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FORMULATION AND EVALUATION OF MUCOADHESIVE ORAL SUSTAINED RELEASE TABLETS OF ETODOLAC TO ENHANCE BIOAVAILABILITY AND PROLONG THERAPEUTIC EFFECT

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ABSTRACT

The word mucoadhesion is used when the biological substrate is a mucosal surface. With the help of mucoadhesive polymer, we target various absorptive mucosal layers of the body parts which include the ear, nose, eye, gastrointestinal tract, urogenital tract which will get attached on to the related tissue. This system of drug delivery is called as mucoadhesive drug delivery system. The mucoadhesive systems as drug a carrier has been used for maintenance of the residence time at the absorption site, performance its intensified contact with the epithelial barrier. The development of controlled drug delivery system using bioadhesive molecules includes a decrease in dose frequency and an increase in patient compliance. The present study was to formulating the mucoadhesive oral sustained release tablets containing Etodolac as an active ingredient which is used in the treatment of for the short- and long-term relief of rheumatoid arthritis and osteoarthritis. It works by relieving pain and by reducing swelling and inflammation. The present study involves Prolong release of the drug and increased bioavailability leads to significant reduction in the dose and consequently dose related side effects also reduced. In the present research work to formulate mucoadhesive oral Etodolac tablets in order to avoid extensive first pass metabolism and for prolonged effect. Mucoadhesive tablets of Etodolac were prepared by direct compression method using various bioadhesive polymers like Guar gum, gumkaraya and HPMC K15M in different concentration. The present study concludes that mucoadhesive delivery of Etodolac tablets can be a good way to presence of drug at the site of absorption and to prolong duration of action of drug by reducing the frequency of dosing of Etodolac. The optimised formulation was found to be F6 formulation and its followed peppas release kinetics.

Keywords: Mucoadhesive tablets, Etodolac, Guar gum, Gumkaraya.

INTRODUCTION

Mucoadhesion emerged as an important concept in pharmaceutical drug delivery systems during the 1980s, gaining considerable attention for its ability to prolong drug residence time at absorption sites (Park & Robinson, 1984). Mucoadhesion refers to the adhesion between a synthetic or natural polymer and a mucosal surface, enhancing drug localization and bioavailability (Peppas & Buri, 1985). Bioadhesion specifically describes the attachment of polymers to biological tissues, while mucoadhesion is restricted to mucosal membranes such as those in the gastrointestinal tract (GIT), nasal cavity, buccal mucosa, ocular surface, and vaginal epithelium (Smart, 2005). The mucus layer is a viscoelastic gel composed primarily of water (≈95%), glycoproteins (mucins), lipids, mineral salts, and immunoglobulins (Allen, 1990). Mucins, with molecular weights ranging from 0.5×10^6 to 4×10^6 g/mol, provide the gel-like structure responsible for mucoadhesive interactions. The negatively charged sialic acid and sulfate residues present in mucus facilitate electrostatic and hydrogen bonding interactions with mucoadhesive polymers (Lehr et al., 1990).

Several theories have been proposed to explain mucoadhesion, including the wettability theory, electronic theory, adsorption theory, fracture theory, and diffusion–interpenetration theory (Huang et al., 2000). Among these, the diffusion theory is widely accepted, suggesting interpenetration between polymer chains and mucin

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glycoproteins leads to strong adhesive bonding. Factors such as molecular weight, polymer flexibility, cross-linking density, hydration, pH, and polymer concentration significantly influence mucoadhesive strength (Peppas et al., 2000). Mucoadhesive drug delivery systems offer multiple advantages, including prolonged residence time, improved bioavailability, reduced dosing frequency, avoidance of first-pass metabolism, and enhanced patient compliance (Andrews, Laverty, & Jones, 2009). Various dosage forms such as tablets, films, patches, gels, and microspheres have been developed for oral, nasal, ocular, and gastrointestinal delivery (Goswami et al., 2014; Zate et al., 2014).

Etodolac is a non-steroidal anti-inflammatory drug (NSAID) indicated for the treatment of rheumatoid arthritis and osteoarthritis. It acts primarily by inhibiting cyclooxygenase (COX), particularly COX-2, thereby reducing prostaglandin synthesis responsible for inflammation and pain. Although Etodolac shows good oral absorption and high protein binding (>99%), its relatively short half-life (~7 hours) necessitates repeated dosing, which may increase gastrointestinal side effects (Brune & Hinz, 2004). Therefore, formulating Etodolac into a mucoadhesive sustained-release system could enhance therapeutic efficacy while minimizing dose-related adverse effects.

Previous studies have successfully developed mucoadhesive tablets using polymers such as Carbopol, sodium carboxymethyl cellulose, HPMC, guar gum, and gum karaya (Bangale et al., 2011; Patel et al., 2009; Goswami et al., 2014). These polymers enhance adhesion strength and provide controlled drug release following Higuchi or non-Fickian diffusion kinetics. Based on this background, the present study focuses on the formulation and evaluation of mucoadhesive oral sustained-release tablets of Etodolac using natural and synthetic polymers to improve bioavailability and prolong therapeutic action.

MATERIALS AND METHODS

Materials

Etodolac was used as the active pharmaceutical ingredient. Mucoadhesive polymers included guar gum, gum karaya, hydroxypropyl methylcellulose (HPMC K15M), and Carbopol 940. Microcrystalline cellulose (MCC) was used as a diluent. Magnesium stearate and talc were used as lubricants and glidants. All chemicals and reagents were of analytical grade

Analytical Method Development

The absorption maxima (λmax) of Etodolac were determined using UV–Visible spectrophotometry in 0.1N HCl and phosphate buffer pH 6.8. A calibration curve was prepared in the concentration range of 5–25 µg/mL at 279 nm.

Drug–Excipient Compatibility

Fourier Transform Infrared (FTIR) spectroscopy was performed to evaluate potential interactions between Etodolac and selected polymers.

Formulation of Mucoadhesive Tablets

Tablets were prepared by the direct compression method. The drug and polymers were blended uniformly with MCC, followed by the addition of magnesium stearate and talc. The blend was compressed into tablets using a tablet compression machine.

Evaluation Parameters

Pre-compression parameters included bulk density, tapped density, Hausner's ratio, compressibility index, and angle of repose. Post-compression evaluation included hardness, thickness, weight variation, friability, drug content uniformity, mucoadhesive strength, and in-vitro drug dissolution studies. Drug release kinetics were analyzed using zero-order, first-order, Higuchi, and Korsmeyer–Peppas models.

RESULTS AND DISCUSSION

The present work was designed to developing mucoadhesive tablets of Etodolac using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies. The scanning of the 10µg/ml solution of Etodolac in the ultraviolet range (200-400nm) against 0.1 N HCl blank gave the λ_{max} as 279 nm. The standard concentrations of Etodolac (5-25µg/ml) prepared in 0.1N HCl showed good linearity with R^2 value of 0.999, which suggests that it obeys the Beer-Lamberts law.

Table 1. Standard curve for Etodolac in 0.1N HCl. (n=6) Values (Absorbance ± %RSD).

Concentration (µg ml)	Absorbance ± % RSD
0	0
5	0.136 ± 0.151
10	0.245 ± 0.098
15	0.361 ± 0.135
20	0.472 ± 0.146
25	0.589 ± 0.085

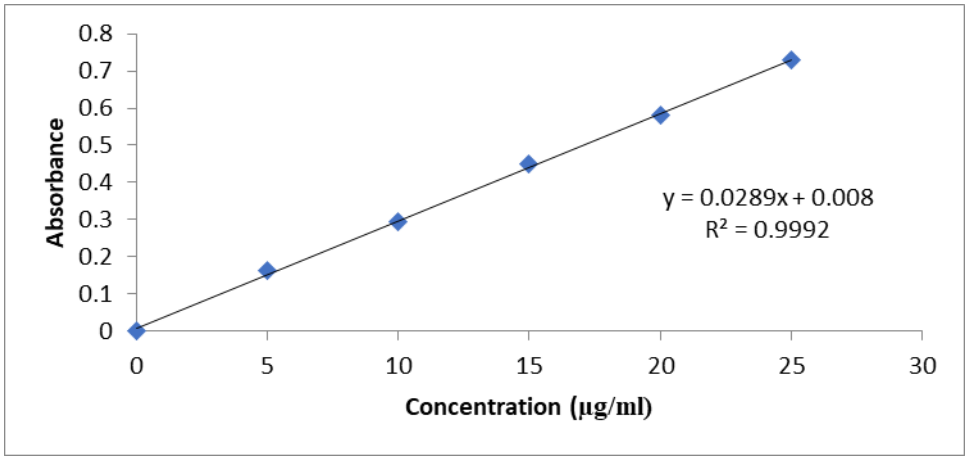

Figure 1. Standard Curve of Etodolac in Phosphate buffer pH 6.8.

The scanning of the 10µg/ml solution of Etodolac in the ultraviolet range (200-400nm) against 6.8 pH phosphate buffer as blank gave the λ_{max} as 276 nm. The standard concentrations of Etodolac (5-25µg/ml) prepared in 6.8 pH phosphate buffer showed good linearity with R^2 value of 0.999, which suggests that it obeys the Beer-Lamberts law.

Table 2. Standard curve of Etodolac in Phosphate buffer pH 6.8 (n=6) Values (Absorbance ± % RSD).

Concentration (µg / ml)	Absorbance± % R.S.D.
0	0
2	0.168 ± 0.18
4	0.293 ± 0.168
6	0.451 ± 0.141
8	0.582 ± 0.161
10	0.728 ± 0.106

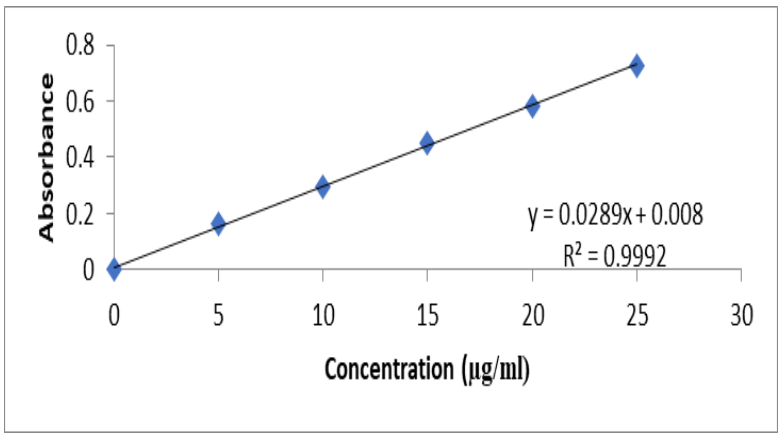

Figure 2. Calibration of Etodolac in Phosphate buffer pH 6.8 at 276nm.

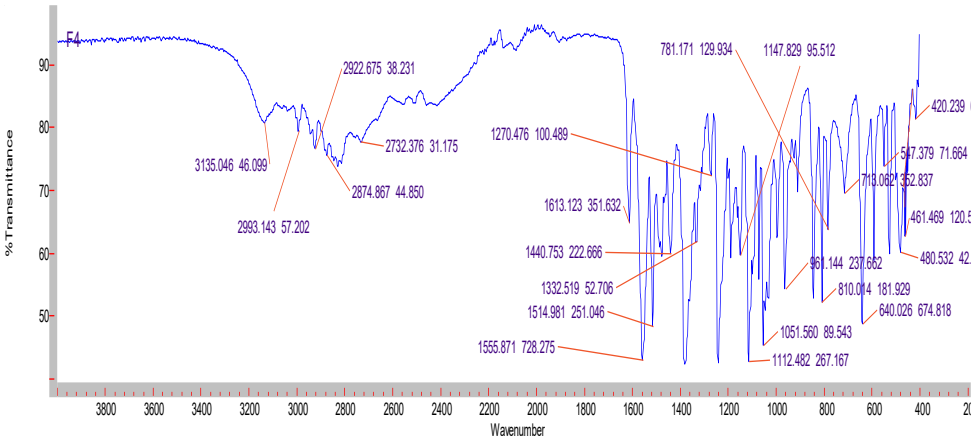

Figure 3. FTIR spectrum of Etodolac.

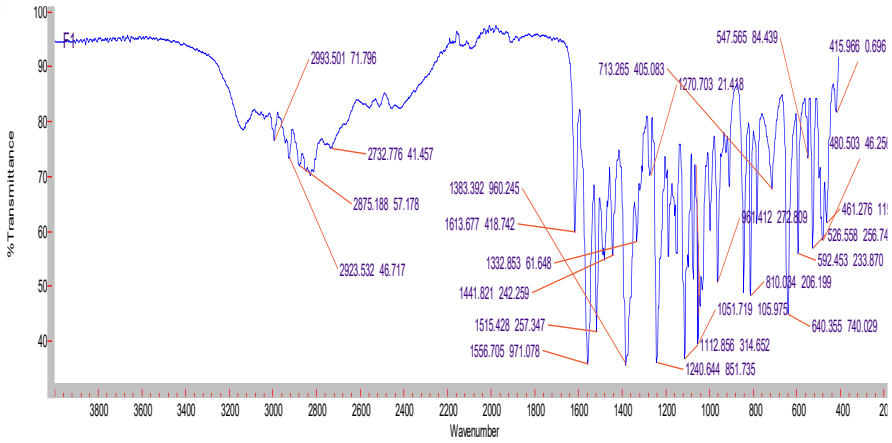

Figure 4. FTIR of optimized Etodolac formulation.

From the above FTIR graphs showed no interaction between drug and excipients, it indicates good compatibility between drug and polymers.

Table 3. Pre compression parameters of Etodolac powder blend.

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	24.11 ± 0.11	0.47 ± 0.05	0.53 ± 0.057	11.32 ± 0.58	1.12 ± 0.015
F2	26.67 ± 0.57	0.45 ± 0.057	0.56 ± 0.015	16.07 ± 0.47	1.24 ± 0.015
F3	26.54 ± 0.57	0.52 ± 0.01	0.60 ± 0.051	13.33 ± 0.57	1.15 ± 0.012
F4	24.43 ± 0.63	0.55 ± 0.015	0.62 ± 0.057	11.29 ± 0.15	1.12 ± 0.012
F5	27.34 ± 0.58	0.47 ± 0.05	0.56 ± 0.015	12.50 ± 0.21	1.19 ± 0.005
F6	26.22 ± 0.51	0.56 ± 0.015	0.63 ± 0.011	11.11 ± 0.35	1.12 ± 0.012
F7	25.18 ± 0.56	0.49 ± 0.02	0.58 ± 0.01	15.51 ± 0.42	1.18 ± 0.011
F8	27.22 ± 0.56	0.57 ± 0.055	0.66 ± 0.017	13.63 ± 0.57	1.15 ± 0.013
F9	26.15 ± 0.41	0.54 ± 0.041	0.62 ± 0.011	12.90 ± 0.43	1.14 ± 0.011

Quality Control Parameters For tablets

Table 4. Post Compression Parameters of Etodolac tablets.

Formulation codes	Weight variation (mg)	Hardness (kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	498.95 ±1.15	4.4 ± 0.11	0.45 ±0.015	5.12 ± 0.1	98.3 ± 0.1
F2	499.15 ±1.25	4.7 ± 0.15	0.54 ± .015	5.15 ±0.057	99.3 ± 0.15
F3	500.26 ±0.81	4.5 ± 0.27	0.55 ± 0.02	5.20 ± 0.057	98.2 ± 0.15
F4	505.36 ±1.17	4.6 ± 0.24	0.56 ± 0.03	5.21 ± 0.1	99.2 ± 0.1
F5	497.25 ±2.02	4.8 ± 0.19	0.48 ± 0.05	5.15 ± 0.057	99.3 ± 015
F6	496.26 ± .25	4.7 ± 0.21	0.45 ±0.015	5.21 ± 0.11	97.2 ± 0.1
F7	502.5 ± 1.15	4.6 ± 0.24	0.51± 0.01	5.25 ± 0.1	98.3 ± 0.2
F8	503.63 ±1.64	4.8 ± 0.10	0.52 ± .015	5.31± 0.1	99.5 ± 0.15
F9	500.31 ±1.52	4.6 ± 0.21	0.53±0.011	5.14±0.1	98.5 ± 0.15

Table 5. Swelling index of mucoadhesive Etodolac tablets.

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	10.25 ± 1.02	13.54 ± 1.15	17.24 ± 1.23	11.15 ± 1.05	15.05 ± 1.32	19.24 ± 1.35	10.53 ± 1.61	14.42 ± 1.36	16.75 ± 1.47
2	16.47 ± 1.52	17.41 ± 1.28	22.42 ±1.35	14.32 ±1.15	19.42 ± 1.24	25.18 ± 0.95	16.48 ± 1.43	19.56 ± 1.25	22.85 ± 1.85
3	21.48 ± 1.36	21.80 ± 1.34	29.28 ±1.42	20.14 ± 1.34	23.31 ± 1.61	31.43 ± 1.48	21.72 ± 1.15	25.61 ± 1.46	28.14 ± 1.08
4	26.64 ± 1.42	26.46 ± 0.96	34.13 ±1.18	24.05 ± 1.05	27.52 ± 1.52	39.61 ± 1.31	25.35 ± 1.35	30.42 ± 1.55	33.46 ± 2.08
5	31.41 ± 0.95	30.23 ± 0.85	39.05 ±1.09	29.15 ± 1.15	31.43 ± 1.42	45.73 ± 1.26	31.15 ± 1.43	34.15 ± 1.31	39.51 ± 1.34
6	36.09 ± 1.16	35.36 ±1.08	43.16 ± 2.04	33.08 ± 1.23	35.18 ± 1.37	52.15 ± 1.43	37.69 ± 0.81	39.08 ± 1.61	46.07 ± 1.87
7	40.04 ± 1.08	41.05 ± 1.14	48.47 ±1.43	37.72 ± 1.34	39.09 ±1.23	59.26 ± 0.95	43.51 ± 1.06	44.43 ± 0.92	51.23 ± 1.43
8	44.41 ± 2.04	45.32 ± 1.62	52.51 ± 1.15	41.14 ± 1.51	44.11 ±1.16	65.41 ± 1.14	47.04 ± 1.19	49.82 ± 1.13	56.42 ±1.76
9	49.36 ± 1.56	51.27 ± 1.57	57.71 ± 1.57	46.63 ± 1.54	48.86 ± 1.27	71.85 ± 2.05	51.24 ± 1.57	53.17 ± 2.08	62.51 ±1.85
10	54.04 ± 1.47	55.74 ± 1.58	61.72 ± 2.04	51.47 ± 2.16	53.43 ± 1.51	75.64 ± 1.81	54.08 ± 2.04	57.63 ± 1.58	69.75 ±2.05
11	59.41 ± 1.33	60.04 ± 1.73	64.17 ± 1.85	54.28 ± 1.87	58.65 ± 1.76	80.08 ± 1.54	59.65 ± 2.14	62.78 ± 1.31	76.43 ±1.64
12	59.12 ± 2.04	60.74 ± 2.01	67.48 ± 1.56	54.07 ± 1.05	64.31 ± 1.41	86.47 ± 2.08	59.34 ± 1.41	68.07 ± 2.04	82.47 ± 1.58

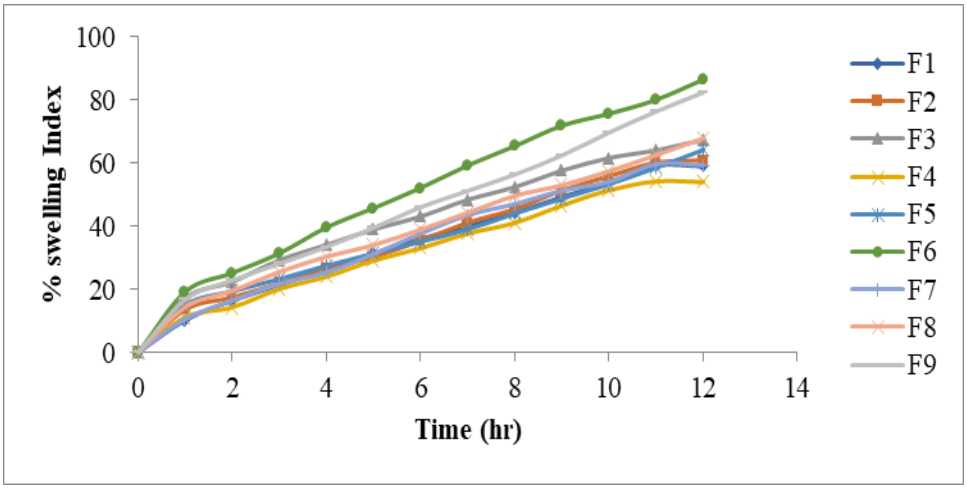

Figure 5. %Swelling index of mucoadhesive Etodolac tablets.

Table 6. Dissolution Data of Etodolac Tablets Prepared with Guar gum in Different Concentrations.

Time (hr)	Cumulative Percent Drug Released		
	F1	F2	F3
0	0	0	0
0.5	15.82±1.05	10.51±0.98	7.46±1.51
1	25.35±1.12	19.72±0.58	16.81±0.85
2	47.81±1.51	30.84±1.24	27.54±1.54
3	64.71±0.99	45.55±2.05	38.48±0.65
4	88.89±1.52	57.08±1.25	49.34±1.71
5	97.78±0.57	70.46±1.85	60.47±0.99
6	97.45±0.85	86.38±2.57	71.52±1.85
7		99.08±1.72	82.45±2.16
8			99.30±1.95

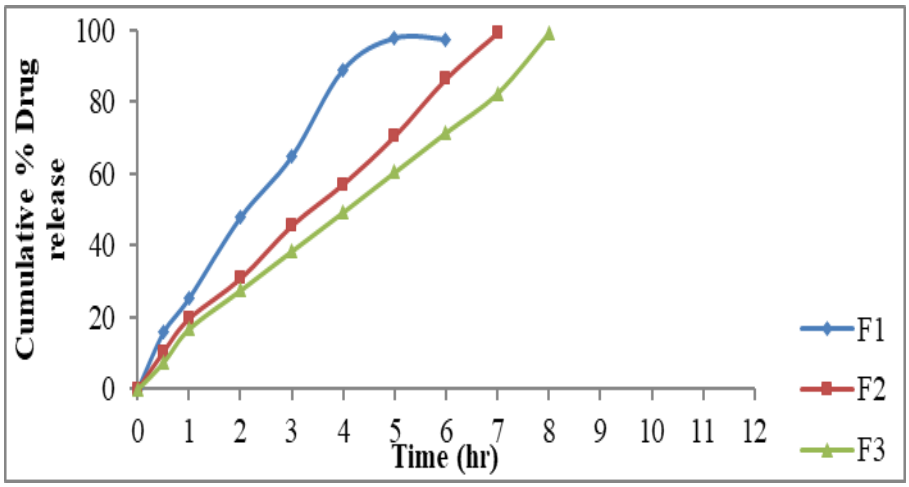

Figure 6. Dissolution study of Etodolac mucoadhesive tablets (F1 to F3).

Table 7. Dissolution Data of Etodolac Tablets Prepared With Guar karaya In Different Concentrations.

Time (Hr)	Cumulative Percent Drug Released		
	F4	F5	F6
0	0	0	0
0.5	14.32±1.24	10.42±2.06	6.25 ± 1.34
1	33.69±2.01	25.14±1.65	11.24 ± 0.96
2	55.71±1.35	36.63±1.82	20.52 ± 1.04
3	77.22±0.95	49.39±0.98	29.54 ± 2.41
4	99.84±1.27	57.16±1.43	37.45 ± 1.86
5		66.92±1.27	45.85 ± 1.52
6		75.19±1.95	52.47 ± 2.06
7		86.34±1.45	60.26 ± 1.85
8		98.45±2.01	69.18 ± 2.11
9		98.51±1.12	76.15 ± 1.67
10			82.24 ± 1.24
11			91.05 ± 1.07
12			99.54 ± 2.13

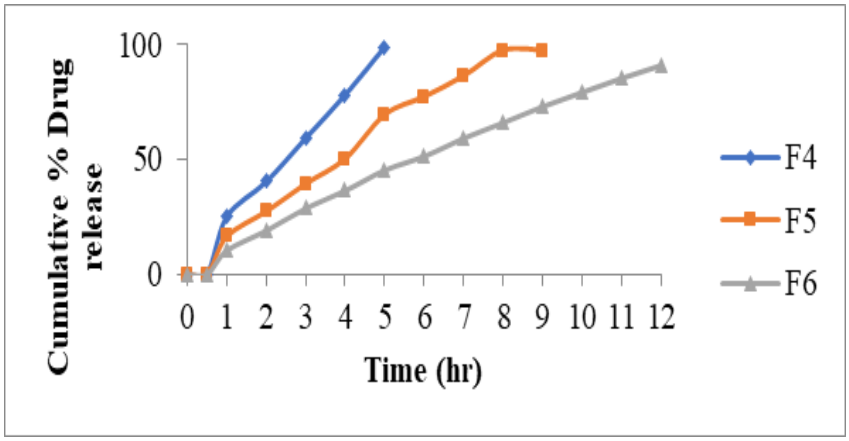

Figure 7. Dissolution study of Etodolac mucoadhesive tablets (F4 to F6).

Table 8. Dissolution Data of Etodolac Tablets Prepared with HPMC K15M in Different Concentrations.

Time (Hr)	Cumulative Percent Drug Release		
	F7	F8	F9
0	0	0	0
0.5	25.13 ± 1.09	16.32 ± 1.82	10.34 ± 1.41
1	40.34 ± 1.85	27.24 ±1.34	19.05 ± 0.87
2	59.34 ± 2.01	39.34 ±2.12	28.72 ± 1.34
3	78.13 ± 1.15	50.21 ± 0.99	36.47 ± 2.11
4	99.01 ± 2.08	69.43 ± 1.36	45.38 ± 1.42
5		77.32 ± 1.11	51.42 ± 1.41
6		88.34 ±1.63	59.32 ± 1.85

7	99.52 ± 1.45	66.07 ± 1.34
8	99.46 ± 2.01	73.08 ± 1.51
9		79.34 ± 1.24
10		85.47 ± 2.15
11		91.05 ± 2.03
12		99.03 ± 1.85

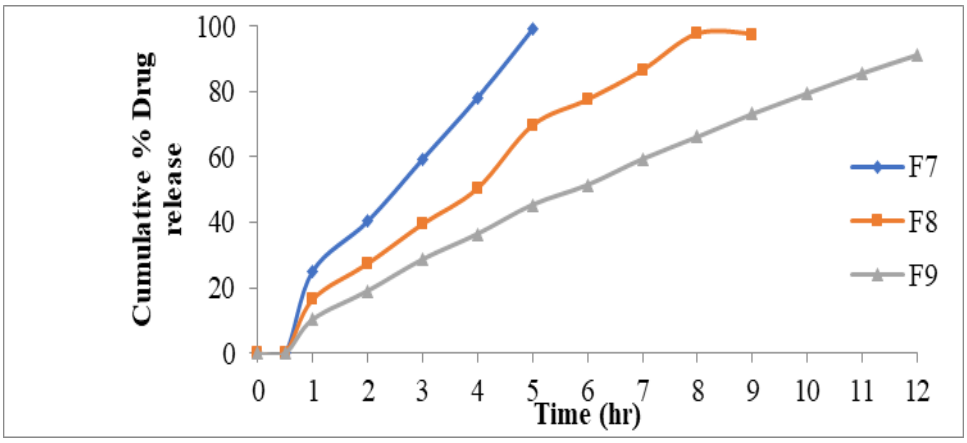

Figure 8. Dissolution study of Etodolac mucoadhesive tablets (F7 to F9).

Mucoadhesive strength: it was measured for the selected formulations**.** From these two parameters such as peak detachment force (N) and work of adhesion were calculated and they were found to be good for the formulation F6

Formulation code	**Mucoadhesion strength**	
	Peak detachment force (N)	**Work of adhesion (mJ)**
F6	4.3	16.83

Application of release rate kinetics to dissolution data

Table 9. Release kinetics data for optimized formulation (F6).

Cumulative (%) Release Q	**Time (t)**	**Root (T)**	**Log (%) Release**	**Log (T)**	**Log (%) Remain**
0	0	0			2.000
6.25	0.5	0.707	0.796	-0.301	1.972
11.24	1	1.000	1.051	0.000	1.948
20.52	2	1.414	1.312	0.301	1.900
29.54	3	1.732	1.470	0.477	1.848
37.45	4	2.000	1.573	0.602	1.796
45.85	5	2.236	1.661	0.699	1.734
52.47	6	2.449	1.720	0.778	1.677
60.26	7	2.646	1.780	0.845	1.599
69.18	8	2.828	1.840	0.903	1.489
76.15	9	3.000	1.882	0.954	1.377

82.24	10	3.162	1.915	1.000	1.249
91.05	11	3.317	1.959	1.041	0.952
99.54	12	3.464	1.998	1.079	-0.337

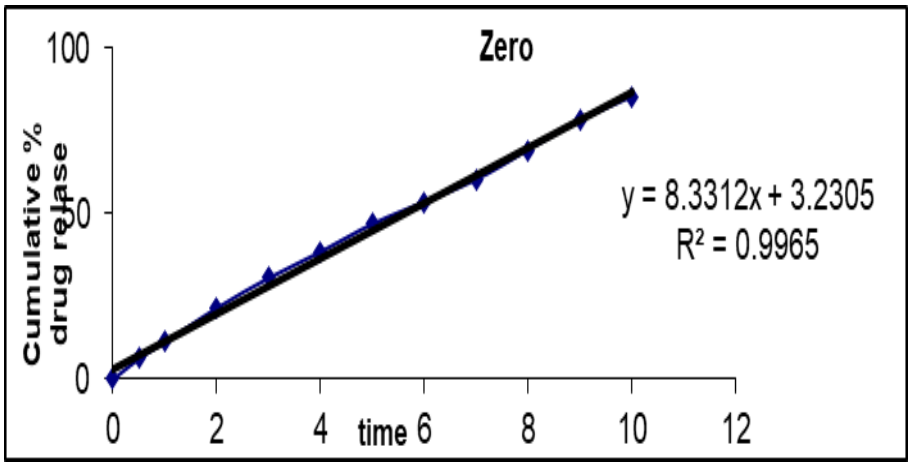

Figure 9. Graph of zero order kinetics.

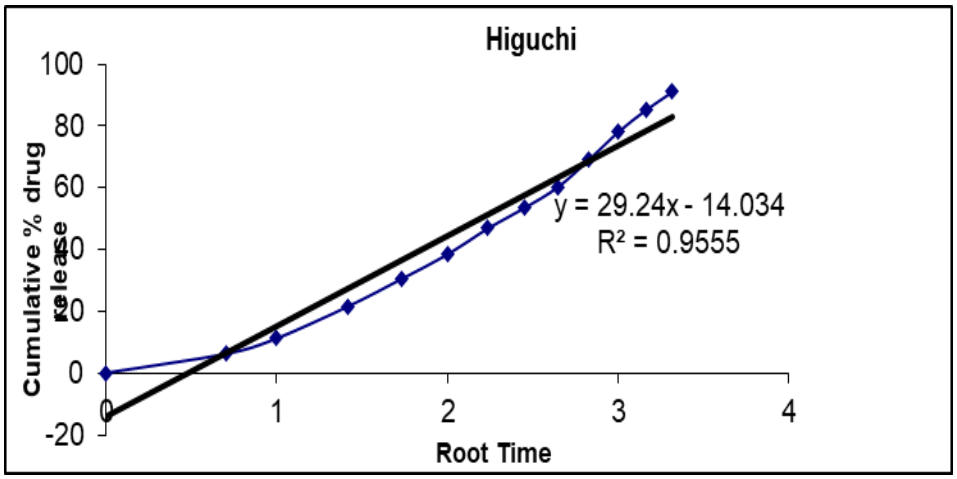

Figure 10. Graph of Higuchi release kinetics.

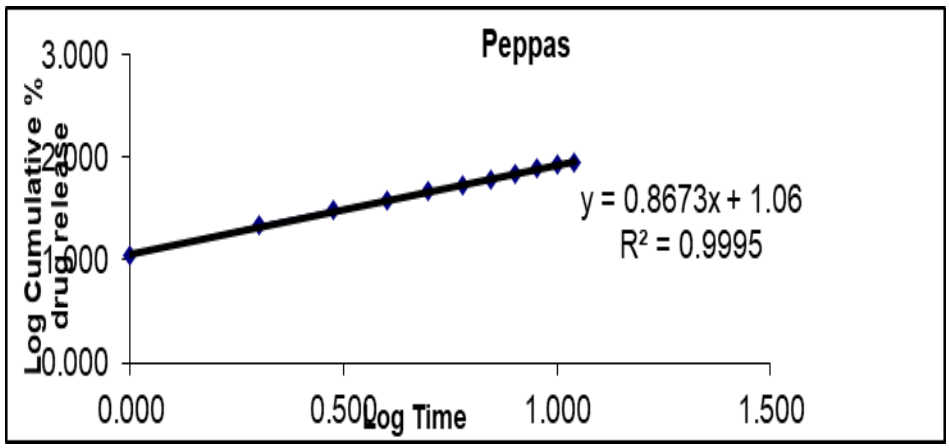

Figure 11. Graph of Peppas release kinetics.

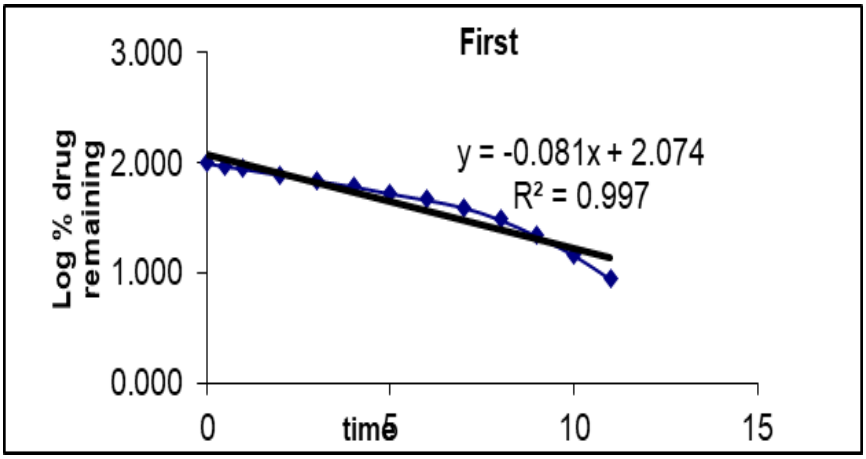

Figure 12. Graph for first order release kinetics.

The present study aimed to develop mucoadhesive sustained-release tablets of Etodolac to enhance drug residence time at the site of absorption and prolong therapeutic action. Tablets were prepared by the direct compression method using bioadhesive polymers such as guar gum, gum karaya, and HPMC K15M in varying concentrations. All formulations were evaluated for drug excipient compatibility, weight variation, thickness, hardness, friability, drug content uniformity, in vitro drug release, and in vitro mucoadhesive strength. Dissolution studies were carried out in pH 1.2 (0.1N HCl) for 2 hours followed by phosphate buffer pH 6.8 for up to 12 hours. The release data were analyzed using zero-order, first-order, Higuchi, and Korsmeyer–Peppas kinetic models. FTIR studies confirmed the absence of any interaction between Etodolac and the selected polymers. All formulations complied with pharmacopeial limits for physicochemical parameters. Among the tested formulations, F6 demonstrated optimal swelling behavior, satisfactory mucoadhesive strength, and sustained drug release up to 12 hours. Drug release from the optimized formulation followed the Korsmeyer–Peppas model, indicating a non-Fickian (anomalous) diffusion mechanism.

CONCLUSION

The study successfully developed mucoadhesive Etodolac tablets capable of providing both sustained drug release and prolonged retention at the absorption site. The optimized formulation (F6) showed desirable physicochemical properties, strong mucoadhesive strength, and controlled drug release over 12 hours. The findings suggest that mucoadhesive delivery of Etodolac is an effective strategy to maintain the drug at the site of absorption, prolong its duration of action, and reduce dosing frequency. This approach may improve therapeutic efficacy and patient compliance in the management of inflammatory conditions.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

FUNDING

This study received no specific funding from public, commercial, or not-for-profit funding agencies.

AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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