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Development and Evaluation Buccal Tablets

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Abstract: *The present study was undertaken to develop and evaluate buccal tablets of Cinnarizine intended for prolonged mucosal residence and controlled drug release. Tablets were prepared by wet granulation using varying concentrations of t gum and sodium carboxymethyl cellulose as bioadhesive polymers, along with microcrystalline cellulose, talc, saccharin, magnesium stearate, and eucalyptus oil. The prepared formulations were evaluated for weight variation, hardness, thickness, friability, drug content uniformity, ex vivo mucoadhesion time, surface pH, swelling index, bioadhesive strength, in vitro drug release, and stability under ICH guidelines. All formulations exhibited uniform weight, acceptable hardness (5.54–6.43 kg), low friability (<1%), and consistent drug content (99.82–102.82%). Mucoadhesion time varied notably among formulations, with F6 showing the highest (460 ± 2.5 min), indicating prolonged mucosal contact. In vitro release studies revealed that formulations with higher polymer content, particularly F6, provided sustained release profiles over 3 hours, correlating with extended mucoadhesion. The optimized batch F6 demonstrated an ideal balance of mechanical strength, prolonged adhesion, controlled release, and surface pH close to salivary pH, making it a promising candidate for buccal delivery of Cinnarizine to enhance bioavailability and patient compliance.*

Keywords: Cinnarizine; buccal tablets; mucoadhesion; t gum; sodium carboxymethyl cellulose; controlled release; bioadhesive strength; in vitro release; stability studies

I. INTRODUCTION

Buccal drug delivery has emerged as a promising alternative to conventional oral administration, especially for drugs that undergo extensive first-pass metabolism or have limited gastrointestinal stability. The buccal mucosa offers an attractive route due to its rich vascularization, relatively low enzymatic activity compared to the gastrointestinal tract, and ease of administration and removal, which can enhance patient compliance. By adhering to the mucosal surface, buccal formulations can prolong the residence time of the drug at the absorption site, enabling sustained release and improved bioavailability.[1,2]

Cinnarizine, a piperazine derivative widely used for the management of vestibular disorders such as vertigo and for prophylaxis of motion sickness, is characterized by extensive first-pass hepatic metabolism, resulting in reduced systemic availability when administered orally. This pharmacokinetic limitation highlights the need for alternative delivery strategies to enhance its therapeutic efficacy.[3,4]

Buccal tablets present a suitable platform for the delivery of Cinnarizine, allowing direct absorption into the systemic circulation while bypassing hepatic metabolism. The incorporation of bioadhesive polymers, such as t gum and sodium carboxymethyl cellulose (NaCMC), plays a critical role in ensuring prolonged contact with the mucosal surface, facilitating sustained drug release and improved therapeutic outcomes. T gum, a natural polysaccharide, offers excellent mucoadhesive and swelling properties, whereas NaCMC, a semi-synthetic polymer, enhances hydration and gel formation, collectively contributing to improved residence time and controlled drug release.[5,6]

This study was designed to develop and evaluate buccal tablets of Cinnarizine using varying proportions of t gum and NaCMC to optimize mechanical strength, mucoadhesion, drug release, and overall patient acceptability. The tablets were subjected to comprehensive physicochemical, mechanical, and in vitro evaluations, including mucoadhesive strength and stability under accelerated conditions, to identify an optimized formulation capable of providing sustained

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delivery of Cinnarizine through the buccal route. This approach aims to overcome the limitations associated with oral delivery, potentially leading to enhanced therapeutic efficiency and better patient adherence.

II. MATERIALS AND METHODS

The physicochemical properties of Cinnarizine were systematically evaluated to guide formulation development. Solubility studies were performed by dissolving Cinnarizine in various solvents such as water, ethanol, and propylene glycol to identify suitable solubilizing media. The pH of Cinnarizine solutions was measured using a calibrated pH meter, while its pKa was determined by potentiometric titration. The partition coefficient between n-octanol and water was assessed by the standard shake-flask method to understand its lipophilicity. The melting point was determined using a calibrated melting point apparatus. Stability studies were conducted by storing Cinnarizine under varying temperature and humidity conditions to observe any physical or chemical changes over time. Compatibility studies were carried out employing differential scanning calorimetry (DSC), where approximately 2 mg samples of Cinnarizine and its excipients were sealed in aluminum pans and heated from 25 °C to 450 °C at 10 °C/min under a nitrogen flow of 25 mL/min to detect any interactions affecting thermal behavior. Additionally, Fourier transform infrared spectroscopy (FTIR) was utilized for structural compatibility analysis. Infrared spectra were recorded using the KBr pellet method, first running the baseline with dried KBr, followed by spectra of pure Cinnarizine and its physical mixtures with various excipients, ensuring that absorption maxima matched in position and relative intensity to confirm absence of significant interactions, thus ensuring formulation stability.[7,8]

Preparation of Tablets

Cinnarizine tablets were prepared by first accurately weighing all ingredients, which were then passed through a #40 mesh sieve to ensure uniform particle size and remove any impurities. The powders were thoroughly mixed in a bowl for about 10 minutes. Distilled water was added gradually with continuous trituration in a mortar and pestle until a damp mass formed, taking care not to overwet. This wet mass was evenly spread on a tray and dried in a hot air oven until adequate moisture reduction was achieved. The dried mass was passed through a sieve to break agglomerates and form uniform granules, which were then further dried at 50–60 °C to attain a final moisture content of 1–3%. The dried granules were blended with magnesium stearate for 1–2 minutes to ensure proper lubrication. Finally, the lubricated granules were compressed into tablets using an 8 mm punch on a tablet compression machine to produce uniform tablets of the desired size.[9]

Batch	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cinnarizine	4 mg	4 mg	4 mg	4 mg	4 mg	4 mg	4 mg	4 mg	4 mg
T gum	45 mg	55 mg	65 mg	40 mg	80 mg	-	30 mg	50 mg	45mg
Sodium carboxymethyle cellulose	35 mg	25 mg	15 mg	40 mg	-	80 mg	50 mg	30 mg	35mg
Magnesium sterate	2.0 mg	2.0 mg	2.0 mg	2.0 mg	2.0 mg	2.0 mg	2.0 mg	2.0 mg	2.0 mg
Talc	2.5 mg	2.5 mg	2.5 mg	2.5 mg	2.5 mg	2.5 mg	2.5 mg	2.5 mg	2.5 mg
Microcrystalline cellulose	60 mg	60 mg	60 mg	60 mg	60 mg	60 mg	60 mg	60 mg	60 mg
Saccharine	1.0 mg	1.0 mg	1.0 mg	1.0 mg	1.0 mg	1.0 mg	1.0 mg	1.0 mg	1.0 mg
Eucalyptus oil	0.5 ml	0.5 ml	0.5ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
Final weight	150 mg	150 mg	150 mg	150 mg	150 mg	150 mg	150 mg	150 mg	150 mg

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The prepared Cinnarizine buccal tablets were thoroughly evaluated for multiple quality parameters to ensure their performance and patient acceptability. Tablet thickness and diameter were measured using a vernier caliper, while hardness was assessed with a Monsanto tester, ensuring mechanical integrity. Friability was checked using a friabilator to confirm resistance to abrasion, with values kept below 1%. Disintegration studies were conducted in water at 37 ± 0.5 °C to ensure the tablets met buccal limits, while content uniformity was verified via UV spectrophotometry after dissolving powdered samples. Weight variation tests confirmed consistency among tablets. Moisture absorption was evaluated using agar gel to simulate humid conditions, and surface pH studies confirmed compatibility with salivary pH. Swelling index studies on agar gel assessed hydration behavior critical for mucoadhesion. Bioadhesive strength was measured using a modified balance setup against porcine buccal mucosa to determine retention capability. In vitro drug release studies employed a USP-II apparatus to monitor release over 3 hours. Finally, stability studies under ICH conditions over 90 days ensured that physical properties, mucoadhesive strength, and release profiles remained consistent, confirming the formulation's robustness and suitability for buccal delivery.[10-13]

III. RESULTS AND DISCUSSION

The preliminary evaluation of buccal tablets demonstrated consistent weight across all batches (154.2 ± 2.40 mg in F1 to 155.8 ± 2.12 mg in F4 and F8), indicating excellent control over formulation and compression essential for dose precision. Tablet hardness ranged from 5.54 ± 0.18 kg (F1) to 6.43 ± 0.15 kg (F5), with F5 displaying superior mechanical integrity, while F4 and F7 offered a balanced hardness suitable for durability and rapid mucosal interaction. Thickness remained within tight bounds (1.98 ± 0.02 mm to 2.14 ± 0.023 mm), ensuring uniformity. Drug content was consistently high (99.82 ± 1.82% in F6 to 102.82 ± 2.21% in F3), confirming effective blending and minimal segregation. Friability values were well below 1% (0.17 ± 0.05% in F5 to 0.38 ± 0.06% in F8), indicating excellent mechanical robustness, with F5's combination of highest hardness and lowest friability suggesting optimal strength to withstand handling.

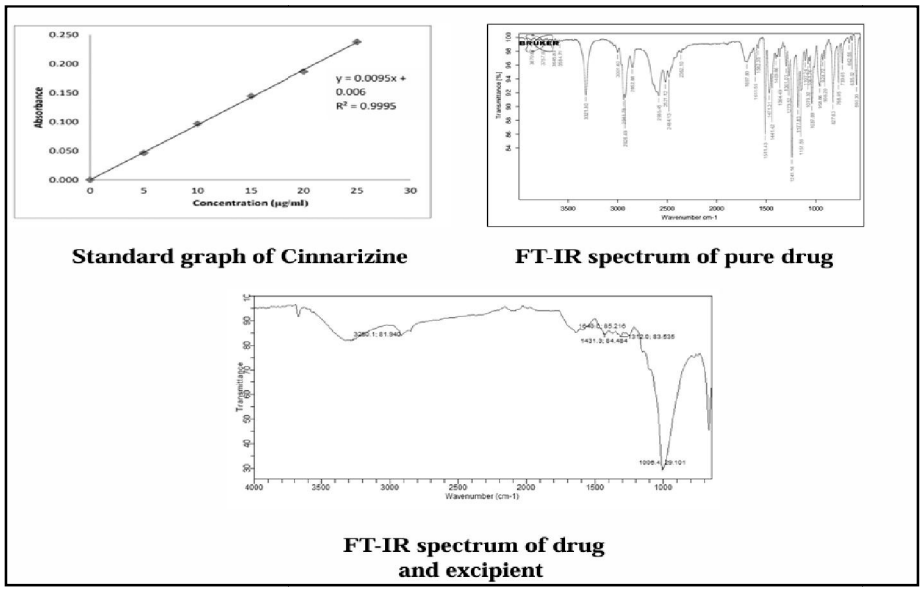

Fig 1: preliminary evaluation of drug

Mucoadhesion time, crucial for prolonged residence and absorption, varied notably, with F6 showing the highest (460 ± 2.5 min) due to likely optimal polymer hydration and mucin interaction, while F1 had the shortest (220 ± 1.2 min). Surface pH remained within the safe physiological range (6.0–7.0), reducing irritation risks, with F4 and F7 nearest neutrality. In vitro drug release profiles revealed that formulations with greater mucoadhesion and swelling, like F5 and especially F6, achieved more sustained release—reducing burst effects and supporting steady plasma levels—whereas F1 showed a faster release, correlating with its lower mucoadhesion. Integrating these findings,

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F5 and F6 emerged as standout formulations by balancing high mechanical strength, minimal friability, extended mucoadhesion, uniform drug content, and a near-neutral pH, with F6 particularly promising for ensuring sustained delivery, enhanced therapeutic coverage, and improved patient compliance.

Table 2: Evaluation of tablet

Sr No	Weight Variation	Hardness	Thickness	Drug Content	Friability	Friability (%)	Ex Mucoadhesion Time (Min)	Surface pH
F1	154.2±2.40	5.54±0.18	1.98±0.02	101.82±0.92	0.34±0.10	0.34±0.10	220±1.2	6 ±0.015
F2	155.5±1.82	5.82±0.25	2.02±0.05	101.63±1.23	0.32±0.15	0.32±0.15	300±1.4	6±0.017
F3	155.4±1.43	5.78±0.17	2.04±0.03	102.82±2.21	0.28±0.05	0.28±0.05	440±2.3	6±0.015
F4	155.8±2.12	6.21±0.18	2.14±0.023	101.84±1.28	0.19±0.12	0.19±0.12	240±1.5	7±0.030
F5	155.4±1.54	6.43±0.15	2.03±0.024	101.92±1.92	0.17±0.05	0.17±0.05	420±2.6	6±0.015
F6	155.3±1.92	5.98±0.15	2.01±0.023	99.82±1.82	0.30±0.15	0.30±0.15	460±2.5	6±0.015
F7	155.5±2.43	5.88±1.17	2.12±0.02	102.04±0.28	0.18±0.25	0.18±0.25	427±2.3	7±0.015
F8	155.8±0.40	5.72±0.17	2.08±0.06	100.84±1.22	0.38±0.06	0.38±0.06	430±2.2	6±0.025
F9	155.2±1.23	5.63±2.17	2.11±0.03	101.04±1.4	0.27±0.15	0.27±0.15	428±2.7	6±0.035

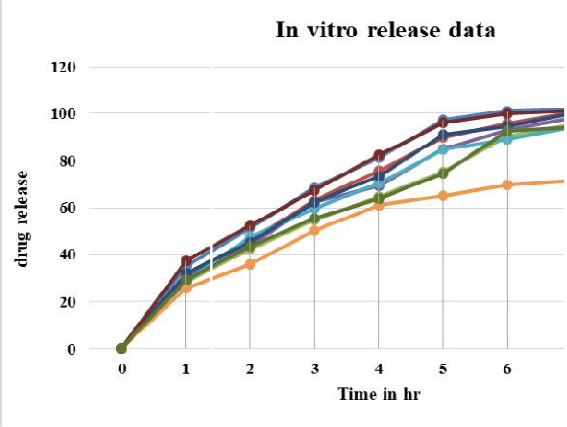

Fig 2: In vitro drug release

IV. CONCLUSION

The study successfully formulated and evaluated buccal tablets of Cinnarizine utilizing t gum and sodium carboxymethyl cellulose as key bioadhesive polymers. All batches exhibited satisfactory physicochemical and mechanical properties, with excellent uniformity and stability. Among them, formulation F6 emerged as the most promising, exhibiting the highest mucoadhesive residence time, sustained in vitro drug release, low friability, and surface pH compatible with the buccal cavity. These findings suggest that F6 offers significant potential for buccal

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administration of Cinnarizine, providing improved bioavailability and patient compliance by enabling prolonged contact time and controlled drug delivery. Future in vivo studies are warranted to confirm these benefits and establish the formulation's clinical applicability.

REFERENCES

[1]. Ahuja, A., Khar, R. K., & Ali, J. (1997). Mucoadhesive drug delivery systems. *Drug Development and Industrial Pharmacy, 23*(5), 489–515.

[2]. Andrade, M. A., et al. (2019). Development and evaluation of mucoadhesive buccal films for local delivery of clobetasol propionate. *Journal of Drug Delivery Science and Technology, 54*, 101296.

[3]. Andrews, G. P., Laverty, T. P., & Jones, D. S. (2009). Mucoadhesive polymeric platforms for controlled drug delivery. *European Journal of Pharmaceutics and Biopharmaceutics, 71*(3), 505–518.

[4]. Balasubramaniam, A., & Sankar, V. (2004). Formulation and evaluation of buccoadhesive tablets of nifedipine. *Indian Drugs, 41*(12), 716–720.

[5]. Bhalodia, R., & Shelat, P. (2011). Buccal drug delivery system: A review. *International Journal of Pharmaceutical Sciences and Research, 2*(6), 1323–1335.

[6]. Gandhi, R. B., & Robinson, J. R. (1994). Oral cavity as a site for bioadhesive drug delivery. *Advanced Drug Delivery Reviews, 13*(1-2), 43–74.

[7]. Jani, G. K., Shah, D. P., Prajapati, V. D., & Jain, V. C. (2009). Gums and mucilages: Versatile excipients for pharmaceutical formulations. *Asian Journal of Pharmaceutical Sciences, 4*(5), 309–323.

[8]. Kumar, S., & Gupta, S. K. (2012). Formulation and evaluation of buccal tablets of metoprolol tartrate. *International Journal of Pharmacy and Pharmaceutical Sciences, 4*(3), 210–214.

[9]. Patel, V. F., Liu, F., & Brown, M. B. (2011). Advances in oral transmucosal drug delivery. *Journal of Controlled Release, 153*(2), 106–116.

[10]. Perioli, L., Ambrogi, V., Rubini, G., Giovagnoli, S., Ricci, M., & Rossi, C. (2004). Development of mucoadhesive patches for buccal administration of ibuprofen. *Journal of Controlled Release, 99*(1), 73–82.

[11]. Rathod, S., & Patel, V. (2015). A review on mucoadhesive buccal drug delivery system. *International Journal of Pharmaceutical and Chemical Sciences, 4*(1), 1–14.

[12]. Reddy, M. S., Kumar, R. V., & Mutalik, S. (2011). Buccal delivery of propranolol hydrochloride using natural polymer based mucoadhesive tablets. *Indian Journal of Pharmaceutical Sciences, 73*(5), 535–540.

[13]. Shaikh, R., Raj Singh, T. R., Garland, M. J., Woolfson, A. D., & Donnelly, R. F. (2011). Mucoadhesive drug delivery systems. *Journal of Pharmacy and Bioallied Sciences, 3*(1), 89–100