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Formulation and Characterization of Apixabin Mucoadhesive Buccal Tablets

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Abstract
The present study was aimed at the formulation and evaluation of Apixaban mucoadhesive buccal tablets for prolonged drug release and improved bioavailability. Apixaban is an oral anticoagulant used in the prevention and treatment of thromboembolic disorders; however, its conventional administration may be associated with variable bioavailability and frequent dosing requirements. FTIR studies confirmed the absence of any significant interaction between Apixaban and the selected excipients. Among all formulations, F5 containing Carbopol 934 exhibited the highest drug content (88.70%), swelling index (109%), and cumulative drug release (97.25%). Drug release kinetic analysis revealed that the optimized formulation followed zero-order release kinetics with a high correlation coefficient (R^2 = 0.994), indicating controlled drug release behavior. Stability studies conducted for three months under accelerated conditions showed no significant changes in drug release characteristics or physical appearance of the optimized formulation. In conclusion, the developed Apixaban mucoadhesive buccal tablets demonstrated satisfactory physicochemical properties, prolonged drug release, and good stability. Formulation F5 was identified as the optimized formulation and may serve as a promising alternative for the buccal delivery of Apixaban, offering sustained therapeutic action, improved patient compliance, and enhanced treatment efficacy.

Keywords: Apixaban, Ethyl Cellulose, Carbopol 934, FTIR Studies, Direct compression method, In vitro drug release studies

Introduction

Oral drug delivery remains the most preferred route of drug administration because of its convenience, ease of use, patient compliance, and cost-effectiveness.[1] Mucoadhesive buccal drug delivery has emerged as a promising non-invasive approach for the systemic administration of drugs. The buccal mucosa is highly vascularized and provides a relatively permeable membrane through which drugs can be directly absorbed into the systemic circulation, thereby bypassing hepatic first-pass metabolism and gastrointestinal degradation.[2] Buccal dosage forms are easy to administer and remove, improve patient compliance, and provide controlled and prolonged drug release[3]. A mucoadhesive buccal tablet of apixaban offers several advantages over conventional oral tablets. Buccal administration allows the drug to be absorbed directly into the systemic circulation through the buccal mucosa, thereby avoiding hepatic first-pass metabolism and potentially improving bioavailability.[4] Apixaban is a direct oral anticoagulant (DOAC) that selectively inhibits activated Factor Xa, thereby preventing thrombin generation and thrombus formation. It is widely prescribed for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, prophylaxis of deep vein thrombosis (DVT) following orthopedic surgery, treatment of DVT and pulmonary embolism (PE), and prevention of recurrent venous thromboembolism.[5] Therefore, the present study aims to formulate and characterize Apixaban mucoadhesive buccal tablets using suitable bioadhesive polymers to improve systemic drug delivery. The developed formulation is expected to enhance bioavailability, prolong drug residence time on the buccal mucosa, provide controlled drug release, and offer an effective alternative to conventional oral therapy for long-term anticoagulant management.[6]

Materials

Brivaracetam was procured from Hetero Labs, Hyderabad. Carbopol 934 and Ethyl cellulose was obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

Methodology

Formulations Table

Table 1: Formulation of buccal tablets of Apixaban

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8
Apixaban	5	5	5	5	5	5	5	5
Ethyl cellulose	10	20	30	40	-	-	-	-
Carbopol 934	-	-	-		10	20	30	40
Lactose	79	69	59	49	79	69	59	49
Talc	2	2	2	2	2	2	2	2
Magnesium Stearate	3	3	3	3	3	3	3	3
Aspartame	1	1	1	1	1	1	1	1
Total weight	100	100	100	100	100	100	100	100

Preparation Method

Apixaban mucoadhesive buccal tablets were prepared by the direct compression method. The required quantities of Apixaban, polymer (Ethyl Cellulose or Carbopol 934), lactose, talc, magnesium stearate, and aspartame were accurately weighed according to the formulation compositions (F1–F8). The drug and excipients, except talc and magnesium stearate, were passed through a #60 sieve to obtain uniform particle size and then mixed thoroughly in a mortar for about 10–15 minutes to ensure uniform distribution of the drug throughout the powder blend. After obtaining a homogeneous mixture, talc and magnesium stearate were added as glidant and lubricant, respectively, and blended gently for an additional 3–5 minutes. Care was taken to avoid excessive mixing after the addition of lubricants. The blend equivalent to 100 mg was then compressed into tablets using a single-punch tablet compression machine fitted with flat-faced punches of suitable diameter. Compression force was adjusted to obtain tablets with adequate hardness and mechanical strength. The prepared tablets were collected and stored in airtight containers at room temperature until further evaluation. [7]

Evaluation Parameters[8,9,10,11,12]

Physical Appearance

The tablets are visually inspected for color, shape, surface texture, cracks, and any visible defects.

Weight Variation Test

Twenty tablets are individually weighed using an analytical balance, and the average weight is calculated. Individual tablet weights are compared with the average weight according to pharmacopeial limits.

Thickness

The thickness of ten tablets is measured using a digital Vernier caliper, and the average value is reported in millimeters.

Hardness

Tablet hardness is determined using a Monsanto or Pfizer hardness tester. The force required to break the tablet diametrically is recorded in kg/cm².

Friability

Friability is measured using a Roche friabilator. Twenty tablets are weighed and rotated at 25 rpm for 4 minutes (100 revolutions). The tablets are dedusted and reweighed.

Formula

$$\text{Friability (\%)} = W1/W1-W2\times100$$

Where:
W1 = Initial weight
W2 = Final weight

Drug Content Uniformity

Ten tablets are powdered, and an amount equivalent to 5 mg of Apixaban is dissolved in pH 6.8 phosphate buffer. The solution is filtered, suitably diluted, and analyzed using a UV-Visible spectrophotometer at the predetermined λmax. The percentage drug content is calculated.

Surface pH

The tablets are allowed to swell on agar plates prepared with pH 6.8 phosphate buffer for 2 hours. The surface pH is measured using a digital pH meter by bringing the electrode into contact with the tablet surface.

Swelling Index

The tablet is weighed initially (W_1) and placed on a hydrated agar plate. At predetermined intervals, the swollen tablet is reweighed (W_2).

$$\text{Swelling Index (\%)} = W1W2-W1\times100$$

***In Vitro* Drug Release Study**

The drug release study is carried out using the USP dissolution apparatus (Type II Paddle Apparatus) containing 900 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples are withdrawn at predetermined intervals, filtered, and analyzed spectrophotometrically. The cumulative percentage drug release is calculated.

Drug Release Kinetics

The release data are fitted into various kinetic models such as:

- Zero-order model
- First-order model
- Higuchi model
- Korsmeyer–Peppas model
- Hixson–Crowell model

to determine the mechanism of drug release from the buccal tablets.

Stability Studies

The optimized formulation is packed in suitable containers and stored at 40 ± 2°C / 75 ± 5% RH for 3 months according to ICH guidelines**.** Samples are periodically evaluated for physical appearance, drug content, mucoadhesive strength, and drug release characteristics.

Results and Discussion

Evaluation Parameters

Table 2: Evaluation parameters of Apixaban buccal tablets

F. No.	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	DrugContent (%)	Swelling index
F1	99	3.2	4.57	0.28	82.25	86.25
F2	100	3.5	4.60	0.27	83.16	78.10
F3	101	3.7	4.78	0.26	84.59	83.9
F4	99	3.1	4.52	0.23	80.20	101.5
F5	100	3.9	4.60	0.27	88.70	109
F6	100	3.4	4.32	0.25	87.43	105.7
F7	99	3.8	4.48	0.22	86.23	99.57
F8	100	3.7	4.53	0.20	84.19	98.13

Weight Variation

The weight variation of all formulations (F1–F8) was found to be in the range of 99–101 mg, indicating excellent uniformity of tablet weight. The minimal variation observed among the formulations suggests that the powder blend possessed good flow properties and compressibility during tablet compression. Uniform tablet weight is an important quality parameter because it ensures consistent drug distribution and dose accuracy. The results demonstrate that the direct compression method employed was suitable for preparing Apixaban mucoadhesive buccal tablets.

Thickness

The thickness of the tablets ranged from 3.1 to 3.9 mm. Formulation F5 showed the highest thickness (3.9 mm), whereas F4 exhibited the lowest thickness (3.1 mm). The slight differences in thickness may be attributed to variations in polymer concentration and compression behavior of the formulations. However, the observed values were within an acceptable range, indicating uniform die filling and consistent compression during tablet manufacture.

Hardness

The hardness values varied between 4.32 and 4.78 kg/cm². Formulation F3 exhibited the highest hardness (4.78 kg/cm²), while F6 showed the lowest hardness (4.32 kg/cm²). The hardness values indicate that all tablets possessed sufficient mechanical strength to withstand handling, packaging, and transportation without breakage. The increase in hardness in some formulations may be due to stronger interparticulate bonding produced by higher polymer content. Overall, the hardness values were suitable for buccal tablet formulations.

Friability

Friability values ranged from 0.20% to 0.28%, which are well below the pharmacopeial limit of 1%. Formulation F8 showed the lowest friability (0.20%), indicating maximum resistance to abrasion, while F1 exhibited the highest friability (0.28%). The low friability values confirm the good mechanical integrity and durability of the tablets. The results correlate well with the hardness values and demonstrate that all formulations possessed adequate physical strength.

Drug Content

The percentage drug content was found to range between 80.20% and 88.70%. Formulation F5 showed the highest drug content (88.70%), followed by F6 (87.43%) and F7 (86.23%). The lowest drug content was observed in F4 (80.20%). The relatively uniform drug content among formulations indicates satisfactory mixing and homogeneous distribution of Apixaban throughout the tablet matrix. Higher drug content values observed in formulations containing optimized polymer combinations may be due to improved drug entrapment and uniform dispersion within the polymeric network.

Dissolution Studies

All the 8 formulation of Apixaban buccal tablets were subjected to in vitro drug release studies these studies were carried out using dissolution apparatus. The dissolution medium consisted of 900 ml of Standard buffer pH 6.8 for period of time.

Table 3: Drug release studies of all formulations

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
1	18.26	17.58	16.73	16.89	18.59	17.43	18.77	17.45
2	28.79	27.85	28.49	27.43	29.55	25.79	26.37	25.49
3	34.79	35.20	34.56	35.18	37.82	35.12	34.43	35.48
4	45.82	44.89	47.81	48.47	49.83	42.10	46.37	47.63
5	58.55	57.48	58.58	59.82	60.24	59.86	58.82	56.31
6	66.87	67.52	66.58	68.53	72.36	73.55	70.12	72.21
7	77.12	78.50	76.38	77.89	82.36	83.50	81.25	82.25
8	93.56	94.56	95.85	96.33	97.25	94.27	96.83	95.18

Kinetic Modeling of Drug Release

All the 8 formulation of prepared Apixaban buccal tablets were subjected to in vitro release studies these studies were carried out using dissolution apparatus.

Zero Order Kinetics

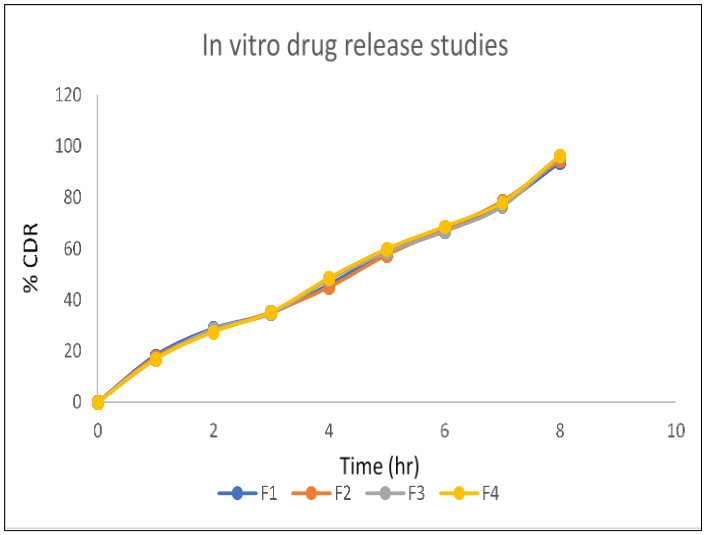


Fig 1: Dissolution Profile of F1to F4 formulations

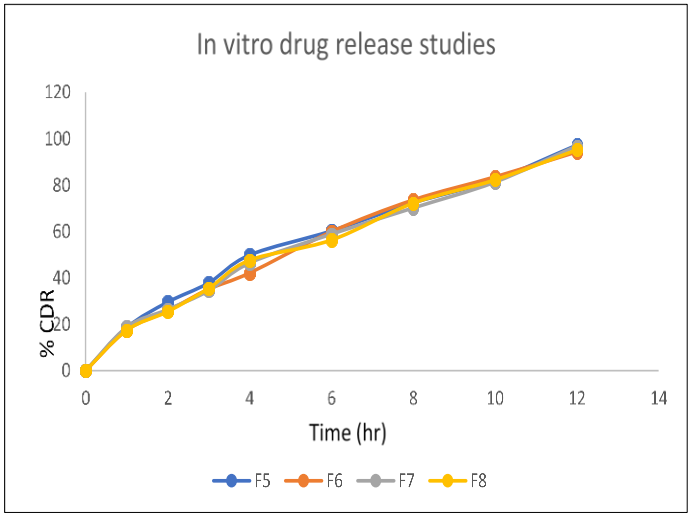


Fig 2: Dissolution Profile of F5to F8 formulations

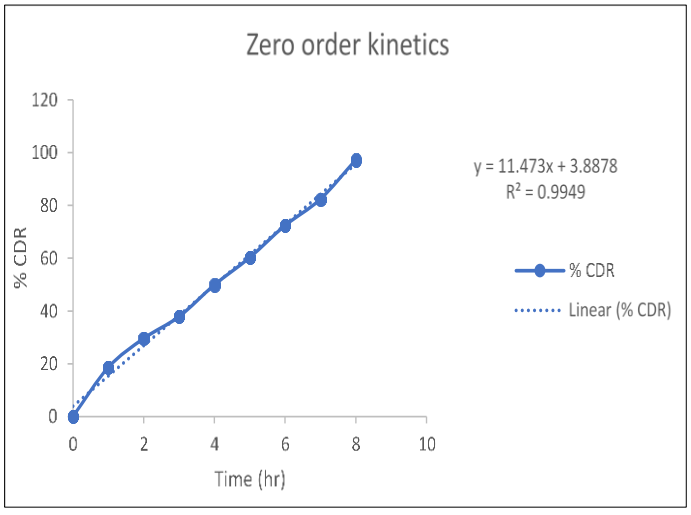


Fig 3: Zero order kinetics of optimized formulation

First Order Kinetics

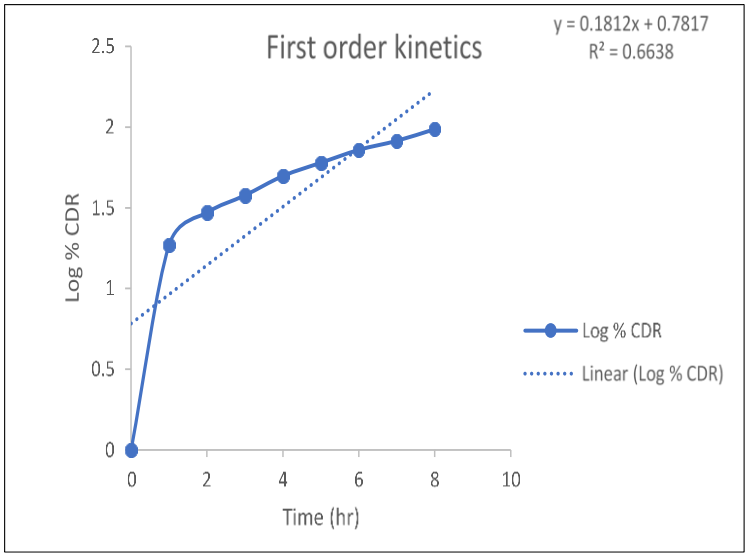


Fig 4: First order kinetics of optimized formulation

Higuchi Model

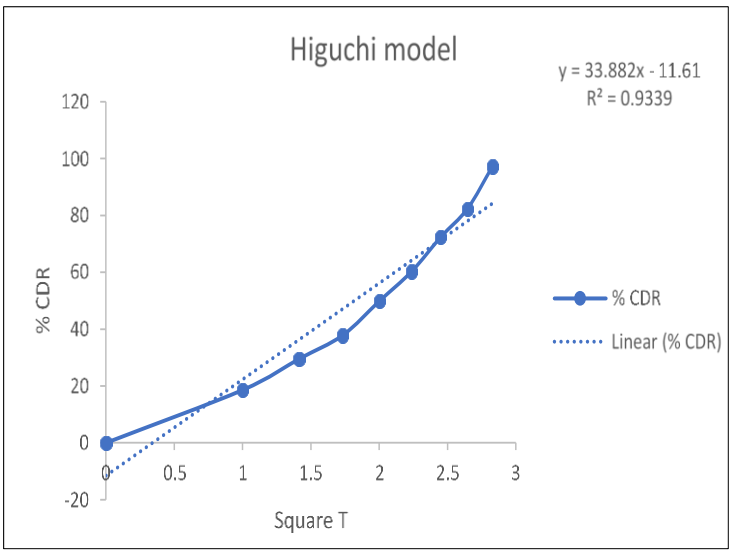


Fig 5: Higuchi model of optimized formulation

Korsmeyer Peppas

The values of in vitro release were attempted to fit into various mathematical models. Plots of zero order, first order, Higuchi matrix and Peppas.

Regression values are higher with Zero order release kinetics. Therefore, all the Apixaban buccal tablets follows Zero order release kinetics. The table indicates that r^2 values are higher for Higuchi's model compared for all the Apixaban buccal tablets formulation. Hence Apixaban release from all the dosage form followed dissolution rate controlled mechanism.

Stability Study

There was no significant change in physical and chemical properties of the buccal tablets of formulation F-5 after 90 days. Parameters quantified at various time intervals were shown.

Conclusion

The present investigation concluded that Apixaban can be successfully formulated into mucoadhesive buccal tablets by the direct compression method. All formulations showed satisfactory physicochemical properties, acceptable mechanical strength, and good mucoadhesive swelling behavior. FTIR studies confirmed compatibility between the drug and excipients, while pre-compression studies indicated excellent flow characteristics of the powder blends. Among all formulations, F5 containing Carbopol 934 was identified as the optimized formulation due to its superior drug content (88.70%), highest swelling index (109%), and maximum cumulative drug release (97.25% within 8 hours). The optimized formulation exhibited controlled drug release following zero-order kinetics and remained stable throughout the stability study period.

Therefore, formulation F5 can be considered a promising mucoadhesive buccal tablet formulation for the effective delivery of Apixaban, with the potential to improve patient compliance, prolong drug residence time, and provide sustained therapeutic action.

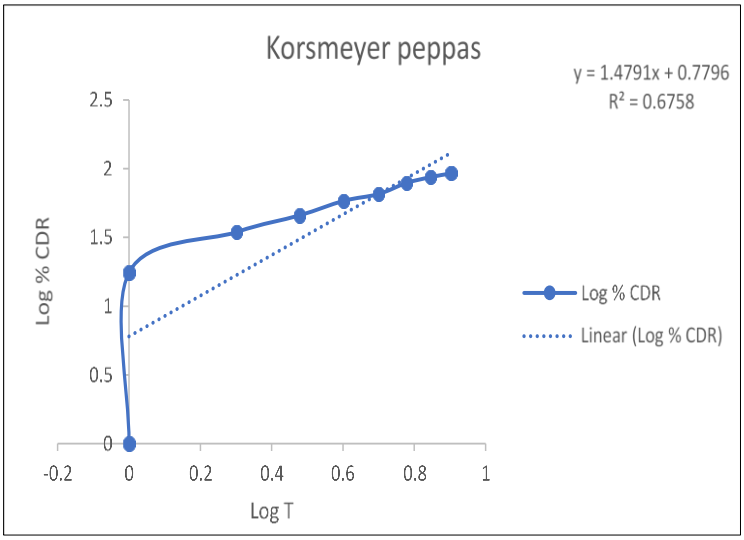


Fig 6: Korsmeyer peppas of optimized formulation

Table 4: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-5	25^{0}C/60%RH % Release	97.25	96.71	95.87	94.57	Not less than 85 %
F-5	30^{0}C/75% RH % Release	97.25	96.25	95.26	94.15	Not less than 85 %
F-5	40^{0}C/75% RH % Release	97.25	96.20	95.21	94.50	Not less than

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