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Review Article

A Comprehensive Review on Formulation and Evaluation of Buccal Patches

Hemantkumar Dhongade*, Sakshi Rande, Avanti Girdekar

Laddhad College of Pharmacy, Yelgaon, Buldhana, Maharashtra, India 443001

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ABSTRACT

Buccal patches are advanced drug delivery systems designed to administer drugs through the buccal mucosa, offering an effective alternative to conventional oral dosage forms. Drug absorption through the buccal route allows direct entry into the systemic circulation, thereby bypassing hepatic first-pass metabolism. This leads to improved bioavailability and enhanced therapeutic efficacy. Buccal drug delivery systems provide controlled and sustained release of drugs, resulting in increased plasma drug concentrations and better patient compliance. The drug is placed between the cheek and gum, where it dissolves and is absorbed through the mucosal membrane into the bloodstream. Buccal formulations are available in various forms such as tablets, films, patches, and sprays, making them suitable for both local and systemic drug delivery.

INTRODUCTION

The Buccal Drug Delivery System (BDDS) involves the administration of drugs through the buccal mucosa, which is the lining of the inner cheek of the oral cavity. In this system, the dosage form such as a tablet, patch, or film is placed between the upper gum and the cheek, allowing the drug to be absorbed through the mucosal membrane. The buccal mucosa is considered an ideal site for drug delivery because of its smooth surface, relatively high permeability, and extensive vascularization. Due to the presence of a rich blood supply, drugs absorbed through the buccal mucosa can rapidly enter the systemic circulation.[1]

Transmucosal drug delivery through the buccal route offers several advantages over conventional oral (peroral) administration. One of the most important benefits is the avoidance of first-pass metabolism in the liver, which often reduces the bioavailability of orally administered drugs. Additionally, buccal drug delivery prevents drug degradation caused by acidic pH and digestive enzymes present in the gastrointestinal tract. The enzymatic activity in the buccal cavity is

***Corresponding Author:** Hemantkumar Dhongade
Address: *Laddhad College of Pharmacy, Yelgaon, Buldhana, Maharashtra, India 443001*
Email : hemantdhongade@gmail.com
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comparatively low, which favors improved stability and absorption of drugs.[2]

Buccal drug delivery is especially useful for drugs that undergo extensive hepatic metabolism, have poor gastrointestinal stability, or require rapid onset of action. The buccal cavity allows both local and systemic drug delivery, making it suitable for treating conditions such as oral infections, pain, inflammation, and systemic diseases. Furthermore, buccal delivery enhances patient compliance because the dosage forms are easy to administer, painless, and non-invasive.[3]

Another major advantage of BDDS is that the buccal cavity is easily accessible for self-medication, making the system safe and patient-friendly. Buccal patches and films can be conveniently applied and removed, allowing immediate termination of drug delivery whenever required. This feature is particularly beneficial in case of adverse drug reactions or overdose. Due to these advantages, buccal drug delivery systems have gained significant attention as an effective alternative to traditional oral and parenteral drug delivery methods.[4]

Buccal Patches [5]

Buccal patch is a non-dissolving, thin matrix, modified-release dosage form composed of one or more polymeric films or layers containing the drug along with suitable excipients. The patch may include a mucoadhesive polymer layer that adheres to the oral mucosa, gums, or teeth, thereby ensuring controlled and prolonged release of the drug into the oral mucosa, oral cavity, or both. Buccal patches are designed to remain in position for a specified period, after which they are removed from the mouth and disposed of. A buccal patch is a small medicated adhesive system intended for placement on the buccal mucosa (inner lining of the cheek), allowing the drug to be absorbed directly through the oral mucosa into the systemic circulation, thus improving bioavailability and avoiding first-pass metabolism.

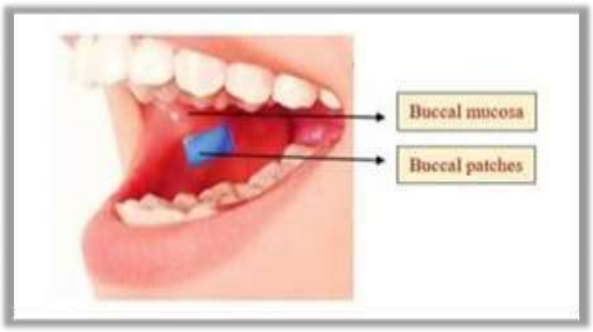

Fig no 1 Buccal patches

Structural Features of the Oral Cavity:

The oral cavity is the region of the mouth delineated by the lips, cheeks, hard palate, soft palate, and the floor of the mouth. It serves as the entry point of the digestive and respiratory systems and plays an important role in drug delivery through the oral mucosa. Anatomically, the oral cavity consists of two main regions. The outer oral vestibule is the space bounded externally by the lips and cheeks and internally by the teeth and gums. The oral cavity proper extends from the teeth and gums posteriorly to the fauces, which lead to the pharynx. The roof of the oral cavity proper is formed by the hard palate anteriorly and the soft palate posteriorly, while the tongue projects upward from the floor of the cavity.[6]

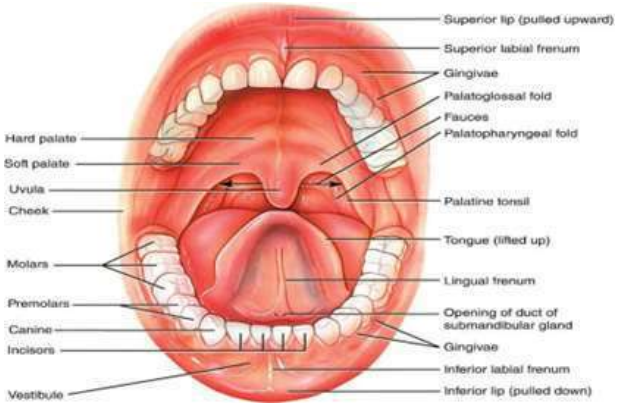

Fig. no. 2 oral cavity

Method of Preparation of Buccal Adhesive Patches [7

Two main methods are commonly used for the preparation of buccal adhesive patches, namely solvent casting and direct milling.

1) Solvent Casting Method:

In this method, all patch excipients including the drug are uniformly co-dispersed in a suitable organic solvent to form a homogeneous solution or dispersion. This mixture is then coated onto a sheet of release liner. The solvent is allowed to evaporate under controlled conditions, resulting in the formation of a thin drug-loaded polymeric film. After complete solvent evaporation, a protective backing material is laminated onto the coated release liner to form a laminate. The laminate is then die-cut into patches of the desired size and shape.

2) Direct Milling Method:

In the direct milling method, buccal patches are prepared without the use of solvents, making it a solvent-free process. The drug and excipients are mechanically mixed by direct milling or kneading, usually without the addition of any liquid. After thorough mixing, the resultant mass is rolled onto a release liner until the desired thickness is achieved. A backing material is then laminated in a manner similar to the solvent casting method. Although there are minimal or no differences in the performance of patches prepared by either method, the direct milling method is preferred as it eliminates the risk of residual solvents and avoids solvent-related health and safety issues.

Materials Used in Buccal Patch [8-10]

A buccal patch is a type of oral transmucosal drug delivery system prepared using specific materials that enable adhesion to the buccal mucosa and controlled release of the drug. The materials used in buccal patches are selected based on their biocompatibility, mucoadhesive properties, flexibility, and ability to control drug release.

1. Backing Layer (Protective Layer)

The backing layer prevents the loss of drug from the outer surface of the patch and ensures unidirectional drug release toward the buccal mucosa. Common materials used include:

- Ethyl cellulose
- Polyethylene
- Polyvinyl acetate
- Aluminum foil (in laminated form)

2. Drug-Containing Layer (Reservoir/Matrix Layer)

This layer contains the drug and controls its release. It is generally composed of hydrophilic or mucoadhesive polymers such as:

- Hydroxypropyl methylcellulose (HPMC)
- Polyvinyl alcohol (PVA)
- Polyvinylpyrrolidone (PVP)
- Chitosan
- Carbopol (polyacrylic acid)
- Sodium alginate

3. Mucoadhesive Polymers

These polymers help the patch adhere firmly to the buccal mucosa, prolonging the residence time and enhancing drug absorption. Commonly used mucoadhesive polymers include:

- Carbopol
- Chitosan
- HPMC
- Sodium carboxymethylcellulose (NaCMC)
- Pectin

4. Plasticizers

Plasticizers improve the flexibility, elasticity, and mechanical strength of the buccal patch, preventing brittleness. Examples include:

- Glycerin
- Propylene glycol
- Polyethylene glycol (PEG)
- Triethyl citrate

5. Permeation Enhancers

Permeation enhancers are optional components added to increase drug penetration through the buccal mucosa. Common permeation enhancers are:

- Oleic acid
- Sodium lauryl sulfate
- Menthol
- Bile salts

6. Other Additives

Additional excipients are incorporated to improve patient acceptability and performance of the patch, such as:

- Sweeteners (e.g., saccharin sodium)
- Flavoring agents (e.g., peppermint, orange flavor)
- Saliva-stimulating agents (e.g., citric acid)

Table no 1 Formulation Table of Buccal Patch [12]

Sr.No.	Ingredient	Category	Function
1	Drug (e.g., Model drug)	Active pharmaceutical ingredient	Provides therapeutic effect
2	HPMC	Film-forming polymer	Controls drug release and forms matrix
3	Carbopol 934	Mucoadhesive polymer	Enhances adhesion to buccal mucosa
4	Chitosan	Mucoadhesive polymer	Improves bioadhesion and permeability
5	Polyvinyl alcohol (PVA)	Film former	Improves mechanical strength
6	Glycerin	Plasticizer	Improves flexibility and prevents brittleness
7	Propylene glycol	Plasticizer / penetration enhancer	Enhances flexibility and drug permeation
8	Sodium lauryl sulfate	Permeation enhancer	Increases drug absorption through mucosa
9	Saccharin sodium	Sweetening agent	Improves taste and patient acceptability
10	Peppermint flavor	Flavoring agent	Masks unpleasant taste
11	Citric acid	Saliva-stimulating agent	Enhances saliva flow and drug dissolution
12	Ethyl cellulose	Backing layer material	Prevents drug loss and ensures unidirectional release

Evaluation of Buccal Patch [13-17]

1. Physical Evaluation

Physical evaluation includes weight uniformity, content uniformity, thickness uniformity, and mass uniformity. These parameters are tested using randomly selected patches from each batch to ensure batch-to-batch consistency. Patch thickness is measured at five different randomly selected points using a screw gauge or digital micrometer, and the average thickness is calculated.

2. Surface pH

The surface pH of buccal patches/tablets is determined to assess the possibility of irritation to the buccal mucosa, as acidic or alkaline pH may cause discomfort in vivo. The surface pH should

be close to neutral. The method described by Bottenberg et al. is commonly used. The tablet is allowed to swell by placing it in contact with 1 mL of distilled water (pH 6.5 ± 0.05) for 2 hours at room temperature. A combined glass electrode is then brought into contact with the tablet surface and allowed to equilibrate for 1 minute before recording the pH.

3. Swelling Index

Buccal patches are individually weighed (W_1) and placed in 2% agar gel plates with the core surface facing the gel. The plates are incubated at 37°C ± 1°C. At predetermined intervals of 1 hour up to 6 hours, the patches are removed, excess surface water is gently wiped using filter paper, and the swollen patches are reweighed (W_2). The swelling index indicates the hydration capacity of the polymer and its role in mucoadhesion.

4. Ex Vivo Mucoadhesive Strength

Fresh buccal mucosa (sheep or rabbit) is fixed to a vial containing buffer solution. The buccal tablet is placed on the mucosal surface and allowed to remain in contact for 5 minutes. Water is then added dropwise until the tablet detaches from the mucosa. The weight of water required to cause detachment is recorded as the mucoadhesive strength.

5. Ex Vivo Mucoadhesion Time

For mucoadhesion time, the core side of the tablet is moistened and pressed onto the buccal mucosa for 30 seconds. The mucosa is then placed in a buffer solution (pH 6.8) maintained at 37°C and stirred at 50 rpm. The time required for complete detachment of the tablet from the mucosa is recorded as the mucoadhesion time.

6. In Vitro Drug Release

In vitro drug release studies of bilayered or multilayered buccal tablets are performed using phosphate buffer (pH 6.8) at 37 ± 0.5°C with a paddle speed of 50 rpm. The tablet is fixed to a glass disk using cyanoacrylate adhesive and placed at the bottom of the dissolution vessel. At predetermined time intervals, 5 mL of the dissolution medium is withdrawn and replaced with fresh buffer. The samples are filtered, suitably diluted, and analyzed using UV spectrophotometry at the selected wavelength.

7. In Vitro Drug Permeation

In vitro buccal drug permeation studies are carried out using Keshary–Chien or Franz diffusion cells at 37°C ± 0.2°C. Fresh buccal mucosa (sheep or rabbit) is mounted between the donor and receptor compartments. The buccal tablet is placed in the donor compartment with the core facing the mucosa. The receptor compartment is filled with phosphate buffer (pH 6.8), and samples are withdrawn at regular intervals to determine the amount of drug permeated through the mucosa.

8. Stability Study in Human Saliva

Stability studies of optimized bilayered or multilayered buccal tablets are performed using natural human saliva collected from healthy volunteers aged 18–50 years. The tablets are placed in Petri dishes containing 5 mL of human saliva and stored in a temperature-controlled oven at 37°C ± 0.2°C for 6 hours. At predetermined intervals (0, 1, 2, 3, and 6 hours), tablets are examined for changes in color, shape, surface integrity, tablet collapse, and drug content.

HOW TO USE BUCCAL PATCH [18-21]

A buccal patch is a medicated adhesive patch that sticks to the inside of your cheek and delivers

medicine directly into your bloodstream through the oral mucosa.

1. Wash your hands

- Clean your hands with soap and water.

2. Rinse your mouth

- Remove any food particles by rinsing with water.

3. Dry the inside of your cheek

- Use a clean tissue or gauze so the patch sticks better.

4. Open the packet

- Remove the patch carefully without damaging it.

5. Place the patch correctly

- Put the medicated side against the inner cheek (upper or lower side).

6. Press and hold

- Press the patch gently for 30–60 seconds so it sticks firmly.

7. Do not disturb it

- Don't chew gum
- Don't touch it with your tongue
- Avoid hot drinks immediately

8. Eating and drinking

- You can eat and drink, but chew food on the opposite side.

9. Removal

- After the prescribed time (hours), gently peel it off and throw it away.
- If it Falls Off:
- Reattach if it's still clean
- Use a new patch if it's dirty or won't stick well

Fig. no. 3 HOW TO USE BUCCAL PATCH

Table no 2 Advantages of Buccal Patches[22-24]

Sr. No.	Advantage	Brief Explanation
1	Avoids first-pass metabolism	Drug directly enters systemic circulation
2	Prevents acid and enzyme degradation	Protects drug from GIT environment
3	Easy removal in toxicity	Therapy can be stopped immediately
4	Good patient compliance	Non-invasive and painless
5	Rich blood supply	Enhances drug absorption
6	Controlled & sustained release	Maintains constant drug level

CONCLUSION

Research in drug delivery systems is essential not only for developing new pharmaceutical therapies but also for improving the safety and efficacy of existing treatments. Optimizing drug delivery in terms of controlled release, site-specific targeting, and predictable biodegradation can enhance therapeutic outcomes while reducing adverse effects. Injectable medications are often costly, inconvenient, and can carry serious risks. Therefore, there is a growing need for inexpensive, multiple-dose formulations with improved bioavailability. Transmucosal and transdermal delivery methods, including buccal adhesive systems, are particularly valuable because they eliminate the pain and complications associated with injections. Buccal patches offer numerous advantages such as easy accessibility, simple administration and removal, prolonged retention, low enzymatic degradation, cost-effectiveness, and high patient compliance, making them an effective alternative to conventional drug delivery methods.

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