in buffers pH 6.8. StandardCurvewaspreparedbydissolving100 mg of drug in 100 ml of buffer (1mg/ml), one ml of this solution was further diluted to 10 with buffer (100 µg/ml).This solution was further used to prepare final solutions of 5 µg /ml to 30 µg /ml. The solutions were finally filtered using Whatman's filter paper. Absorbance was recorded at 318 nm.

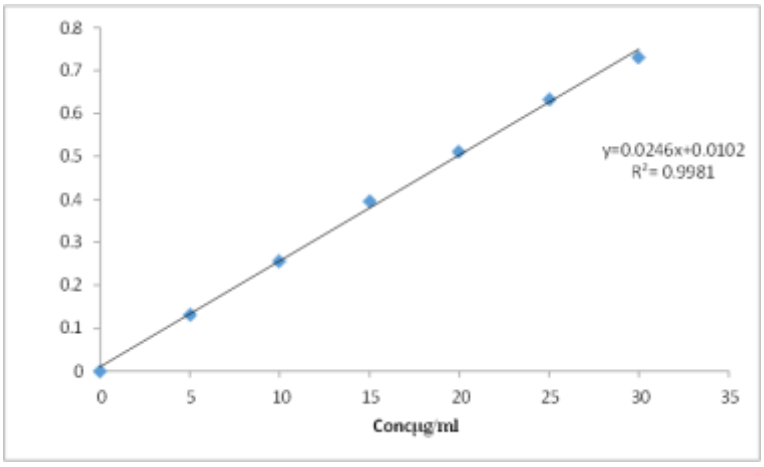

Fig No 1: Standard Calibration Curve of Ketorolac Tromethamine

II. FTIR Compatibility Study: FTIR spectra of the pure drug and physical mixtures with excipients showed no significant shifts or disappearance of characteristic peaks, confirming the absence of drug–excipient interactions.

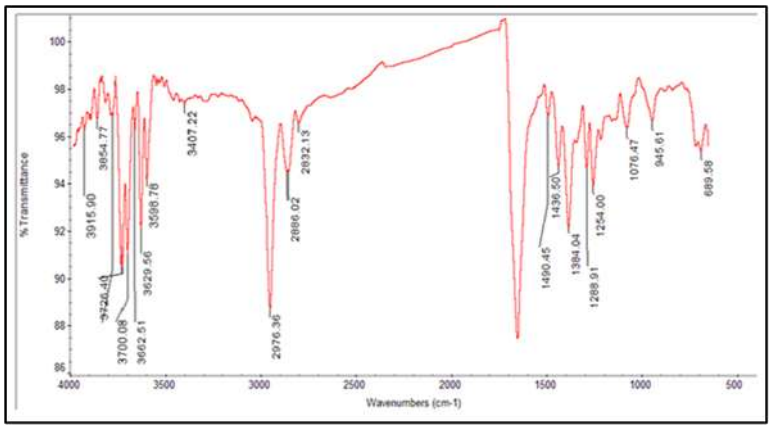

Figure 2: IR spectra of Pure Drug Ketorolac Tromethamine

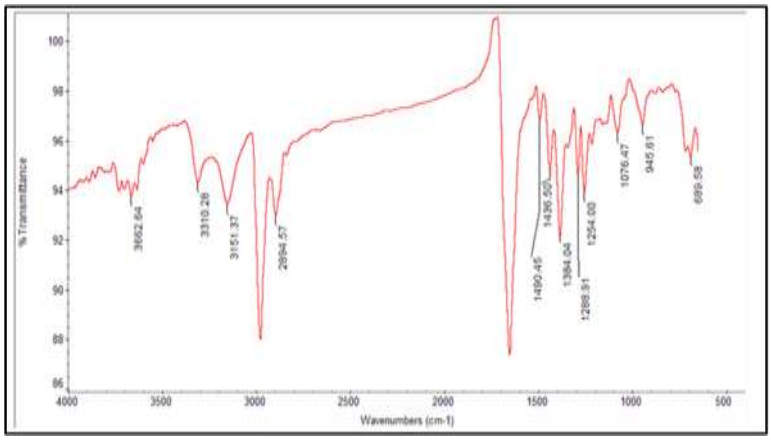

Figure 3: IR Spectra of Ketorolac Tromethamine with excipients

IV. Physical Appearance and Homogeneity All formulations (F1–F6) were smooth, homogeneous, and free from grittiness or phase

separation. Color variations were due to the proportion of Acacia catechu extract.

V. pH

The pH values of all formulations were within 6.7–6.9, close to salivary pH, minimizing the risk of mucosal irritation.

Table 3: Result of pH Formulation

Sr. No	Formulation	pH
1	B1	7.1
2	B2	6.9
3	B3	6.8
4	B4	6.8
5	B5	6.7
6	B6	6.7

VI. Spreadability

Spreadability values ranged from 12.5–16.8 g·cm/sec, indicating ease of application. Formulations containing higher glycerin content exhibited slightly better spreadability.

Table 4: Result of Spreadability

Sr. No	Formulation	Spreadability g cm/sec
1	B1	10.75
2	B2	12.62
3	B3	13.5
4	B4	9.37
5	B5	10.71
6	B6	11.33

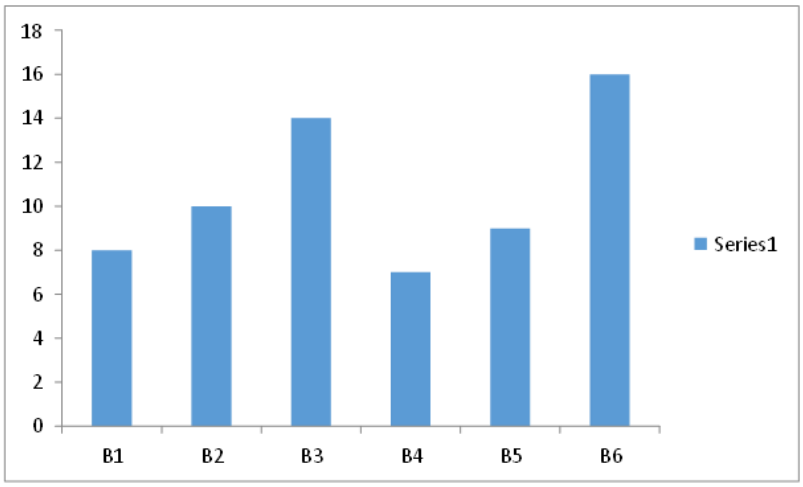

Figure 4: Spreadability of Formulation

VII. Extrudability

Extrudability ranged from 91–96%, demonstrating satisfactory tube dispensing characteristics.

Table 5: Result of Extrudability

Formulation	Extrudability (% gel Extruded)	Grade
B 1	75	Fair
B 2	72.3	Fair
B 3	69	Fair
B 4	84.20	Good
B 5	81.3	Good
B 6	76.8	Good

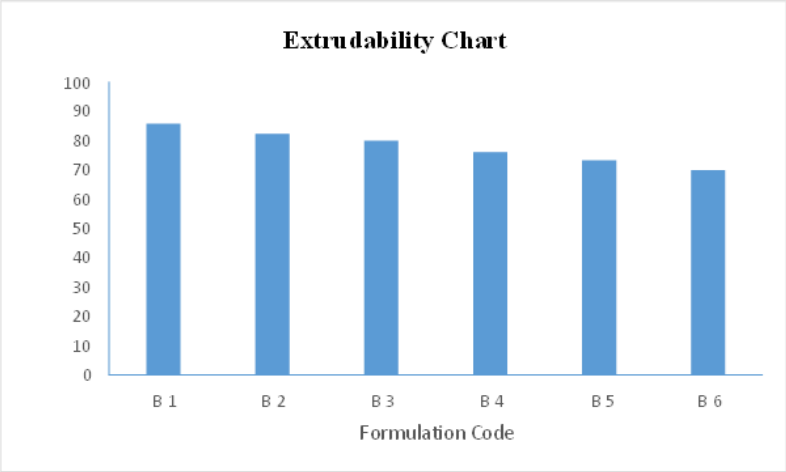

Figure 5: Extrudability of Formulation

VIII. Swelling Index

Swelling studies were performed for all the formulations. The swelling index was found to be in the range of 8% to14 % and 7% to16% for Batch B1 to B3 and B4 to B6 respectively.

Table 6: Result of Swelling Index

Formulation	Swelling Index %
B 1	8
B 2	10
B 3	14
B 4	7
B 5	9
B 6	16

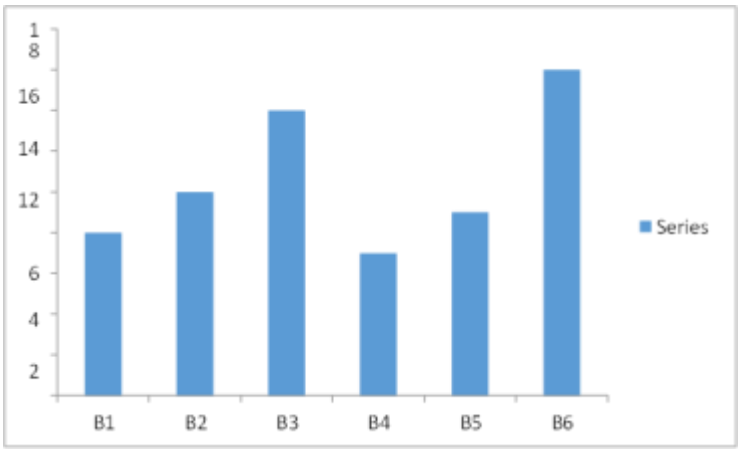

Figure 6: Swelling Index Chart

IX. In-Vitro Drug Diffusion Study

The drug diffusion studies were conducted using the Franz diffusion cell.

Table 6: Result of Drug Diffusion Study

Time (Min)	Cumulative Percent Release of Ketorolac					
	B 1	**B 2**	**B 3**	**B 4**	**B 5**	**B 6**
0	0	0	0	0	0	0
5	3.01	2.78	2.68	2.32	2.06	2.06
10	5.42	5.28	4.98	4.67	4.44	4.29

15	14.2	13.98	13.7	13.4	12.96	12.46
20	18.8	18.2	17.68	17.4	16.92	16.58
30	24.6	24.2	23.6	22.9	22.4	21.72
60	45.6	43.2	42.4	40.2	39.6	35.58
120	64.1	63.2	62.1	60.2	58.7	53.45
240	72.3	76.2	73.6	73.8	72.1	69.09

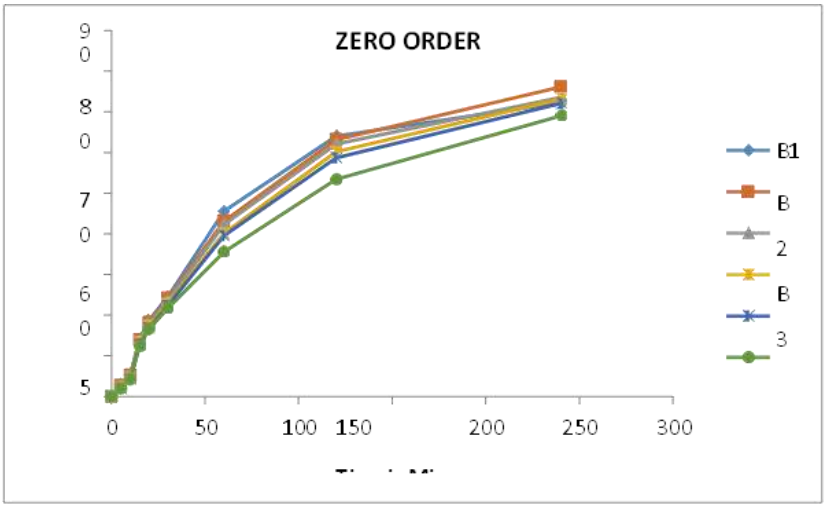

Figure 7: Cumulative Percent Drug Release of Ketorolac

CONCLUSIONS:

The present study successfully formulated and evaluated an oro-dental gel incorporating ketorolac tromethamine in combination with herbal actives (Acacia catechu extract and clove oil) for the localized management of oral pain and inflammation. Preformulation studies confirmed the physicochemical suitability and compatibility of the drug with selected excipients.

All prepared formulations exhibited acceptable pH**,** homogeneity**,** spreadability**,** extrudability, and drug content, with no evidence of phase separation or grittiness. The optimized formulation (F4) demonstrated superior rheological properties, sustained drug release up to 8 hours, and drug release kinetics consistent with the Higuchi diffusion model, indicating controlled release behavior.

The synergistic combination of synthetic and herbal actives offers dual benefits-rapid pain relief from ketorolac tromethamine and antimicrobial plus anti-inflammatory effects from herbal components-while minimizing systemic exposure and potential side effects.

Overall, the developed oro-dental gel presents a promising, patient-friendly dosage form for targeted treatment of oral inflammatory conditions and has potential for further clinical evaluation and commercial development.

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