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International Journal of Advanced Research in Science, Communication and Technology
onal Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 5, Issue 1, July 2025 Impact Factor: 7.67

Formulation and Evaluation of Buccal Patches

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Abstract: *The present study focuses on the formulation and evaluation of buccal patches of Ctz Hcl designed to provide sustained release and improved patient compliance in allergic conditions. Buccal patches were prepared by solvent casting using hydroxypropyl methylcellulose (HPMC K4M) as the primary polymer, along with varying concentrations of plasticizers including polyethylene glycol 400, propylene glycol, and glycerin. The prepared patches were evaluated for their physicochemical properties, including thickness, uniformity of weight, folding endurance, surface pH, drug content, tensile strength, extensibility, swelling index, mucoadhesive strength, and in vitro drug release. Results revealed that increasing polymer concentration led to enhanced mechanical strength and folding endurance but reduced extensibility. All formulations maintained near-neutral surface pH and uniform drug content, indicating minimal risk of mucosal irritation and efficient drug entrapment. Among the batches, formulation F4 exhibited an optimal balance of tensile strength (3.5 N/mm²) and extensibility (22 mm), along with satisfactory folding endurance and drug release characteristics, making it a promising candidate for buccal delivery of Ctz Hcl. The study underscores the critical role of polymer and plasticizer optimization in achieving desirable mechanical and release profiles for effective buccal drug delivery systems.*

Keywords: Ctz Hcl; buccal patches; HPMC K4M; solvent casting; tensile strength; folding endurance; mucoadhesion; sustained release

I. INTRODUCTION

Ctz Hcl is a second-generation antihistamine widely used in the management of allergic conditions such as allergic rhinitis, urticaria, and other hypersensitivity reactions. Despite its efficacy, conventional oral administration of Ctz is often associated with challenges including gastrointestinal side effects, hepatic first-pass metabolism, and the need for frequent dosing to maintain therapeutic levels, which can affect patient compliance. Buccal drug delivery offers a promising alternative route that enables systemic absorption of drugs directly through the mucosal lining of the oral cavity, thereby bypassing hepatic first-pass metabolism and enhancing bioavailability. Additionally, the buccal route facilitates easy administration, rapid onset of action, and improved patient adherence, particularly important in managing chronic allergic conditions.[1,2]

Among various buccal dosage forms, buccal patches have gained considerable interest due to their ability to provide controlled release of the drug, intimate contact with the mucosal surface, and patient-friendly administration. Hydroxypropyl methylcellulose (HPMC K4M), a semi-synthetic polymer, has been extensively used in mucoadhesive formulations owing to its excellent film-forming properties, biocompatibility, and capacity to modulate drug release. Plasticizers such as polyethylene glycol (PEG 400), propylene glycol, and glycerin play a crucial role in improving the flexibility and mechanical properties of the polymeric films, making them suitable for buccal application.[3,4]

The development of an effective buccal patch requires careful consideration of multiple formulation parameters, including polymer type and concentration, choice and level of plasticizers, and compatibility of the drug with formulation components. Moreover, physicochemical characteristics such as thickness, folding endurance, tensile strength, mucoadhesive strength, and in vitro drug release profiles are critical in determining the overall performance, stability, and patient acceptability of the dosage form.[5-8]

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DOI: 10.48175/568

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The present study was undertaken to formulate and evaluate mucoadhesive buccal patches of Ctz Hcl employing HPMC K4M with varying concentrations of plasticizers to optimize mechanical strength, mucoadhesive properties, and sustained drug release. The formulation strategy was supported by preliminary studies including UV spectroscopic determination of λmax, construction of calibration curves in different pH buffers, and drug-polymer compatibility assessment using Fourier-transform infrared (FTIR) spectroscopy. Comprehensive physicochemical evaluations were performed to identify the most promising formulation capable of delivering Ctz Hcl effectively via the buccal route, thereby potentially enhancing patient compliance and therapeutic efficacy in allergic disorders.[9,10]

II. MATERIALS AND METHODS

Ctz Hcl was accurately weighed and dissolved in pH 6.8 phosphate buffer to prepare a 10 µg/mL solution, and the wavelength of maximum absorbance (λmax) was determined by scanning from 200–400 nm using a UV-visible spectrophotometer with pH 6.8 buffer as blank. For construction of standard calibration curves, phosphate buffer pH 6.8 was prepared by dissolving 0.2 M potassium dihydrogen phosphate and adjusting with 0.2 M sodium hydroxide, while 0.2 M potassium dihydrogen phosphate (136.09 g/L) and 0.2 M sodium hydroxide (8 g/L) stock solutions were prepared in distilled water. A stock solution of Ctz Hcl was obtained by dissolving 50 mg in 50 mL water; from this, successive dilutions were performed to achieve concentrations of 2, 4, 6, 8, and 10 µg/mL for pH 6.8, and 1–10 µg/mL for both pH 6.8 and pH 7.4 buffers, with absorbance measured at 249 nm against respective blanks. Standard curves were plotted with concentration on the X-axis versus absorbance on the Y-axis. For drug-polymer compatibility studies, Fourier transform infrared (FTIR) spectroscopy was performed on pure drug and physical mixtures with polymers to detect possible interactions, using the KBr pellet method on a Perkin Elmer FTIR spectrometer. Following compatibility confirmation, formulation development involved selection and optimization of polymer and plasticizer types and concentrations based on literature and preliminary trials. This led to the fabrication of the dosage form through direct compression or solvent casting, ensuring uniformity and integrity of drug-polymer systems for subsequent evaluation.[11,12]

Preparation of Patches:

Buccal patches of Ctz Hcl were prepared by the solvent casting method, where accurately weighed HPMC K4M was dispersed in double distilled water with continuous stirring to form a semisolid solution, left overnight for swelling and air bubble removal. The drug was then incorporated with specified plasticizer under stirring, and the resulting thick solution was cast onto 8 cm diameter Petri plates, dried at 50 °C for 60 min in a microwave oven followed by 24 hrs in a vacuum oven at 37 °C. The dried films were carefully removed, kept in a desiccator overnight, and cut into circular patches of 2.6 cm diameter containing 10 mg of drug using a die-cutter.[13,14]

INGREDIENTS	Ctz HCl (mg)	HPMC (mg)	PEG 400 (mg)	Propylene glycol (mg)	Glycerin (mg)	Distilled water
F1	10	400	-	-	50	q.s
F2	10	400	-	-	100	q.s
F3	10	400	-	-	200	q.s
F4	10	500	-	-	62.5	q.s
F5	10	500	-	-	125	q.s
F6	10	500	-	-	250	q.s
F7	10	400	200	-	-	q.s
F8	10	400	-	200	-	q.s
F9	10	500	250	-	-	q.s

The prepared buccal patches were evaluated for thickness using a dial gauge, uniformity of weight on an electronic balance, and drug content by dissolving in pH 6.8 phosphate buffer and measuring absorbance at 249 nm. Folding endurance was determined by repeatedly folding a patch strip until it broke, while surface pH was measured after

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swelling the patch in water for 10 min using pH paper. Swelling index was calculated by comparing weights before and after immersion in water for 30 min. Tensile strength and mucoadhesive strength were assessed using a TA.XT plus texture analyzer with appropriate probes and goat buccal mucosa. In vitro drug release was performed in USP type VI dissolution apparatus at 37 °C using pH 6.8 phosphate buffer, sampling at intervals up to 3 hrs, with drug content analyzed spectrophotometrically at 249 nm.[15-20]

III. RESULTS AND DISCUSSION

The physicochemical evaluation of the formulated buccal patches revealed distinct trends across various formulations. The weight of the patches ranged from 54.09 ± 0.6 mg (F1) to 86.78 ± 0.5 mg (F6), reflecting the increasing polymer load, with a corresponding gradual rise in thickness from 77.67 µm in F1 to 131.33 µm in F9. This pattern of increasing weight and thickness indicated successful incorporation of higher polymer content, critical for modulating drug release and mechanical integrity. Folding endurance values, indicative of the patches' flexibility and mechanical resilience, varied notably across batches. F1 exhibited the lowest folding endurance (562 ± 2 folds), whereas F6 demonstrated the highest (738 ± 3 folds), suggesting that higher polymer content imparted greater structural robustness, likely due to enhanced matrix integrity and elasticity. All patches maintained a uniform surface pH near neutrality (5.5–6), ensuring minimal risk of mucosal irritation upon application.

Drug content across formulations remained satisfactorily uniform, ranging between 9.88 ± 0.21 mg (F6) and 10.12 ± 0.04 mg (F2), confirming efficient drug entrapment and minimal loss during fabrication. However, tensile strength and extensibility exhibited inverse trends. Formulations with higher polymer content, such as F6 and F9, displayed reduced tensile strength (2.6 N/mm²) and lower extensibility (12–15 mm), indicating stiffer but less stretchable films, possibly due to increased polymer-polymer interactions restricting chain mobility. In contrast, F4 achieved the highest tensile strength (3.5 N/mm²) coupled with good extensibility (22 mm), suggesting an optimal balance between flexibility and strength, which is essential for maintaining patch integrity during application and adherence to the buccal mucosa.

Overall, the results highlighted that while increasing polymer concentration improved mechanical strength and folding endurance, it modestly compromised extensibility and tensile adaptability. This trade-off underscores the importance of carefully optimizing polymer concentration to achieve a desirable balance between mechanical durability and flexibility for comfortable and effective buccal application. These findings provide valuable insights into selecting an appropriate formulation, with F4 emerging as a particularly promising batch due to its favorable combination of tensile strength, extensibility, folding endurance, and consistent drug content, which are critical parameters for ensuring patient acceptability and therapeutic efficacy.

Table 2: Physicochemical evaluations

Formulation	Weight	Thickness (µm)	Folding endurance	pH	Drug content(mg)	Tensile Strength (N/mm²)	Extensibility (mm)
F1	54.09 + 0.6	77.67 ± 0.33	562 ± 2	6	10.08 + 0.09	3.2	18
F2	61.38 ± 0.3	91.33 ± 0.89	614 ± 2	6	10.12 ± 0.04	3.1	16
F3	71.94 + 0.7	107.67 0.57	731 ± 3	6	10.08 0.08	3.0	15
F4	69.57 + 0.8	93.33 + 0.64	628 ± 1	6	10.05 + 0.07	3.5	22
F5	74.38 + 0.2	115.67 + 0.97	689 ± 2	6	10.06 + 0.08	2.8	14
F6	86.78 ± 0.5	129.00 + 0.85	738 ± 3	6	9.88 + 0.21	2.6	12
F7	72.26 ± 0.6	111.67 + 0.69	725 ± 3	5.5	10.02 + 0.04	2.5	11
F8	70.94 ± 0.7	114.00 + 0.83	732±3	5.5	10.02 + 0.03	3.0	17
F9	84.78 ± 0.5	131.33 + 0.76	726±3	5.5	10.07 + 0.06	2.6	15

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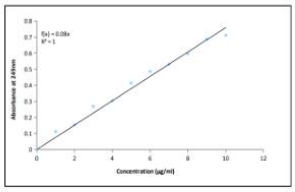
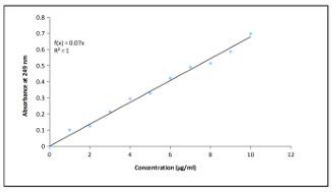
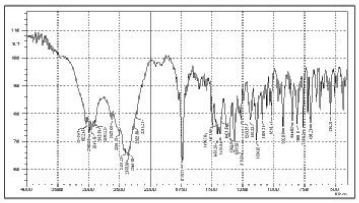


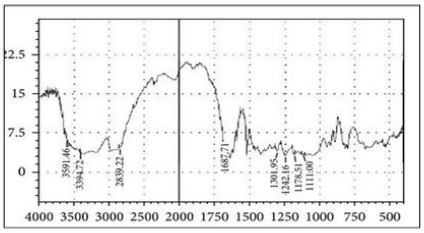
Calibration Curve fo pH 6.8



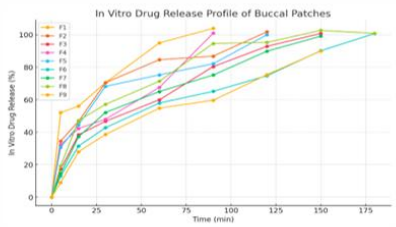
Calibration Curve fo pH 7.4



Pure drug FTIR



FTIR final formulation



In Vitro Drug Release study

IV. CONCLUSION

The research successfully demonstrated the formulation and evaluation of Ctz Hcl buccal patches using HPMC K4M and selected plasticizers to achieve sustained release with desirable mechanical and mucoadhesive properties. The findings revealed that increasing the polymer content significantly improved mechanical integrity and folding endurance, though at the cost of reduced extensibility, highlighting the need for careful optimization. All formulations maintained a neutral surface pH, minimizing the risk of mucosal irritation, and displayed uniform drug content, ensuring consistent dosing. Formulation F4 stood out by achieving an optimal balance between tensile strength and extensibility, along with satisfactory folding endurance and sustained release characteristics, making it an excellent candidate for buccal administration of Ctz Hcl. This study provides a robust foundation for future development of buccal drug delivery systems aimed at improving patient compliance and therapeutic outcomes in the management of allergic conditions.

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ISSN: 2581-9429 Volume 5, Issue 1, July 2025 Impact Factor: 7.67

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