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FORMULATION AND IN-VITRO ASSESSMENT OF CHLORZOXAZONE BUCCAL TABLETS FOR SUSTAINED DRUG RELEASE

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ABSTRACT

The present study was aimed at the formulation and evaluation of Chlorzoxazone-loaded buccal mucoadhesive tablets using natural and synthetic polymers to achieve controlled drug release and improved bioavailability. Preformulation studies, including physical characterization, melting point determination, solubility analysis, FTIR, loss on drying, and UV spectroscopic analysis, confirmed the purity, identity, and suitability of the drug for formulation development. Buccal tablets were prepared by the direct compression method using polymers such as hydroxypropyl methylcellulose (HPMC K4), Carbopol 934, and sodium alginate in varying proportions. The powder blends were evaluated for precompression parameters, which indicated fair to good flow properties suitable for compression. The prepared tablets were subjected to postcompression evaluation, including thickness, hardness, friability, weight variation, and drug content, all of which were found to be within acceptable pharmacopoeial limits. Swelling studies demonstrated good hydration capacity of the polymeric matrices, which is essential for mucoadhesion and controlled drug release. In vitro drug release studies revealed a sustained release profile, with formulation F5 showing the most desirable release characteristics. Drug release kinetics indicated that the release followed first-order kinetics with a significant contribution of diffusion, as confirmed by Higuchi and Korsmeyer–Peppas models. Overall, the results suggest that Chlorzoxazone buccal mucoadhesive tablets can be successfully formulated to provide controlled drug delivery, improved patient compliance, and enhanced therapeutic efficacy.

KEYWORDS: Chlorzoxazone; Buccal tablets; Mucoadhesive; Controlled release; Preformulation studies; Direct compression; Drug release kinetics; HPMC K4; Carbopol 934; Sodium alginate.

INTRODUCTION

The design and development of novel drug delivery systems have gained significant attention in recent years with the aim of improving therapeutic efficacy, minimizing side effects, and enhancing patient compliance. Among the various routes of drug administration, the oral route is the most widely accepted due to its convenience, non-invasiveness, and ease of administration. However, conventional oral dosage forms are often associated with several limitations, including extensive first-pass hepatic metabolism, enzymatic degradation in the gastrointestinal tract, and variable absorption profiles. These factors can lead to reduced bioavailability and inconsistent therapeutic outcomes, particularly for drugs that are highly metabolized in the liver.

To address these limitations, buccal drug delivery has emerged as an effective alternative route for systemic drug administration. The buccal mucosa, which lines the inner cheek, offers a highly vascularized surface that allows for rapid drug absorption directly into the systemic circulation. This route bypasses the hepatic first-pass effect and avoids degradation in the gastrointestinal environment, thereby enhancing bioavailability. Additionally, buccal drug delivery systems provide ease of administration and can be easily terminated in case of adverse drug reactions, offering better control over drug therapy.

Mucoadhesive drug delivery systems represent an important advancement in buccal drug delivery. These systems are designed to adhere to the mucosal surfaces, thereby increasing the residence time of the dosage form at the site of absorption. The prolonged contact between the drug and the mucosal surface facilitates improved drug absorption and sustained release of the active pharmaceutical ingredient. Mucoadhesion is primarily achieved through the use of polymers that can interact with the mucin layer via hydrogen bonding, electrostatic interactions, and physical entanglement. The effectiveness of a mucoadhesive system depends on factors such as polymer properties, degree of hydration, and environmental conditions within the oral cavity.

In recent years, there has been growing interest in the use of natural polymers in pharmaceutical formulations due to their numerous advantages over synthetic polymers. Natural polymers such as guar gum, xanthan gum, sodium alginate, and plant-derived mucilages are widely used owing to their biocompatibility, biodegradability, low toxicity, and economic feasibility. These polymers exhibit excellent swelling, gel-forming, and mucoadhesive properties, making them suitable for the development of buccal drug delivery systems. Furthermore, natural polymers are environmentally friendly and readily available, which supports sustainable pharmaceutical development.

Chlorzoxazone is a centrally acting skeletal muscle relaxant commonly prescribed for the relief of muscle spasms and associated pain in musculoskeletal conditions. It acts primarily at the level of the spinal cord and subcortical regions of the brain to inhibit multisynaptic reflex arcs involved in muscle spasm. Despite its therapeutic benefits, Chlorzoxazone is characterized by extensive hepatic metabolism, which significantly reduces its oral bioavailability. The drug also exhibits a relatively short biological half-life, necessitating frequent dosing to maintain effective plasma concentrations. These limitations make Chlorzoxazone an ideal candidate for the development of an alternative drug delivery system that can improve its pharmacokinetic profile.

Buccal mucoadhesive tablets offer a promising strategy for delivering Chlorzoxazone in a controlled and sustained manner. By adhering to the buccal mucosa, these tablets can provide prolonged drug release and improved absorption, thereby reducing dosing frequency and enhancing patient compliance. The incorporation of natural polymers in the formulation not only improves mucoadhesive strength but also contributes to controlled drug release through matrix formation and swelling behavior. The selection of appropriate polymers and optimization of formulation variables are crucial to achieving the desired therapeutic outcomes.

The present research focuses on the formulation and characterization of buccal mucoadhesive tablets of Chlorzoxazone using natural polymers. The study involves the preparation of tablets by suitable techniques such as direct compression, followed by comprehensive evaluation of their physicochemical properties, including hardness, friability, thickness, and drug content uniformity. In addition, specialized studies such as swelling index, surface pH, mucoadhesive strength, and in vitro drug release are carried out to assess the performance of the developed formulations. Compatibility studies using techniques such as FT-IR spectroscopy are also conducted to ensure the stability of the drug in the presence of selected polymers.

Overall, the development of buccal mucoadhesive tablets of Chlorzoxazone using natural polymers represents a novel and effective approach to enhance drug bioavailability, provide sustained drug release, and improve patient compliance. This research contributes to the advancement of mucoadhesive drug delivery systems and highlights the potential of natural polymers as promising excipients in modern pharmaceutical formulations.

Preformulation Studies

Preformulation studies constitute the initial step in the rational development of pharmaceutical dosage forms. These studies involve a systematic evaluation of the physicochemical properties of a drug substance, both alone and in combination with excipients, to ensure its suitability for formulation development.

Organoleptic Properties

Colour

A small quantity of the drug powder was placed on butter paper and observed under well-illuminated conditions to determine its colour.

Taste and Odour

A minimal quantity of the drug was evaluated for taste using the tongue, and odour was assessed by smelling the sample.

Melting Point Determination

The melting point was determined to assess the purity of the drug. A small amount of the drug powder was filled into a capillary tube and placed in a melting point apparatus. The temperature range from the onset of melting to complete melting was recorded.

Solubility Analysis

Solubility was qualitatively evaluated by adding small incremental quantities of solvent to a fixed amount of solute in a test tube (or vice versa). After each addition, the mixture was shaken vigorously and visually observed for dissolution.

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectroscopy was employed to identify the functional groups present in the drug molecule. The infrared spectrum was obtained using the KBr pellet

method. Characteristic peaks were analyzed to confirm the presence of specific functional groups. The spectrum was recorded using an FTIR spectrophotometer.

Loss on Drying (LOD)

Loss on drying was determined to estimate the amount of moisture and volatile components present in the drug sample. The analysis was carried out using an infrared moisture balance. Approximately 5 g of the sample was weighed and heated at 100–105°C for 15 minutes until a constant weight was obtained, and the percentage weight loss was recorded.

UV Spectroscopic Analysis

UV spectrophotometry was used to determine the absorption maxima (λmax) of the drug. The sample was exposed to UV radiation in the range of 200–400 nm, resulting in electronic transitions from the ground state to the excited state and producing a characteristic absorption spectrum.

For analysis, 10 mg of Chlorzoxazone was accurately weighed and dissolved in phosphate buffer (pH 6.8) in a 10 ml volumetric flask. From this solution, 1 ml was withdrawn and diluted to 100 ml with the same buffer to obtain a concentration of 10 µg/ml. The solution was scanned using a UV/Vis spectrophotometer (Labindia 3000+) against a reagent blank to determine λmax.

The λmax is a characteristic property of the compound and provides valuable qualitative and quantitative information in accordance with Beer–Lambert's law.

Quantitative Estimation of Drug

A standard calibration curve of Chlorzoxazone in phosphate buffer (pH 6.8) was prepared. The drug was accurately weighed, and the solvent system was purified and filtered prior to use. Buffers were freshly prepared, filtered, and their pH was verified using a pH meter.

Phosphate buffer (pH 6.8) was prepared by dissolving potassium dihydrogen phosphate and sodium hydroxide in distilled water and making up the volume to 1000 ml.

Calibration Curve of Chlorzoxazone

An accurately weighed quantity (10 mg) of Chlorzoxazone was dissolved in 10 ml of phosphate buffer (pH 6.8) to obtain a stock solution of 1 mg/ml (1000 µg/ml). From this, 1 ml was diluted to 10 ml to obtain a secondary stock solution of 100 µg/ml.

Aliquots ranging from 0.1 ml to 0.5 ml were withdrawn from the secondary stock solution and diluted to 10 ml to obtain concentrations of 10–50 µg/ml. These solutions were analyzed using a UV/Vis spectrophotometer against a blank, and a standard calibration curve was plotted.

Preparation of Chlorzoxazone-Loaded Buccal Mucoadhesive Tablets

Buccal mucoadhesive tablets of Chlorzoxazone were prepared using the direct compression method. Multiple formulations were developed using different ratios of polymers.

All ingredients, including the drug, polymers, and excipients, were passed through sieve No. 40 prior to formulation. The required quantities were accurately weighed and blended according to the formulation design. The prepared mixtures were then compressed into tablets and further evaluated.

Polymers used in the formulation included hydroxypropyl methylcellulose (HPMC K4), Carbopol 934, and sodium alginate.

Table 1: Various formulations of buccal mucoadhesive tablets of Chlorzoxazone using natural polymer.

Excipients (mg)	F1	F2	F3	F4	F5	F6
Chlorzoxazone	250	250	250	250	250	250
HPMC K-4	25	50	75	25	50	75
Carbopol	-	-	-	25	50	75
Na Alginate	25	25	25	25	25	25
Magnesium stearate	10	10	10	10	10	10
Talc	10	10	10	10	10	10
Lactose	180	155	130	155	105	55
Total Weight	500	500	500	500	500	500

Precompression Studies

The flow properties of the powder blend were evaluated prior to compression by determining bulk density, tapped density, compressibility index, and Hausner's ratio.

Bulk density and tapped density were determined by accurately weighing a known quantity of granules and transferring them into a 50 ml measuring cylinder. The initial volume was noted to calculate bulk density. The

cylinder was then tapped 100 times on a hard surface, and the final volume was recorded to determine tapped density.

The compressibility index of the powder blend was calculated using Carr's index, which provides an indication of flow properties. Based on the percentage compressibility values, the flow characteristics of the powder were categorized as excellent, good, fair to passable, poor, very poor, or very poor. The addition of glidants such as talc was considered to improve flow properties when required.

Hausner's ratio was determined as the ratio of tapped density to bulk density. A Hausner's ratio value less than 1.25 indicates good flow properties of the powder blend.

Postcompression Studies

The prepared tablets were evaluated for various physicochemical parameters to ensure quality, uniformity, and performance.

Tablet thickness and diameter were measured using a Vernier caliper. Five tablets from each batch were selected randomly, and the average values were calculated.

Drug content uniformity was determined by taking twenty tablets and crushing them into a fine powder. A quantity of powder equivalent to 10 mg of drug was transferred into a volumetric flask, dissolved in phosphate buffer (pH 6.8), and the volume was adjusted accordingly. The solution was mixed thoroughly, filtered through a 0.45 µm membrane filter, and suitably diluted. The absorbance was measured using a UV spectrophotometer at 234 nm against phosphate buffer as blank.

The hardness of the tablets was measured using a Monsanto hardness tester. Five tablets from each formulation were tested, and the average hardness was recorded.

Friability was evaluated using a friability tester. Ten tablets were weighed and rotated at 25 rpm for 4 minutes. After dedusting, the tablets were reweighed and the percentage weight loss was calculated.

Uniformity of weight was assessed by randomly selecting twenty tablets from each batch and weighing them individually. The average weight and standard deviation were calculated.

Swelling studies were carried out to determine the hydration behavior of the tablets. The study was performed using a USP type I dissolution apparatus at 50 rpm with phosphate buffer (pH 6.8) as the medium, maintained at 37 ± 0.5°C. The initial weight of the tablet was recorded prior to the study, and subsequent weights were measured at predetermined time intervals to calculate the swelling index.

In Vitro Dissolution Studies

In vitro drug release studies were performed using a USP type II (paddle type) dissolution apparatus. The dissolution medium consisted of 900 ml phosphate buffer (pH 6.8), maintained at 37 ± 0.5°C, with a rotation speed of 75 rpm. One tablet was placed in each dissolution vessel, and the study was carried out for a specified duration.

At predetermined time intervals, samples were withdrawn and replaced with an equal volume of fresh dissolution medium maintained at the same temperature. The samples were analyzed spectrophotometrically at 234 nm to determine drug release.

Drug Release Kinetic Studies

The in vitro release data were analyzed using various kinetic models to understand the mechanism of drug release.

The zero-order model describes systems where drug release occurs at a constant rate, independent of concentration, providing prolonged pharmacological action.

The first-order model describes drug release as a concentration-dependent process, where the release rate decreases over time.

The Higuchi model explains drug release as a diffusion-controlled process based on Fick's law, where the amount of drug released is proportional to the square root of time.

The Korsmeyer–Peppas model was applied to analyze the release mechanism from polymeric systems. The release exponent (n) was used to characterize the type of diffusion mechanism, such as Fickian diffusion, anomalous transport, or case-II transport. This model is widely used for evaluating drug release from controlled-release dosage forms.

RESULTS OF PREFORMULATION STUDIES

Physical Characterization of Chlorzoxazone

The physical characterization of Chlorzoxazone revealed that the drug appeared as a white to off-white, crystalline powder with a bitter taste and no detectable odour. These observed properties are in close agreement with the standard reported characteristics of the pure drug. The crystalline nature indicates a well-defined molecular arrangement, suggesting the purity of the sample and its suitability for formulation development. Overall, the organoleptic properties confirmed the identity and acceptable quality of the drug.

Melting Point Determination

The melting point of Chlorzoxazone was found to be in the range of 190–192°C, which closely corresponds to the standard reported range of 189–192°C. The sharp melting range observed indicates the absence of significant impurities and confirms the purity and authenticity of the drug sample.

Solubility Studies

The solubility profile of Chlorzoxazone demonstrated that the drug is slightly soluble in water and sparingly soluble in methanol, ethanol, and 0.1 N HCl. However, it exhibited good solubility in chloroform, 0.1 N NaOH, and phosphate buffer (pH 6.8). This behavior indicates that the drug possesses pH-dependent solubility, with enhanced solubility in alkaline and buffer media, which is advantageous for formulation and drug release considerations.

FTIR Analysis

The FTIR spectrum of Chlorzoxazone exhibited characteristic absorption peaks corresponding to its functional groups. A prominent peak around 3425 cm^{-1} was attributed to N–H stretching, while the peak near 1620 cm^{-1} indicated aromatic C=C stretching. The absorption band at approximately 1465 cm^{-1} corresponded to C–O stretching, and peaks around 873 cm^{-1} were associated with C–H bending and C–Cl stretching. These characteristic peaks confirm the structural integrity of the drug and indicate the absence of chemical degradation.

Loss on Drying

The percentage loss on drying of Chlorzoxazone was found to be 0.197 ± 0.002%, indicating a very low moisture content. This result confirms the stability of the drug and suggests minimal presence of volatile impurities.

UV Spectroscopic Analysis

UV spectroscopic analysis of Chlorzoxazone showed a distinct absorption maximum (λmax) at 282 nm in phosphate buffer (pH 6.8), which is characteristic of its conjugated system. The calibration curve constructed over the concentration range of 10–50 µg/ml exhibited a linear relationship between absorbance and concentration. This confirms the applicability of Beer–Lambert's law within the studied range and validates UV spectrophotometry as a reliable method for quantitative estimation of the drug.

Based on the overall preformulation studies, including physical characterization, melting point, solubility, FTIR, and UV analysis, the drug sample was confirmed to be pure and authentic, with no significant deviations observed. These findings indicate that Chlorzoxazone is suitable for further formulation into buccal mucoadhesive tablets.

Precompression Studies

The precompression parameters of all formulations demonstrated acceptable flow and compressibility characteristics. Bulk density and tapped density values indicated uniform packing ability across all batches, suggesting consistency in powder handling properties.

The compressibility index values ranged within the fair to passable category, indicating moderate flow properties suitable for direct compression with minimal modification. Hausner's ratio values further supported this observation, with most formulations exhibiting values indicative of fair to good flow behavior.

Among the formulations, F4 exhibited comparatively better flow properties, whereas F2 showed slightly higher compressibility, suggesting relatively lower flowability. Overall, none of the formulations demonstrated poor flow characteristics, confirming their suitability for tablet compression.

Postcompression Studies

The evaluation of postcompression parameters indicated that all formulations complied with pharmacopoeial specifications. The tablet thickness showed minimal variation, confirming uniform die filling during compression.

The hardness values indicated adequate mechanical strength, ensuring that the tablets could withstand handling and transportation without breakage. Friability values for all formulations were below 1%, demonstrating excellent resistance to abrasion.

Weight variation was within acceptable limits, reflecting uniformity in tablet weight and reproducibility of the manufacturing process. Drug content analysis revealed uniform distribution of the drug in all formulations, falling within the acceptable range of 90–110% of the labeled claim.

Among the formulations, F5 exhibited the highest drug content, while F3 demonstrated superior mechanical strength with the lowest friability. Overall, the results confirm the robustness and reproducibility of the prepared buccal tablet formulations.

Swelling Studies

The swelling behavior of the buccal tablets showed a progressive increase in swelling index with time for all formulations, indicating effective hydration of the polymer matrix. This swelling behavior is essential for mucoadhesion and controlled drug release.

Formulation F1 exhibited the lowest swelling index, while F5 demonstrated the highest swelling capacity, indicating superior hydration and expansion of the polymer network. Enhanced swelling contributes to increased surface area, improved drug diffusion, and better adhesion to the buccal mucosa.

The results suggest that polymer concentration and composition significantly influence the swelling behavior, with F5 emerging as the most promising formulation due to its superior hydration properties.

In Vitro Drug Release Studies

The in vitro drug release studies demonstrated a sustained release profile for all formulations. Initial rapid release was observed in some formulations, followed by a gradual and controlled release over time.

Formulations F1 and F2 showed faster drug release, whereas F5 exhibited a more controlled and sustained release pattern. The extended release observed in F5 can be attributed to its higher polymer content and swelling capacity, which regulate drug diffusion from the matrix.

Drug Release Kinetics

The release kinetics of the optimized formulation (F5) were analyzed using zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. The highest correlation coefficient (r^2) was observed for the first-order model, indicating that drug release is concentration-dependent.

The Higuchi model also showed a high correlation, suggesting that diffusion plays a significant role in the release mechanism. The Korsmeyer–Peppas model further confirmed that drug release follows a combined mechanism involving diffusion and polymer relaxation.

Overall, the results indicate that the drug release from the buccal tablets is governed primarily by diffusion-controlled mechanisms with contribution from polymer matrix dynamics.

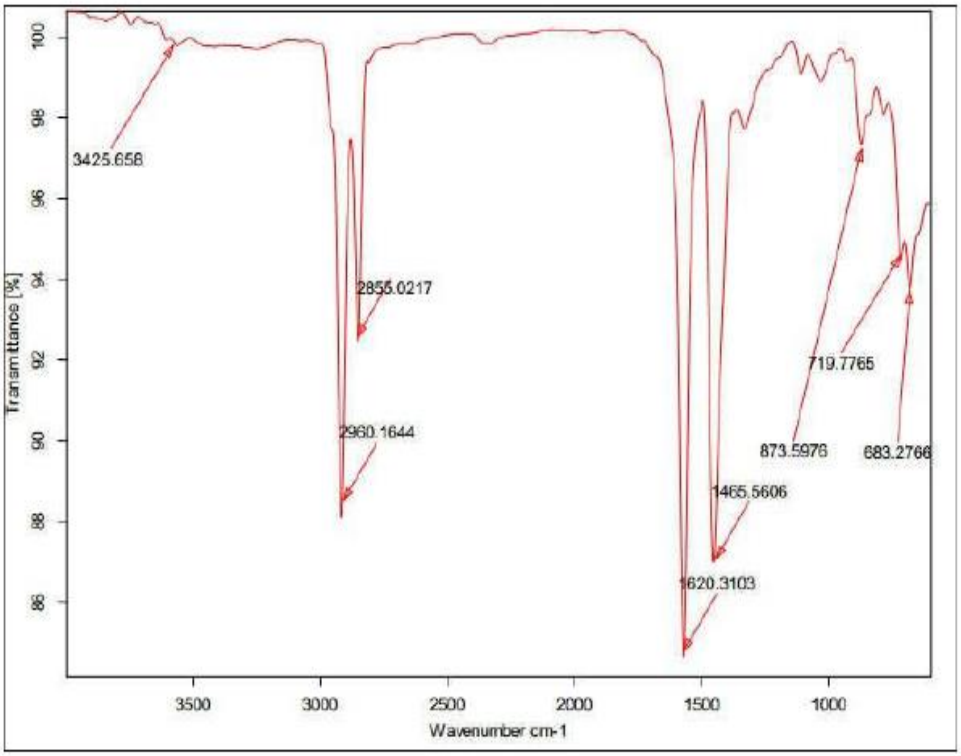

Figure 1: FT-IR spectra of standard Chlorzoxazone.

Table 2: Result of pre-compression properties of Chlorzoxazone.

F. Code	Bulk density (gm/ml)	Tapped density (gm/ml)	Compressibility index	Hausner ratio
F1	0.345	0.456	24.34	1.322
F2	0.336	0.465	27.74	1.384
F3	0.348	0.458	24.02	1.316
F4	0.365	0.478	23.64	1.310
F5	0.354	0.465	23.87	1.314
F6	0.362	0.479	24.43	1.323

Table 3: Results of post compression properties of Chlorzoxazone buccal tablets.

Formulation code	Thickness (mm)	Hardness (kg/cm2) n=3	Weight variation (mg) n=3	Friability (%) n=3	Drug content (%) n=3
F1	3.25±0.15	5.6±0.3	505±5	0.615±0.052	97.85±0.15
F2	3.33±0.32	5.8±0.5	510±7	0.632±0.036	98.85±0.32
F3	3.45±0.25	5.7±0.7	495±±6	0.558±0.045	97.65±0.65
F4	3.38±0.14	5.6±0.6	500±3	0.713±0.036	97.12±0.47
F5	3.35±0.22	5.4±0.6	503±4	0.658±0.023	99.45±0.55
F6	3.45±0.36	5.7±0.3	499±6	0.746±0.032	98.96±082

Table 4: Results of Swelling Index of Chlorzoxazone Buccal tablets.

Formulation Code	1 hr (%)	2 hrs. (%)	3 hrs. (%)	4 hrs. (%)
F1	23.65	45.85	65.25	74.56
F2	27.45	48.95	68.85	78.12
F3	29.15	50.65	71.32	82.25
F4	30.25	52.32	74.45	85.65
F5	35.85	60.12	80.25	102.65
F6	31.25	57.45	76.85	94.45

Table 5: *In-vitro* drug release study of buccal tablets.

Time	% Cumulative Drug Release					
(hr)	F1	F2	F3	F4	F5	F6
0.5	44.10	40.25	35.10	33.00	29.50	26.20
1	56.20	53.10	47.20	43.50	34.20	31.50
1.5	64.00	67.10	59.30	52.50	44.10	41.20
2	89.20	89.00	74.10	62.20	56.50	53.10
3	99.00	95.90	89.20	76.10	69.20	63.80
4	99.30	99.20	97.10	89.10	75.10	70.50
6	99.50	99.40	99.30	93.80	87.10	82.80
8	99.70	99.60	99.50	98.30	92.80	90.20
12	99.85	99.75	99.78	99.40	98.90	94.80

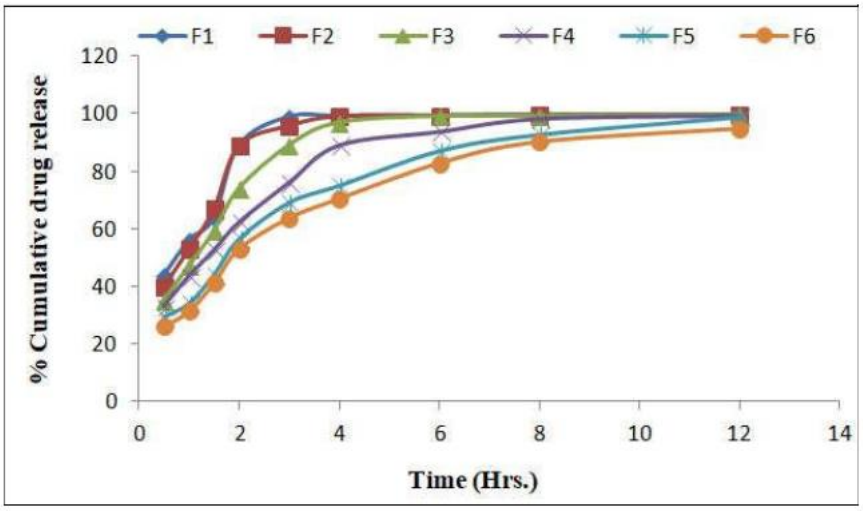

Figure 2: *In-vitro* drug release study of buccal tablets.

Table 6: *In-vitro* drug release data for optimized formulation F5.

Time (h)	Square Root of Time(h)$^{1/2}$	Log Time	Cumulative* % Drug Release	Log Cumulative % Drug Release	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
0.5	0.707	-0.301	29.5	1.470	70.5	1.848
1	1.000	0.000	34.2	1.534	65.8	1.818
1.5	1.225	0.176	44.1	1.644	55.9	1.747
2	1.414	0.301	56.5	1.752	43.5	1.638
3	1.732	0.477	69.2	1.840	30.8	1.489
4	2.000	0.602	75.1	1.876	24.9	1.396
6	2.449	0.778	87.1	1.940	12.9	1.111
8	2.828	0.903	92.8	1.968	7.2	0.857
12	3.464	1.079	98.9	1.995	1.1	0.041

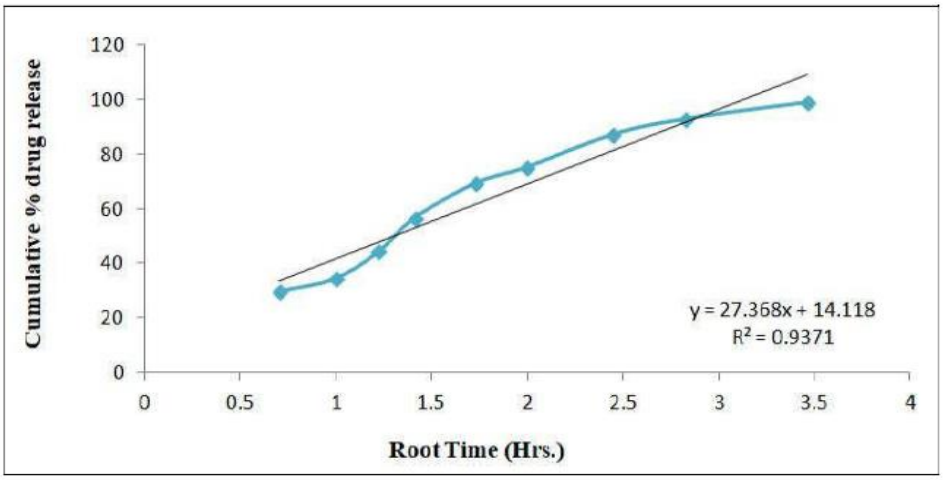

Figure 3: Higuchi release Kinetics (Cumulative % drug released Vs Root Time).

CONCLUSION

The present study successfully demonstrated the formulation and evaluation of Chlorzoxazone-loaded buccal mucoadhesive tablets using suitable polymers and direct compression technique. Preformulation studies confirmed that the drug possessed appropriate physicochemical properties, purity, and compatibility required for formulation development.

The evaluation of precompression parameters indicated that all powder blends exhibited acceptable flow and compressibility characteristics, ensuring uniform die filling during tablet compression. Postcompression studies confirmed that all formulations complied with pharmacopoeial standards in terms of hardness, friability, weight variation, thickness, and drug content, indicating good mechanical integrity and uniformity.

Swelling studies revealed that the formulations possessed adequate hydration capacity, which plays a crucial role in mucoadhesion and sustained drug release. Among all formulations, F5 exhibited superior swelling behavior and optimal drug release profile. In vitro dissolution studies demonstrated sustained drug release, and kinetic analysis indicated that drug release followed predominantly first-order kinetics with diffusion-controlled mechanisms.

Based on the overall evaluation, formulation F5 was identified as the optimized formulation due to its desirable physicochemical properties, controlled drug release behavior, and enhanced mucoadhesive potential. The study concludes that buccal delivery of Chlorzoxazone is a promising approach for improving therapeutic efficacy and patient compliance.

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