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Formulation and Evaluation of Mucoadhesive Bilayer Buccal Batches of Aceclofenac

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ABSTRACT

Aceclofenac is a nonsteroidal anti-inflammatory drug (NSAID) drug, exhibits poor aqueous solubility and low oral bioavailability due to extensive hepatic first-pass metabolism. Buccal delivery offers a potential alternative route to bypass first-pass metabolism and achieve sustained drug release for the clinical management of dental pain and arthritis. The aim of the work was to formulate and evaluate mucoadhesive bilayer buccal patch of Aceclofenac for sustained drug delivery and reducing dose frequency. Bilayer buccal patches were formulated by solvent casting method using an ethyl cellulose backing layer and mucoadhesive layers formulated with varying proportions of hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) followed by evaluation of thickness, weight uniformity, folding endurance, surface pH, swelling index, drug content uniformity, in-vitro release and in-vitro release kinetics study. FTIR spectroscopy confirmed preformulation compatibility between the drug and excipients. Among six formulations (F1–F6) demonstrated that formulation F3 achieved optimal characteristics, exhibiting uniform thickness (0.41 ± 0.03 mm), weight uniformity (0.27 ± 0.03 g), folding endurance (>300), non-irritating surface pH (6.9 ± 0.10), high swelling index (61%), and uniform drug content (99.73 ± 0.06%). In-vitro dissolution testing showed sustained drug release from F3 over 8 hours (reaching 99.67%). Kinetic modeling fitted zero-order release (R^2 = 0.9983) governed by non-Fickian diffusion (Korsmeyer-Peppas n = 0.8851). The optimized F3 bilayer buccal patch represents a successful formulation for sustained buccal delivery to reduce dosing frequency suggesting its potential as an effective alternative clinical management of dental pain and arthritis.

Introduction

Although oral administration is the preferred method for systemic drug delivery, many therapeutic agents are limited by gastrointestinal degradation and hepatic first-pass metabolism, which reduce their systemic bioavailability and shorten their duration of action. Buccal drug delivery presents a viable alternative, allowing drugs to be absorbed through the mucosal membrane, thereby bypassing hepato-gastrointestinal clearance [1]. The highly accessible buccal mucosa supports both rapid absorption and sustained therapeutic effects, establishing it as an advantageous site for systemic delivery.

Drug permeation through the buccal mucosa proceeds mainly via transcellular or paracellular pathways, with the dominant route determined by the drug's physicochemical properties, such as molecular size, lipophilicity, charge, and hydrogen-bonding capacity. Structurally, the buccal mucosa comprises a stratified squamous epithelium, a basement membrane, and connective tissue. Saliva serves to hydrate mucosal dosage forms, whereas mucus facilitates lubrication and bioadhesion. [2]

Bioadhesion is initiated by contact between a polymer and the biological membrane, followed by the establishment of secondary interactions. This phenomenon is explained by several theories, including wetting, diffusion, electronic, adsorption, and fracture mechanisms [3].

Aceclofenac is a nonsteroidal anti-inflammatory drug (NSAID) from a class of organic acids with analgesic, antipyretic, anti-inflammatory, and antiplatelet properties. Classified as a phenylacetic acid derivative and a BCS Class II compound, it is commonly indicated for the clinical management of dental pain and arthritis. The standard regimen for Aceclofenac is 100 mg twice daily; however, its systemic bioavailability is limited to 40–50% due to a narrow absorption window and significant first-pass metabolism. To address these limitations, buccal patches have been developed for its administration [4].

Mucoadhesive buccal patches are engineered to adhere to the mucosa and facilitate sustained, ideally unidirectional, drug release. These systems can be designed as matrix or reservoir configurations, incorporating polymers like hydroxypropyl methylcellulose and polyvinyl alcohol, alongside appropriate backing layers and permeation enhancers [5]. They are typically manufactured via solvent casting, a process wherein the polymers, active ingredient, and excipients are blended, cast onto an inert substrate, and dried [6].

Consequently, mucoadhesive bilayer buccal patches offer a highly effective strategy for optimizing buccal drug delivery by integrating mucoadhesive properties with controlled, unidirectional release.

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Materials and Methods

Materials

The materials utilized in this investigation consisted of aceclofenac, which was provided as a gift by Pharmafabrikon (Madurai, India), along with ethyl cellulose (EC), polyvinyl alcohol (PVA), and propylene glycol (PG) obtained from Loba Chemie (India). Hydroxy propyl methyl cellulose (HPMC), Glycerin purchased from Micro Fine chemicals, India. Di-butyl phthalate and acetone purchased from Thermo Fisher Scientific, India. Menthol purchased from Spectrum reagents and chemicals, India.

Methods

Preformulation study was carried out to check the compatibility between drug and various polymers. The IR spectra of the test samples were obtained by pressed pellet technique. The resulting pellet is transparent to IR radiation and is run. FTIR spectra of physical mixtures of polymer and drug were studied [7]. FTIR Spectra of Aceclofenac was measured and it was compared with the standard FTIR spectra and UV spectrophotometer (UV 1061 Shimadzu Scientific) was used for the estimation of Aceclofenac. The absorbance was measured at 273 nm [8].

Preparation of backing layer

The backing layer was prepared by a solvent casting technique [9,10]. Ethyl cellulose (EC) was dissolved in acetone containing varying proportions of dibutyl phthalate (DBP) and propylene glycol (PG) plasticizers. The solutions were agitated on a magnetic stirrer, cast into petri dishes, and allowed to dry fully at room temperature.

Table 1: Composition of backing layer

Component	B1	B2	B3	B4
EC (mg)	600	600	600	600
DBP (mg)	60	180	-	-
PG (mg)	-	-	60	180
Acetone(ml)	20	20	20	20

EC-Ethyl cellulose, DBP-Di-butyl phthalate, PG-Propylene glycol

Preparation of drug mucoadhesive layer

Patches containing drug and different proportions of polymers were formulated by solvent casting method.[11] Plasticized polymer solutions were prepared by dissolving different proportions of polymer in a solvent containing drug and adding a suitable plasticizer. An amount of drug was added in such a way that it would give final dose of drug 100 mg in polymer solution. In addition to the mucoadhesive component, also incorporated additives as a permeation enhancer. Menthol was taken in different concentrations to incorporated in plasticized polymer solution. The viscous polymer solution allows to stand for 15-30 minutes to remove entrapped air to ensure a clear, bubble free solution. [12]

The plasticized drug and polymer solution was poured into a glass Petridish (9 cm diameter) and allowed to oven drying at 40ºC until a constant weight flexible patches was formed. Dried patches were carefully removed, checked for any imperfections and cut into patches of 2×2 cm^2 area containing 100 mg of drug per patch. The patches were packed in aluminium foil and stored in desiccators to maintain the integrity and elasticity of the patches until further use. [13, 14].

Table 2: Composition of drug mucoadhesive layer

Component	F1	F2	F3	F4	F5	F6
Aceclofenac (mg)	100	100	100	100	100	100
HPMC (mg)	500	1000	1500	-	-	-
PVA (mg)	-	-	-	400	600	800
Glycerin (ml)	0.5	0.5	0.5	0.5	0.5	0.5
PG (ml)	0.5	0.5	0.5	0.5	0.5	0.5
Menthol (mg)	0.1	0.1	0.1	0.1	0.1	0.1
Distilled water(ml)	30	30	30	30	30	30

HPMC-Hydroxy propyl methyl cellulose, PVA-Poly vinyl alcohol, SCMC-Sodium carboxy methyl cellulose, PG-Propylene glycol

Thickness

For physical assessment, five patches were randomly selected from each formulation, and their thickness was measured at five distinct locations using either a digital vernier caliper or a micrometer screw gauge to determine the average thickness [15].

Weight uniformity

Weight uniformity is assessed to verify that all buccal patches maintain a consistent weight and a uniform distribution of both the drug and excipients. Five randomly chosen patches from each formulation are weighed to determine the weight variation. [16]

Folding endurance

To evaluate the physical integrity of the formulations, the folding endurance was determined by repeatedly folding three randomly selected patches at the same location until cracking or tearing occurred, from which the average value was calculated. [17]

Swelling Study

To evaluate the swelling characteristics of the buccal patches, hydration-induced weight gain was monitored. Individual patches were weighed on a pre-weighed coverslip (W_1) and then placed in a petri dish containing 20 mL of pH 6.8 isotonic phosphate buffer. At specified intervals over a 4-hour period, the coverslip was removed and reweighed (W_2). The weight increase from water absorption was utilized to calculate the swelling index (SI). These assessments were performed in triplicate, and the average values were documented [18].

$$SI = (W_2 - W_1) / W_1 \times 100$$

Where W_1 represents the initial weight of the patches and W_2 represents the weight of the swollen patches at specific time intervals.

Surface pH

To ensure compatibility with the buccal mucosa and avoid irritation, the surface pH of three randomly selected patches per formulation was determined. For this procedure, an agar plate was prepared by dissolving 2% (w/v) agar in heated, stirred pH 7.4 isotonic phosphate buffer, which was poured into a petri dish and allowed to solidify at room temperature. The patches were then positioned on the agar surface to swell for 2 hours. The surface pH was subsequently measured by placing pH paper directly onto the swollen patch surface, and the average of three pH readings was recorded [19].

Drug content uniformity

Drug content uniformity is analyzed to confirm that each patch contains the target dose. This is achieved by dissolving and homogenizing a single patch in 100 mL of pH 6.6 isotonic phosphate buffer for 2 hours with occasional agitation, after which a 5 mL sample is withdrawn, diluted to 20 mL with the same buffer, and filtered using a 0.45 µm Whatman filter paperThe drug content is subsequently measured spectrophotometrically at 273 nm. The final value represents the average of three determinations. [20]

Invitro drug release

The in vitro release profile of Aceclofenac from the mucoadhesive buccal patches is assessed using a USP dissolution apparatus Type I (basket method) under sink conditions. The study is performed in 900 mL of pH 6.8 phosphate buffer solution at 37 ± 0.5 °C with a basket rotation speed of 50 rpm. A 2 cm × 2 cm patch is secured to the dissolution basket using double-sided adhesive tape, ensuring that the mucoadhesive layer remains in direct contact with the dissolution medium. Although the volume of the dissolution medium is larger than the physiological volume of saliva in the buccal cavity, this excess volume is necessary to maintain sink conditions, ensuring consistent drug diffusion and accurate quantification throughout the release study. At predetermined intervals, 5 mL samples are withdrawn and immediately replaced with an equal volume of fresh, pre-warmed dissolution medium to maintain a constant volume. The collected samples are analyzed using a UV-visible spectrophotometer at 273 nm to quantify the released Aceclofenac. The underlying release mechanism is determined by fitting the dissolution data to Higuchi, Korsmeyer-Peppas, zero-order, and first-order models. [21]

Invitro drug release kinetics study

Studying in vitro drug release kinetics is vital for predicting invivo performance and facilitating the rational design of sustained-release formulations. To identify the mathematical model that best describes the drug release behavior, the in vitro dissolution data are fitted to various model-dependent methods, such as zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. [22,23] These model-dependent methods utilize specific mathematical functions to characterize the dissolution profile. Once an appropriate model is selected, the dissolution profiles are analyzed based on the derived parameters. The selection of the preferred release mechanism is based on the correlation coefficient (r), with the model yielding the highest correlation coefficient being selected as the best fit. The release data of the prepared buccal patches are fitted to the following mathematical models:

Zero-order model : $Q_t = Q_0 + K_0t$

First-order model : $\log C = \log C_0 - K_t / 2.303$

Higuchi model : $Q = K_H \times t^{(1/2)}$

Korsmeyer-Peppas model : $M_t / M_\infty = K_tn$

Where Q_t is the amount of drug dissolved at time t, Q_0 is the initial drug amount in solution (typically $Q_0 = 0$), K_0 is the zero-order release rate constant (expressed in concentration/time), C_0 is the initial concentration of the drug, K is the first-order rate constant, K_H is the Higuchi dissolution constant, W_0 is the initial drug amount in the dosage form, W_t is the drug amount remaining in the dosage form at time t, κ (kappa) is a constant incorporating the surface-volume relationship, M_t / M_∞ is the fraction of drug released at time t, K is the release rate constant, and n is the release exponent. The value of n is used to interpret the diffusional release mechanism from the polymeric films as defined by the Korsmeyer-Peppas model. [24,25]

Results and discussion

Drug-excipients compatibility study by FTIR

Infrared spectroscopy can be used to identify a compound and also to investigate the composition of a mixture thereby we can study incompatibility with two compounds. Compatibility in between both drug and excipients. The IR spectra of the test sampes were obtained by pressed pellet technique. Spectrums in the infrared were chosen between 400 and 4000 cm^{-1}.

From the result it was concluded that there was no interface of functional groups principle peak of Aceclofenac were found to be unaltered in the drug polymer physical mixture that there was no change in peaks of admixture compared with drug which indicates that the drug and excipients are compatible.

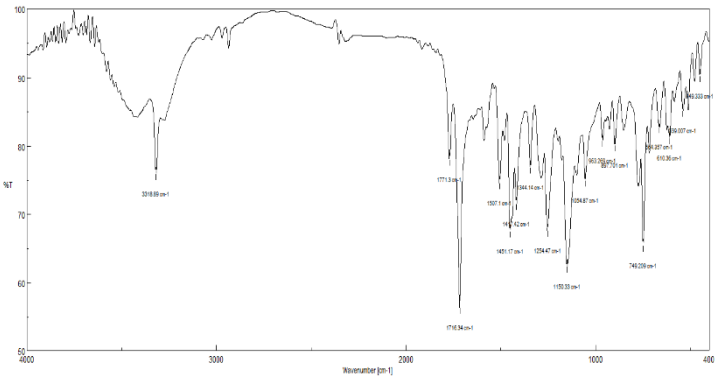

Figure 1: FTIR studies of pure Aceclofenac

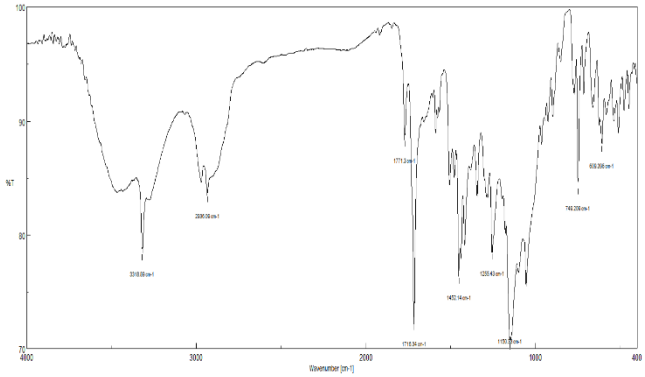

Figure 2: FTIR studies of Aceclofenac & HPMC + Ethyl cellulose polymer mixture

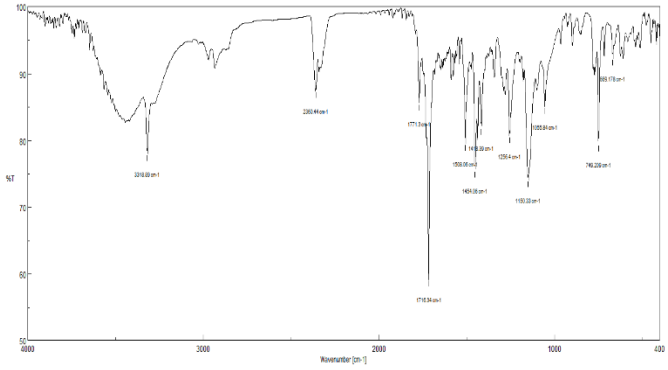

Figure 3: FTIR studies of Aceclofenac & PVA + Ethylcellulose polymer mixture

UV spectrophotometric characterization

The calibration curve of Aceclofenac phosphate 6.8 is given in table and figure

Table 3: Calibration Curve of Aceclofenac

Concentration (µg/ml)	Absorbance (λ_{max})
5	0.142
10	0.283
15	0.422
20	0.561
25	0.707
30	0.823

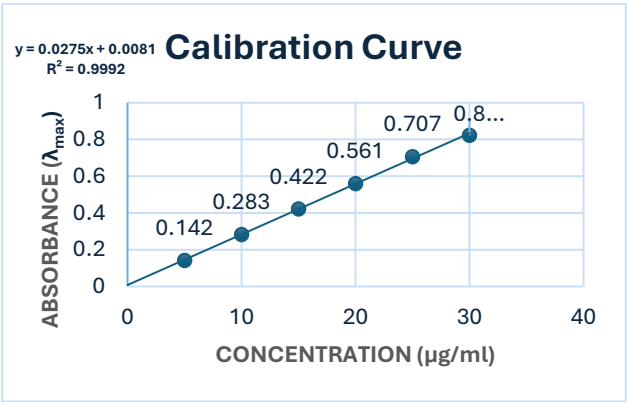

Figure 4: Calibration Curve of Aceclofenac

Evaluation

Backing layer

Thickness

The thickness of each patch was measured at 5 different points and the average thickness with standard deviation was calculated. The thickness of the formulated backing layer of buccal patches ranged from 0.05 ± 0.01 mm to 0.15 ± 0.01 mm. Among 4 formulations, B2 ensure better thickness uniformity.

Table 4: Thickness of backing layer

Formulation	Thickness Uniformity(mm)
B1	0.08 ± 0.01
B2	0.11 ± 0.01
B3	0.09 ± 0.01
B4	0.13 ± 0.01

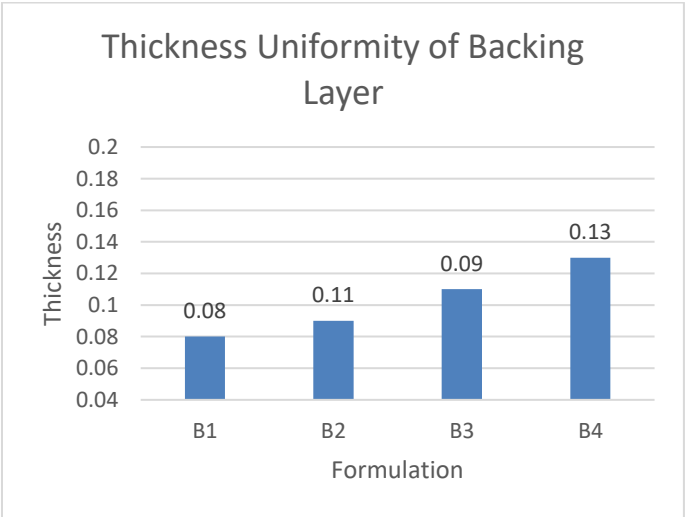

Figure 5: Thickness of backing layer

Folding endurance

The folding endurance value for the backing layer of all buccal patches was > 300; it indicates that all formulations had ideal patch properties. Among 4 formulations, B2 shows better folding endurance properties.

Table 5: Folding endurance of backing layer

Formulation	Folding endurance
B1	315 ± 5
B2	328 ± 4
B3	304 ± 3
B4	316 ± 4

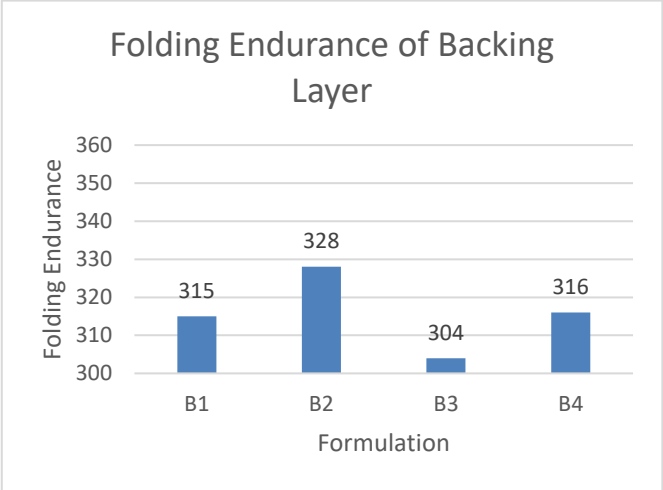

Figure 6: Folding endurance of backing layer

Drug mucoadhesive layer

Thickness

The thickness of each patch was measured at 5 different points and the average thickness with standard deviation was calculated. The thickness of the formulated mucoadhesive layer of buccal patches ranged from 0.33 ± 0.03 mm to 0.50 ± 0.03 mm. Among 6 formulations, F3 ensure thickness uniformity.

Table 6: Thickness of mucoadhesive layer

Formulation	Thickness Uniformity(mm)
F1	0.35 ± 0.03
F2	0.50 ± 0.03
F3	0.41 ± 0.03
F4	0.33 ± 0.03
F5	0.45 ± 0.03
F6	0.47 ± 0.03

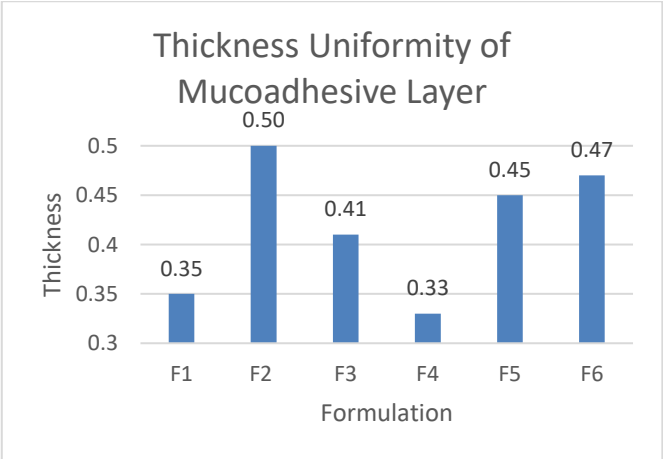

Figure 7: Thickness of mucoadhesive layer

Weight uniformity

Drug loaded patches were tested for uniformity of weight and the results of weight uniformity are given in table. Lesser standard deviation values indicated that the patch were uniform in weight. The weight uniformity of all formulations (F1–F6) was within the acceptable range of 0.25–0.30 g, indicating good uniformity. Among 6 formulations, F3 shows better weight uniformity from all formulations.

Table 7: Weight uniformity

Formulation	Weight Uniformity(mg)
F1	0.26 ± 0.06
F2	0.26 ± 0.07
F3	0.27 ± 0.03
F4	0.30 ± 0.05
F5	0.28 ± 0.06
F6	0.29 ± 0.06

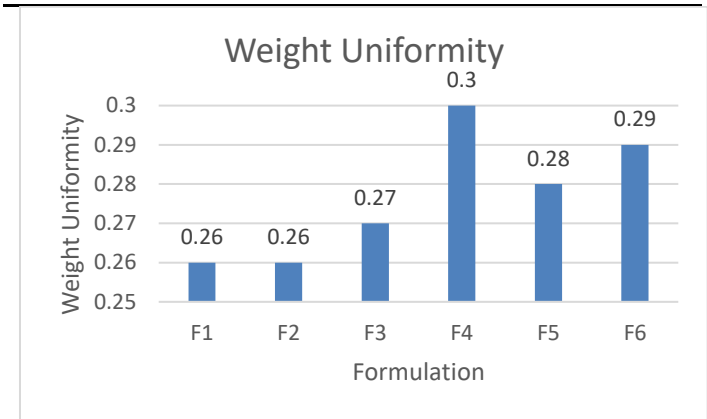

Figure 8: Weight uniformity

Folding endurance

The folding endurance value for mucoadhesive layer of all buccal patches was > 300; it indicates that all formulations had ideal patch properties. Among 6 formulations, F3 shows better folding endurance properties.

Table 8: Folding endurance of mucoadhesive layer

Formulation	Folding endurance
F1	312 ± 4
F2	326 ± 5
F3	348 ± 3
F4	305 ± 6
F5	318 ± 4
F6	330 ± 5

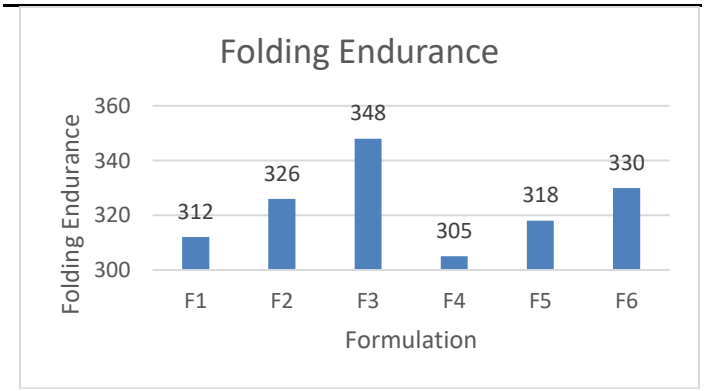

Figure 9: Folding endurance of mucoadhesive layer

Surface pH

The surface pH of all developed formulations ranged from 6.2 to 7.2, indicating that the patches will not alter the natural pH of saliva in the buccal cavity, thereby

preventing potential irritation. Among 6 formulations, F3 shows no irritation through the buccal mucosa.

Table 9: Surface pH

Formulation	Surface pH
F1	6.6 ± 0.12
F2	6.4 ± 0.11
F3	6.9 ± 0.10
F4	6.5 ± 0.15
F5	7.0 ± 0.17
F6	7.2 ± 0.17

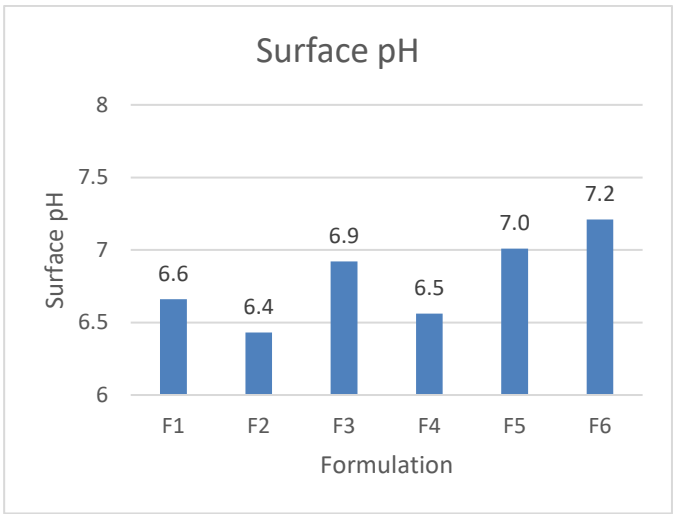

Figure 10: Surface pH

Swelling index

Swelling index of all patches was calculated and it was in the range 34.11±0.12% to 62.11±0.85%. Formulation containing HPMC shows maximum swelling property than the other patches. As the concentration of polymer increased, swelling index also increased. Swelling is very essential before the drug is released from the dosage form. Among 6 formulations, F3 show better shows better swelling properties.

Table 10: Swelling index of buccal patch

Formulation	Swelling Index (%)
F1	48
F2	54
F3	61
F4	45
F5	50
F6	52

Drug content uniformity

The percentage drug content in various formulations ranged from 95-105% of Aceclofenac given in table. It was observed from the drug content data that there was no significant difference in the uniformity of the drug content. However, when compared with the theoretical drug content, the estimated drug content of the patches. Among 6 formulations, F3 ensure the uniform drug content from all the formulations.

Table 11: Drug Content Uniformity test

Formulation	Drug content uniformity (%)
F1	97.30 ± 0.10
F2	98.83 ± 0.29
F3	99.73 ± 0.06
F4	96.41 ± 0.08
F5	96.67 ± 0.57
F6	97.53 ± 0.17

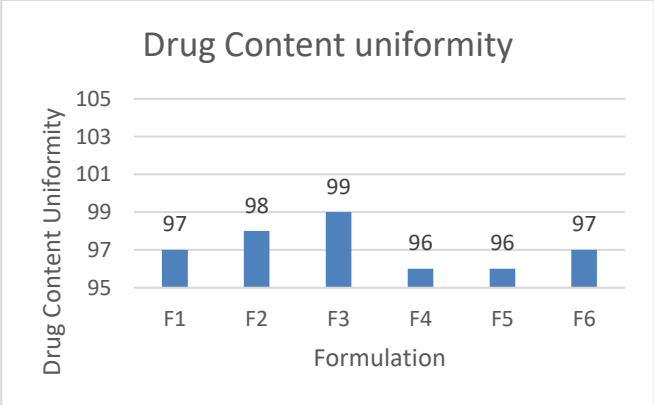

Figure 11: Drug Content Uniformity test

Invitro drug release studies

As salivary pH is in the range of 6.2-7.2 and in many studies of buccal drug delivery system, pH 6.8 phosphate buffer has been used as drug release medium, so the same has been selected for the present study. The *invitro* release profiles of Aceclofenac from formulation batch F1-F6 buccal patches. The release was found to depend on the proportion of HPMC and PVA. *Invitro* release profiles of Aceclofenac was done formulation from F1-F6 figures are presented.

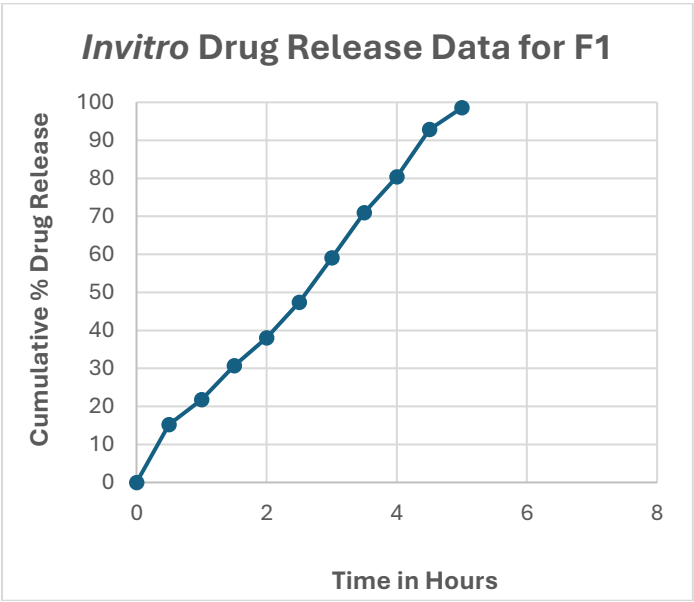

Figure 12: Invitro Drug Release Data for F1

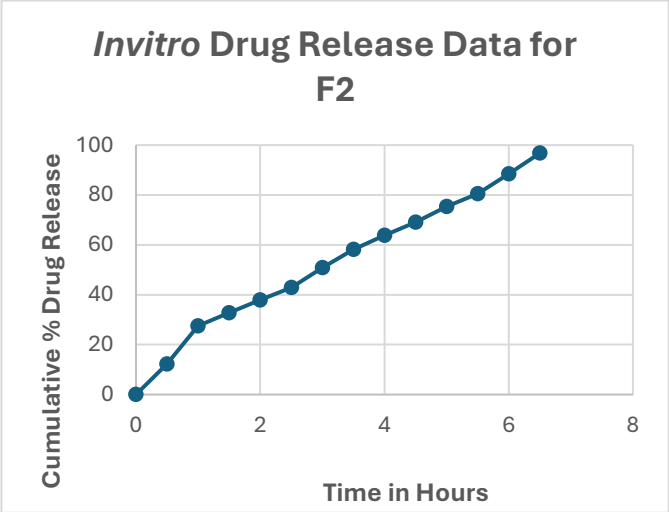

Figure 13: Invitro Drug Release Data for F2

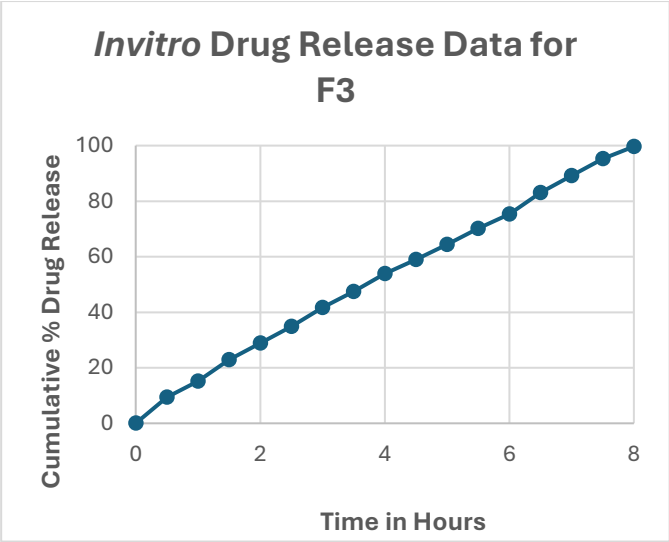

Figure 14: Invitro Drug Release Data for F3

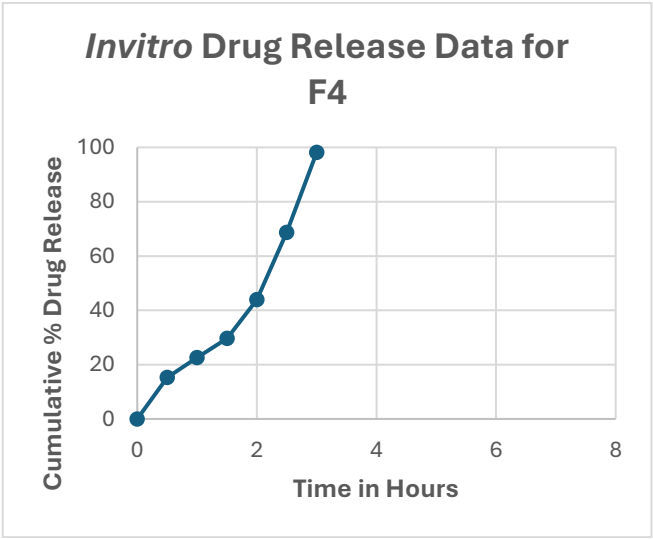

Figure 15: Invitro Drug Release Data for F4

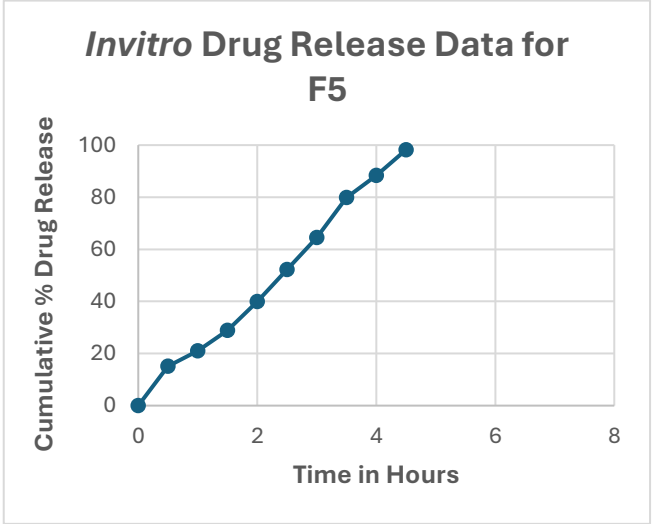

Figure 16: Invitro Drug Release Data for F5

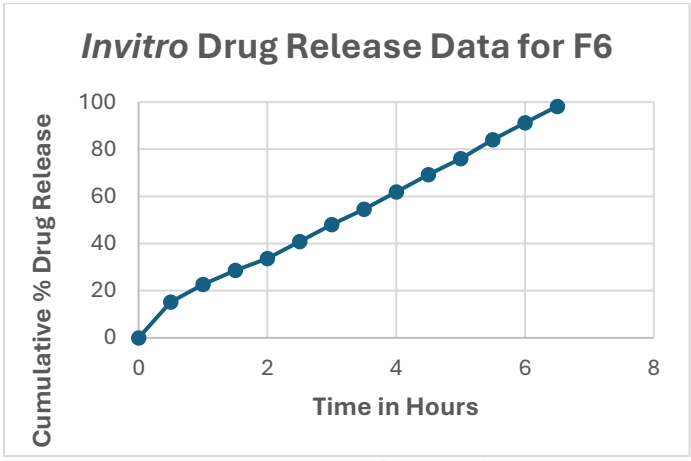

Figure 17: Invitro Drug Release Data for F6

The in-vitro release profiles of Aceclofenac from buccal patch formulations F1 to F6 were determined by the proportions of HPMC and PVA. Testing of these six formulations showed distinct release rates, confirming that polymer concentration and formulation composition directly impact drug release. The optimized formulation, F3, displayed a controlled and progressive release pattern, yielding 9.34% drug release at 0.5 hours, 28.86% at 2 hours, 53.89% at 4 hours, 75.35% at 6 hours, and 99.67% at 8 hours. This represented a more prolonged release compared to F1 (which reached 98.56% at 5 hours) and F2 (which reached 97.76% at 6.5 hours). Conversely, F4 exhibited the most rapid release, achieving 98.14% in 3 hours, making it unsuitable for a sustained-release target. Formulations F5 and F6 also released the drug more quickly than F3, reaching 98.20% at 4.5 hours and 98.18% at 6.5 hours, respectively. Ultimately, F3 was selected as the optimal formulation because its sustained-release profile can extend drug delivery and reduce the required frequency of dosing.

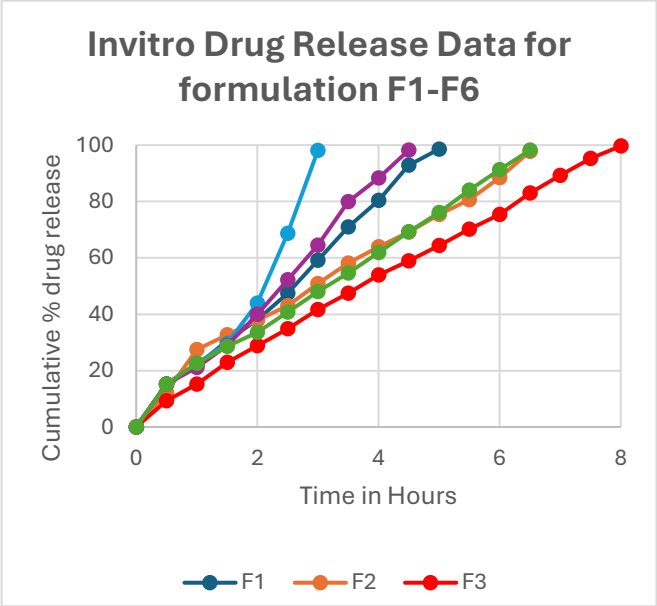

Figure 18: Invitro Drug Release Data for Formulation F1-F6

Invitro drug release kinetics study for optimized formulation F3

First-order kinetics

The optimized formulation F3 was introduced into graphical treatment for first-order kinetics for drug release.

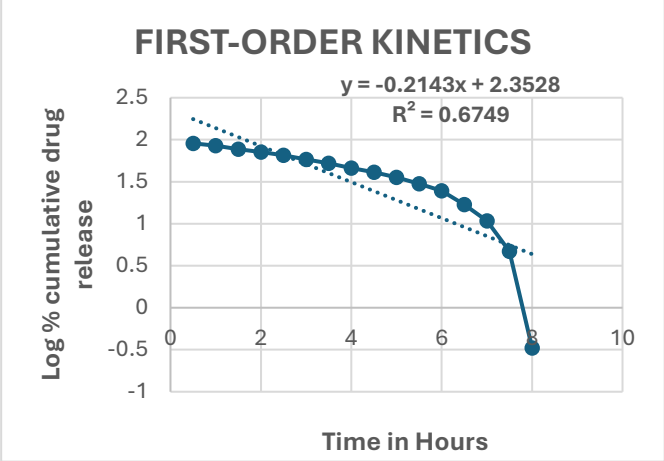

Figure 19: First-order plot for optimized formulation F3

The first order plots were obtained by plotting log remaining cumulative percentage drug release versus time. The regression value is 0.6749.

Zero-order kinetics

The optimized formulation F3 was introduced into graphical treatment for zero-order kinetics for drug release.

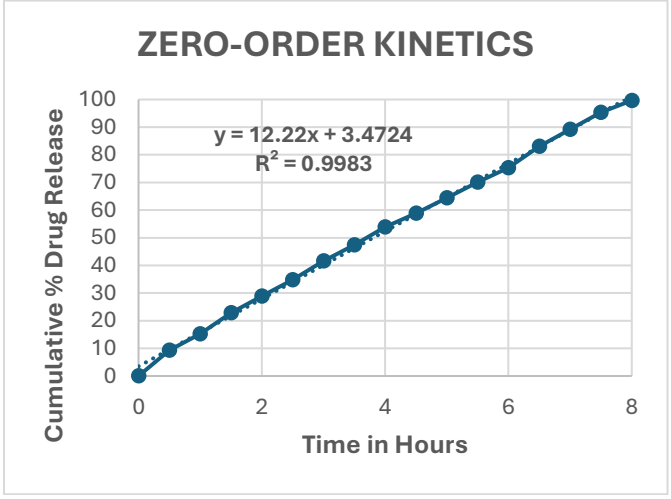

Figure 20: Zero-order plot for optimized formulation F3

The zero order plots were obtained by plotting log remaining cumulative percentage drug release versus time. The regression value is 0.9983.

Korsmeyer-Peppas plot

The optimized formulation F3 was introduced into graphical treatment Korsmeyer-Peppas plot for drug release.

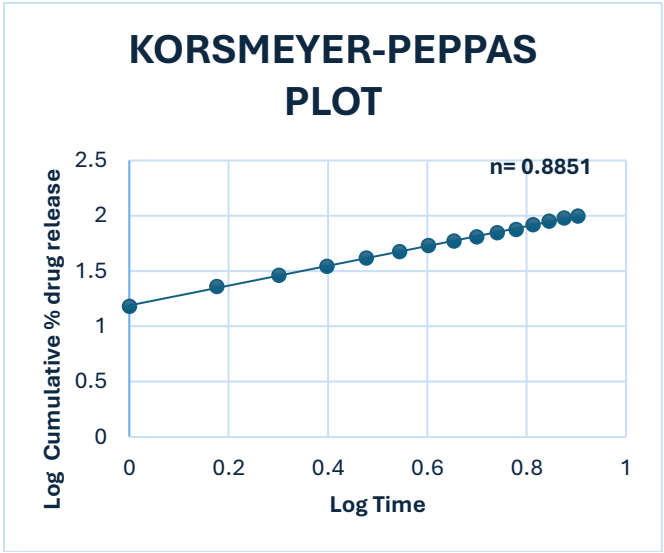

Figure 21: Korsmeyer-Peppas plot for optimized formulation F3

Korsmeyer-peppas plot was made by plotting log cumulative percentage % drug release against log time. The exponential component i.e.'n' was found to be 0.8851 indicate non-fickian diffusion mediated.

Higuchi plot

The optimized formulation F3 was introduced into graphical treatment for Higuchi plot for drug release.

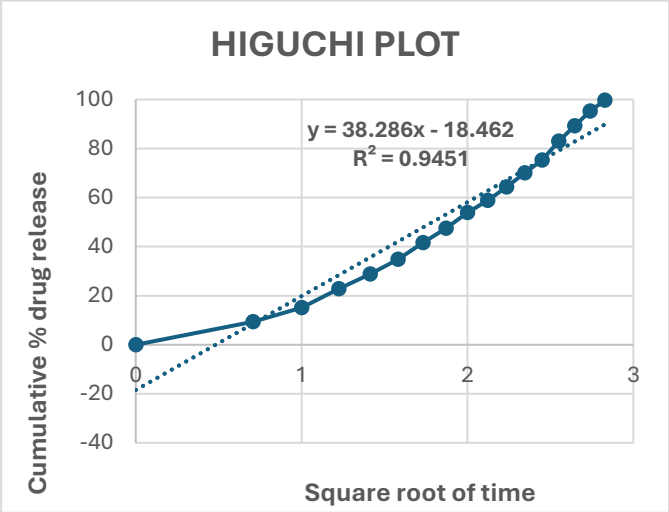

Figure 22: Higuchi plot for optimized formulation F3

Higuchi plot was made by plotting cumulative percentage % drug release against square root of time. The regression value was found to be 0.9451. This indicates that diffusion is one of the mechanisms of drug release

Conclusion

This study successfully developed and evaluated Aceclofenac-loaded bilayer mucoadhesive buccal patches designed to achieve prolonged and sustained drug delivery through the buccal mucosa. The prepared formulations were thoroughly characterized for thickness, weight uniformity, folding endurance, surface pH, swelling index, drug content uniformity, as well as in-vitro drug release and its corresponding release kinetics. FTIR analysis confirmed the compatibility of Aceclofenac with the selected polymers, showing no significant modifications in the drug's characteristic peaks. All developed formulations demonstrated satisfactory physical properties, appropriate thickness and weight uniformity, excellent flexibility, compatible surface pH, and uniform drug content. Additionally, the swelling behavior of the patches indicated proper hydration capacity, which is essential for facilitating drug release. Among the six formulations, F3 was identified as the optimal formulation based on its superior evaluation outcomes. F3 exhibited a thickness of 0.41 ± 0.03 mm, a weight of 0.27 ± 0.03 g, a folding endurance of 348 ± 3, a surface pH of 6.9 ± 0.10, a swelling index of 61%, and a drug content of 99.73 ± 0.06%. These parameters confirmed that F3 possessed favorable physical properties, flexibility, hydration behavior, and drug content uniformity. The in-vitro drug-release analysis showed that F3 provided a prolonged and sustained release profile, with cumulative drug release increasing gradually from 9.34% at 30 minutes to 99.67% at 8 hours, showing a more sustained release pattern than the other formulations. Kinetic analysis of F3 demonstrated a high correlation with the zero-order model (R^2 = 0.9983), while the Korsmeyer–Peppas model yielded an n-value of 0.8851, indicating a non-Fickian diffusion-controlled release mechanism. The Higuchi model (R^2 = 0.9451) further verified the contribution of diffusion to the drug release process. Consequently, F3 was established as the most optimized formulation developed in this study. These findings indicate that the bilayer mucoadhesive buccal patch is a promising system for the sustained delivery of Aceclofenac, which may help minimize dosing frequency.

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