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Buccal drug delivery systems: A gateway to non-invasive therapeutic

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Abstract
Mucoadhesive drug delivery systems have emerged as an innovative approach in pharmaceutical science that leverages the ability of polymers to adhere to mucosal surfaces. These systems offer targeted drug delivery to specific areas of the body, making them suitable for systemic and local applications. The efficacy of mucoadhesive drug delivery is influenced by factors such as the physicochemical properties of the drug and physiological characteristics of the target site. The oral cavity, particularly the buccal and sublingual regions, serves as an ideal target for mucoadhesive drug delivery because of its high blood supply, which facilitates rapid drug absorption and bypasses hepatic first-pass metabolism. Polymers with hydrophilic groups enhance bio-adhesion, making them crucial components in mucoadhesive formulations. However, the amount of drug that can be administered via the buccal route is limited to 25 mg. Mucoadhesive buccal drug delivery systems offer several advantages, including a rapid onset of action, improved patient compliance, reduced enzymatic degradation, and enhanced bioavailability. These systems are suitable for drugs that are unstable in the alkaline environment of intestine, and can be administered to unconscious patients. However, there are also limitations, such as the need to avoid eating and drinking during administration. Mucoadhesive buccal drug delivery systems represent a promising approach for targeted drug delivery and improved therapeutic outcomes.

Keywords: Mucoadhesive drug delivery, buccal drug delivery, local drug delivery, bioavailability, buccal mucosa, polymer

Introduction
The term 'muco-adhesion' specifically refers to the attachment of polymers to the mucin layer of mucosal tissue [1]. This drug delivery method is particularly effective for systemic and local effects, making it a versatile option for various therapeutic applications [2].
The efficacy of mucoadhesive drug delivery systems is influenced by several factors, including the physicochemical properties of the drug and physiological characteristics of the target site. For example, drugs with pka values between 2 and 10 and partition coefficients ranging from 40 to 2000 are most effectively absorbed at the buccal site [3]. This makes the buccal mucosa an ideal target for drugs, such as papain's, barbiturates, trypsin, and steroids [4]. The high blood supply in the mucosal lining tissue facilitates rapid drug absorption, with the absorbed drug transferring to the facial or lingual vein and then circulating through the jugular vein, effectively by-passing hepatic first-pass metabolism [5]. The presence of hydrophilic groups, such as -COOH and -OH, in high-molecular-weight polymers enhances bio-adhesion, making these polymers crucial components in mucoadhesive formulations [6]. However, it is important to note that the amount of drug that can be administered through the buccal route is limited to ≤ 25 mg [7, 8]. The oral cavity, with a surface area of approximately 170 cm², provides an adequate absorption site, while the daily saliva production of 0.5-2L aids in drug dilution and distribution [9].

Mucoadhesive drug-delivery system through oral-cavity [10]
- **Buccal drug delivery:** Drug administration through the mucosal membrane lining the floor of the oral cavity.
- **Sublingual drug delivery:** Drug administered through the mucosal lining of the cheeks in the oral cavity.

- **Local drug delivery:** except sublingual and buccal drug delivery system drug delivery into the oral cavity.

Advantages of muco-adhesive buccal drug delivery system

- Rapid onset of action compared with the oral route [11].
- Buccal patches can be removed if requested to be discounted [12].
- Improve patient compliance [13].
- Avoiding hepatic first-pass metabolism by reducing enzymatic reactions.
- Self-medication therapy is highly flexible in terms of size, shape, and physical state.
- Buccal drug delivery systems are suitable for drugs that are unstable in the alkaline environment of intestinal pH when administered orally [14, 15].
- Enhancement of bioavailability by reducing the dose frequency and side effects.
- Easy to administer and terminate is painless.
- It can be administered to unconscious patients [16].
- High blood supply and rich absorption owing to the passive system are not required for the activation of ATP molecules.
- Drugs are easily dissolved due to salivary secretion.
- Patients of pediatric and old age may experience vomiting and nausea.
- Thus, a reduction in cost may be achieved.
- Buccal drug delivery system are targeted drug delivery systems.
- Compared with the skin, the buccal mucous is highly perfused with blood vessels, leading to greater permeability.
- This saves time because it requires a very short treatment period [17-20].

Disadvantages of mucoadhesive buccal drug delivery system

- Eating drinking should be avoided
- A drug at a high dose cannot be administered via the buccal route.
- Daily dose is limited.
- Some drugs have a bitter taste and odors cannot be administered.
- Drugs unsuitable for buccal administration cannot be administered through the oral cavity.
- Only a small dose of the drug is administered by passive diffusion through the buccal drug delivery system.
- The total surface area of the oral cavity for absorption was 170 cm [2, 21-24].

2. Method of the preparation of mucoadhsive buccal patches

2.1 Solvent Casting Method: Initially, all ingredients were accurately weighed, and then all ingredients were added gradually to the solvent until a clear solution was observed. Two drops of plasticizer were added by continuous stirring in a magnetic stirrer. The above solution was then poured into a petri dish with uniform distribution by cleaning the petri dish with Glycerin. Kept drying for 24hr by using inverted funnel cover for uniform drying of buccal patch. After solvent evaporation thin film is formed that is desired for cutting the patches into desired size and shape [25].

2.2 Direct Milling: The buccal patches were prepared using this method. In this method, solvents are not used without the use of solvent drugs, and ingredients are mixed using the direct milling method. The resultant material was rolled onto the release liner until the desired thickness was achieved. Subsequently, the backing membrane was laminated onto the sheet of the coated release liner to form a laminate and finally cut into the desired size and shape [26].

2.3 Hot Melt Extrusion: In this method, all ingredients are taken into solid dosage form, and all ingredients are melted using an extruder that contains a heater and melts the solid dosage into the film. Subsequently, the films were cooled, and the desired shape was cut and packaged [27].

2.4 Solid Dispersion Extrusion: First, the more active ingredients are dispersed into the suspended carrier in the solid state owing to the presence of amorphous hydrophilic polymers. Drug dissolved into a suitable solvent and added a suitable polymer without removing the liquid solvent below 70 °C using dies, and the solid dispersion was converted into a film [28].

2.5 Semisolid Casting Method: Some polymers are water soluble and some are water insoluble in that the water-soluble film forming polymers are dissolved into the acid insoluble polymer in the ratio of 1:4 respective. Resultant mass in that add the suitable plasticizer then cast into films or in ribbon form by using heat-controlled drums. The diameter was limited 0.015-0.05 inches [29].

3. Mechanism of Mucoadhesion

The mechanism of muco-adhesion explained by the two steps

- Contact stage
- Consolidation stage

The mucoadhesive material and mucous membrane come in contact with each other and wet the mucous present in the mucous membrane. In the consolidation stage, the mucoadhesive material is attached to the mucous membrane by different forces of attraction. In the adhesion stage, the mucoadhesive material forms a strong bond with the mucous membrane through various intermolecular forces. These forces may include hydrogen bonding, van der Waals interactions, and electrostatic attractions. The strength and duration of adhesion depend on factors such as the chemical composition of the mucoadhesive material, the properties of the mucous membrane, and environmental conditions [30].

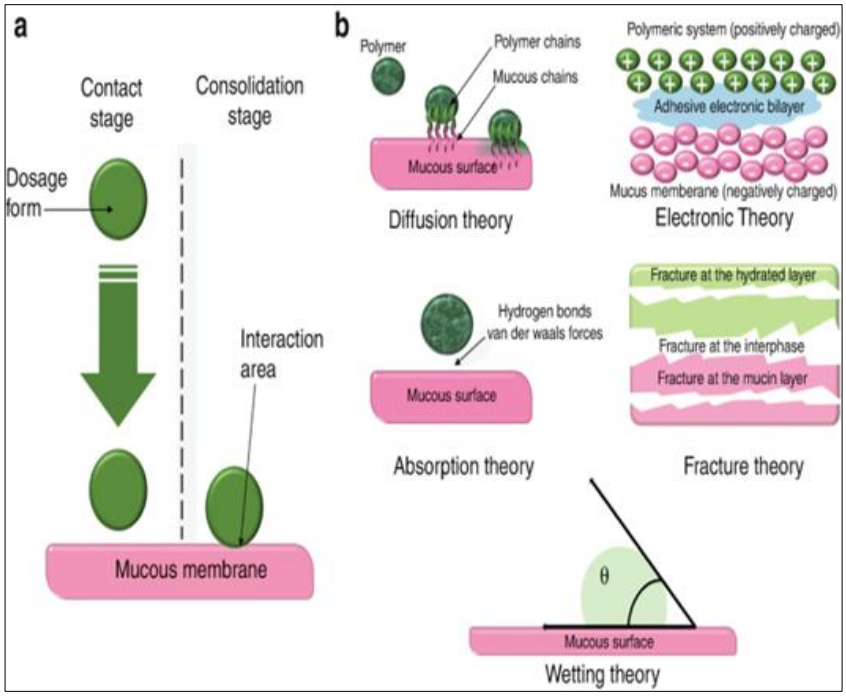

Fig 1: Mechanism of muco-adhesion

3.1 Mucoadhesive mechanism explained by six theories

3.1.1 Electronic Theory

- **Mechanism:** This mechanism is based on electrons between mucosal membrane and Muco-adhesive polymer.
- **Explanation:** Transfer of electron between mucoadhesive material and mucus membrane creates an electrical double layer at interface, leading to attractive forces [31].

3.1.2 Adsorption Theory

- **Mechanism:** This theory explains the ability of the adhesive to spread throughout the mucus membrane.
- **Explanation:** Good wettability increases surface contact, enhancing adhesion.
- **Key word:** Surface energy-more spread better to adhere [32].

3.1.3 Wetting Theory

- **Mechanism:** Emphasizes the role of hydration in swelling the polymer.
- **Explanation:** Swelling helps the polymer spread and entangle with mucus.
- **Key point:** Too much or too little water can reduce adhesion [33].

3.1.4 Diffusion Theory

- **Mechanism:** Based on the interpenetration of polymer chains of the mucoadhesive and mucin (the glycoprotein in mucus).
- **Explanation:** The more similar the structure (e.g., molecular weight, flexibility), the better the intermingling. Ideal penetration depth: 0.2–0.5 µm for effective adhesion [34].

3.1.5 Mechanical Theory

- **Mechanism:** Suggests that adhesion arises due to the interlocking of adhesive material into rough surfaces or pores of the mucosal membrane.
- **Keyword:** Interlocking [35-37].

3.1.6 Fracture Theory

- **Mechanism:** Focused on the Focuses on the force needed to separate the adhesive from the mucus.
- **Explanation:** Relates muco-adhesion to mechanical strength.
- **Key word:** Adhesive strength [38].

4. Composition of buccal dosage forms

4.1 Active pharmaceutical ingredient: To achieve the desired therapeutic effect, the active pharmaceutical ingredient (API) plays a crucial role in enhancing the efficacy by successfully crossing the mucosal membrane. The buccal mucosa, a potential site for drug administration, offers several advantages for drug delivery. However, the effectiveness of buccal drug delivery systems, such as patches, is significantly influenced by various API properties. These properties include molecular weight, chemical functionality, and melting point, which collectively impact the ability of the drug to penetrate the mucosal barrier and exert its therapeutic action [39, 40].

Mucoadhesive formulations are particularly important in buccal drug delivery systems as they help maintain prolonged contact between the drug and mucosal surface. This extended contact time allows increased drug absorption and improved bioavailability [41]. The mucoadhesive properties of the formulation combined with the specific characteristics of the API determine the overall performance of the buccal patch. Factors such as API solubility, lipophilicity, and ionization state at the buccal pH also contribute to its ability to permeate the mucosal membrane and reach the systemic circulation. Therefore, a thorough understanding of both API properties and mucoadhesive formulations is essential for developing effective buccal drug delivery systems that can enhance therapeutic outcomes [42-44].

4.2 Mucoadhesive Polymers: The development of mucoadhesive dosage forms begins with the careful selection and characterization of the appropriate mucoadhesive polymers for the formulation. This critical step involves evaluating the physical and chemical properties of the polymer, such as its molecular weight, charge, hydrophilicity, and functional groups, which influence its ability to interact with mucus [45]. Researchers must also consider factors, such as biocompatibility, biodegradability, and stability in the target environment. By optimizing these parameters, formulators can create drug delivery systems that effectively adhere to mucosal surfaces, enhance drug absorption, and improve therapeutic outcomes in various medical conditions, such as synthetic or natural polymers that interact with the mucus layer covering the mucosal epithelial surface. These polymers adhere to the main molecules constituting a major part of mucus, allowing for prolonged contact and improved drug delivery at specific sites. The mucus layer, primarily composed of glycoproteins called mucins, serves as a protective barrier for various epithelial surfaces throughout the body, including the gastrointestinal tract, the respiratory system, and reproductive organs [46, 47].

4.3 Backing Membrane: The backing membrane plays an important role in the attachment of bio-adhesive devices to mucus membranes. The material used as the backing membrane should be inset and Impermeable to drug penetration enhancers. Commonly used materials in backing membranes include Carbopol, magnesium separation, HPMC, HPC, CMC, and polycarbophil [48].

4.4 Penetration Enhancers: The substances facilitate drug penetration through the buccal mucosa are known as penetration enhancers [49].

4.5 Plasticizers: This increases the flexibility of the buccal patches of polymers. The choice of plasticizer is based on the ability of the plasticizer material to solvate the polymers and polymer-polymer interactions. Plasticizers include castor oil, glycerol, propylene glycol, PEG200, and PEG 400 [50-53].

5. Mucoadhesive buccal dosage forms

5.1 Buccal Tablets: The buccal tablets are similar to the other tablets, but have adhesive properties, such as buccal tablets kept between the cheeks and gums. The tablets adhere to the buccal cavity in a slow order and dissolve or soften owing to the presence of saliva in the oral cavity [54-59]. The drug is completely released into the systemic circulation by avoiding the hepatic metabolism, and patients can easily drink and eat because it is a painless therapy. They are mucoadhesive pillars, and the tablets before administration to the buccal mucosa should be moistened. If a two-layer buccal tablet contained coca butter within the center, containing sodium glycocholate and insulin [60]. The adhesive matrix layer is composed of hydroxypropyl cellulose. In tablet formulations, penetration enhancers and enzyme inhibitors improve the bioavailability [61-64].

5.2 Buccal Patch and Films: Buccal patches are dosage forms that deliver drugs to the buccal mucosa. These patches have the baking layer that prevent the drug loss into the oral cavity. The buccal patches are two types matrix and reservoir type [65, 66]. Films are a two-direction drug-release formulation loaded with drug. The development of multilayered films for controlled release of quickly dissolving films for rapid drug release, which are manufactured by the solvent casting method and hot-melt extrusion method [67-69]. The films are flexible and comfortable to administer to the buccal mucosa, which can adhere to the buccal mucosa for up to 12 hours [70-72].

5.3 Gel and Ointment: These are semi-solid dosage forms used for muco-adhesive drug delivery. Patient compliance was low compared to the other mucoadhesive solid dosage forms for buccal drugs, good for local effects, and showed prolonged residence time on the surface. Some polymers, such as sodium carboxymethylcellulose, Carbopol, Xanthan gum, and hyaluronic acid, increase the viscosity and change the liquid phase to the semi-solid phase [73].

5.4 Hydrogels: This enhances the retention time and can be easily applied to the surface.

- Development of thermosensitive
- Development of the PH sensitive.
- Used as antifungal and anti-inflammatory by topical application [74-76].

5.5 Sprays: Insulin is a large molecule that can easily pass through the oral mucosa when sprayed. Spray is used to relieve angina pectoris by sublingual application and provide quick action, by-passing hepatic metabolism [77-79].

5.6 Buccal Chewing Gums: Buccal chewing is a form of spinal gum used for both local and systemic effects. They are used for the treatment of oral cavities such as dental caries. Nicotine is also used as a local disinfectant and analgesic in motion sickness [80-83].

5.7 Wafers: Wafers are the novel drug delivery system when kept in the mouth they get dissolved by saliva without drinking water. Also known as fast dissolving wafers. These are classified as fallow

- Flash release wafers
- Muco-adhesive melt-away wafers
- Mucoadhesive sustained-release wafers [84-89].

6. Evaluation of buccal patch

6.1 Surface PH: To determine the surface pH of the mucoadhesive material, the pH-sensitive probe was in contact with the mucoadhesive material, either dipped into the buffer solution, and then the pH of the material or buccal patches was measured. Optimum range for buccal patch PH 5.5-7.0 [90-92].

6.2 Thickness Measurement: Electronic micrometer and digital vernier calipers are used to measure the thickness of buccal patches, five different point such as the exactly center point and other four corner point of the patch [93, 94].

6.3 Weight Uniformity: A Shimadzu sensitivity balance was used for weighing as the weight variation of buccal patches by choosing randomly, cutting into the same square meter from each batch, and then the verification was calculated [95].

6.4 Folding Endurance: The buccal patch is repeatedly folded until it breaks or folds up to 300 times, which is considered a good buccal patch [96, 97].

6.5 Swelling Index: Buccal patches are individually (W1) weighed and then placed into a 6.8 buffer solution in a petri dish. After some time, the patches were removed from the buffer solution, and using filter paper, the upper moisture content was removed and again weighed (W2) to determine the swelling index (SI) [98, 99].

SI={W2-W1} \W1

6.6 Drug Content Uniformity: Three patches without a backing membrane were placed in 20:80 ethanol and saliva; the total volume was 100 ml and the solution was continuously stirred for 12 h. Drug concentration was determined using the filtrate. A standard calibration curve was used to enhance the uniform dispersion of the drug content [100, 101].

6.7 Thermal Analysis Study: Thermal analysis of buccal patches was performed using differential scanning calorimetry (DSCs) [102].

6.8 Morphological Characterization: To investigate the morphological characteristics of buccal patches using scanning electron microscopy [103].

6.9 Percentage Moisture Absorption: An initial, accurate weight buccal patch was placed in a desiccator. The desiccator should be containing 100 ml solution of Aluminum chloride in it. Relative humidity should be 76% and 86%. After three days, the patch was removed and weighed [104].

6.10 Percentage moisture loss: Percentage moisture loss can be defined as the weight loss of substances subdued to drying, comparable to percentage the initial weight. This evaluation test accessing the moisture content of the pharmaceutical patches or products. Excess moisture reduced shelf life, and leading to the microbial growth, degradation. The buccal patch was weighed, placed into a desiccator containing anhydrous calcium chloride, and weighed again for three days.
Moisture absorbance and moisture loss will be calculated by using SI% = (Initial weight -final weight /Initial weight) 100

6.10.1 Factor Influencing Moisture Loss

- **Formulation composition**: Due to presence of excipients can influence the moisture content. For example: magnesium nitrate hexahydrate can interact with moisture and influence on drug stability.
- **Processing condition:** Drying process and lyophilization impact the moisture content in drug product.
- **Packaging material:** Glass or foil are used for the packaging of the pharmaceutical products or substances [105].

6.11 Drug Content Estimation
Drug content estimation was performed to determine the drug, and the buccal patch was placed in 100 ml of 6.8 phosphate buffer solution with continuous stirring. After 4 h, 1ml of the solution was withdrawn and dilute with 6.8 phosphate buffer to 10 ml. The solution was filtered, and the drug content was determined using a UV spectrometer [106].

6.12 Percentage Elongation Break: Maximum deformation of patch can under go before tearing and get apart and it can be calculated as %Elongation at break = (L2-L1/L1)100

Were,
L1= Initial patch length
L2 = increase length at break

Accurately weigh buccal patches and place in 100ml of aluminum chloride contained desiccator (Relative humidity 76%-86%). After 74hr patches removed from desiccator and weighed [107].

6.13 Mucoadhesive Strength: Mucoadhesive strength of buccal patches refers to the force required to detach a patch from the buccal mucosa, and it is a critical parameter in evaluating the effectiveness of mucoadhesive drug delivery systems. Strong muco-adhesion ensures that the patch remains in place for prolonged periods, enhancing drug absorption and therapeutic efficacy. This strength is commonly measured using methods such as a texture analyzer or tensile testing, where the detachment force is recorded in grams or Newtons. Other techniques like the modified balance method or shear strength tests may also be employed to assess the adhesive performance. The strength typically varies depending on the type and concentration of the polymer used. For example, buccal patches formulated with polymers such as Carbopol, HPMC, or chitosan generally exhibit mucoadhesive strengths in the range of 15 to 50 grams. Several factors influence this property, including polymer hydrophilicity, degree of swelling, contact time with mucosa, patch thickness, and environmental pH. Highly hydrophilic polymers tend to swell and interpenetrate the mucus layer more effectively, resulting in stronger adhesion [108].

6.14 *In vitro* drug release study
6.14.1 Franz Diffusion Cell: The Franz diffusion cell is a commonly employed technique for evaluating the *in vitro* release of drugs from buccal patches. This system consists of two compartments: the donor compartment, which holds the buccal patch, and the receptor compartment, typically filled with a medium such as phosphate-buffered saline (PBS) or simulated saliva to imitate the conditions of the oral cavity. The drug in the donor compartment diffuses through the patch and, depending on the setup, may pass through a membrane or directly across the buccal mucosa into the receptor solution [109].

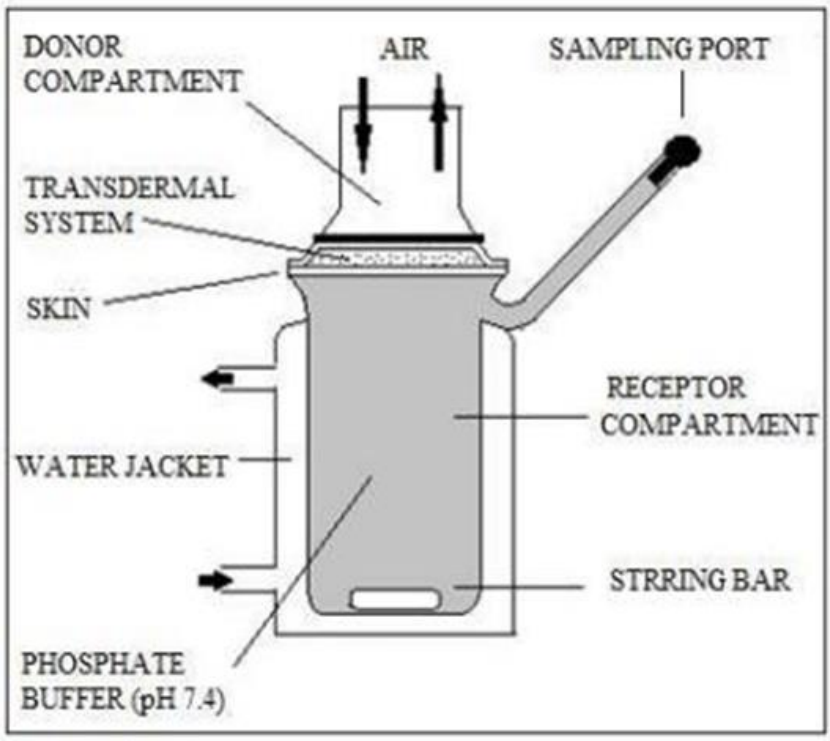

Fig 2: Franz diffusion cell

At regular intervals, samples from the receptor compartment are collected, and the concentration of the drug is analyzed, usually by methods like UV-spectroscopy or HPLC. This allows for the determination of the drug's release profile, which provides insights into parameters such as the rate of release, total cumulative drug release, and release kinetics. By understanding these factors, researchers can fine-tune the formulation to achieve a controlled release, ensuring effective and sustained drug delivery from buccal patches [110].

6.14.2 Dissolution Apparatus: The USP dissolution apparatus, such as the paddle (Apparatus 2) or basket (Apparatus 2) system, can be adapted how buccal patches release drug under simulated oral conditions. In this approach, the patch is placed in a vessel containing a specifically chosen dissolution medium often a buffer that mimics saliva in terms of pH and ionic strength. The medium is gently agitated at a controlled temperature of around 37 ºC, replicating the thermal and fluidic environment of the human mouth. Stirring promotes consistent contact between the patch and medium, allowing the drug to diffuse out gradually. At scheduled time points, small samples are collected from the medium and analyzed using techniques like UV spectrophotometry or high-performance liquid chromatography (HPLC) to determine the concentration of drug released. This method provides insight into the release dynamics of the formulation, helping researchers evaluate how efficiently the drug is delivered over time and whether the system offers sustained or immediate release characteristics [111, 112].

6.14.3 Modified Franz Diffusion Cell: Initially the membrane soak in the receptor medium 30 min. Then the membrane cut and fit to chamber and ensure the no air bubbles. In between receptor and donor chamber place the cell membrane and secure to prevent leakage. Receptor camber filled with receptor fluid and that is 5 to 10 ml. Set the temperature if cell membrane is natural then maintain at 32 °C if it is systemic as like cellulose temperature should be at 37 °C. To ensure uniform concentration place the receptor compartment on magnetic stir bar. Measured amount of formulation apply to donor chamber and seal to prevent evaporation. After predetermined time interval, 0.5, 1, 2, 3, 4, 5, 6 hr. withdraw sample from receptor chamber. To maintain sink condition immediately replace equal volume of fresh medium. Filter the withdrawn sample. Analyze the sample using UV or HPLC. Plot cumulative drug release vs. time [117].

7. Conclusion

Buccal drug delivery systems represent a promising frontier in non-invasive therapeutic administration, offering a compelling alternative to traditional oral and parenteral routes. Their ability to bypass first-pass metabolism, provide rapid onset of action, and improve patient compliance makes them particularly suited for both systemic and localized treatments. Advancements in mucoadhesive polymers, permeation enhancers, and nanocarrier technologies are continually enhancing drug residence time and bioavailability in the buccal cavity. However, challenges such as limited drug absorption surface, saliva-induced dilution, and enzymatic degradation persist. Future innovations must focus on tailoring buccal systems to address these limitations through smart materials, bio-responsive formulations, and patient-centric designs. With continued interdisciplinary research, buccal delivery platforms are poised to become integral in precision medicine and controlled-release therapies.

8. Conflict of interest statement

The author(s) declare that they have no conflicts of interest to disclose.

9. Funding statement

"This research received no external funding"

10. Author contribution

- **Shaheena begum:** Conceptualization, literature search, data analysis, original draft preparation.
- **Mallikarjun B Kinagi**: Literature review, drafting specific section, critical revision of the manuscript, supervision.
- **Subhanalla Abdulgani G**: Methodology design, Data curation, review and editing.
- All authors have read and approved the final version of the manuscript.

11. Data availability statement

No new data were created or analyzed in this study. Data sharing is not applicable to this article.

12. Ethical Statement

This review article is based on previously published studies and does not involve any new studies with human participants or animal performance by the authors. All sources have been properly cited to ensure the authors declare that there are no conflicts of interest regarding the publication of this article.

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