



BUCCAL PATCHES: A COMPREHENSIVE REVIEW

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Abstract

The buccal mucosa is one of the administration sites that might provide an alternative for peroral administration. The successful delivery of drugs across the oral mucosa represents a continuing challenge, as well as a great opportunity. Buccal delivery, has progressed far beyond the use of traditional dosage forms with novel approaches emerging continuously. Buccal drug delivery system in which drug enters directly in systemic circulation thereby by passing the first pass effect. This is painless and without discomfort, precise dosage form and facilitates ease of removal without significant associated pain. Moreover it shows better stability, patient compliance; uniform and sustained drug release and above all easy and cheap methods of preparation which can be done with various commonly available biocompatible polymers. The buccal route has been researched for a wide variety of drugs and has gained significant attention and momentum since it offers remarkable advantages. Over past few decades, buccal route for systemic drug delivery using mucoadhesive polymers to significantly improve the performance of many drugs has been of profound interest.

Present article deals with the different aspect of the buccal patches.

Keywords: Buccal mucosa; delivery, metabolism; Drug plasma concentrations.

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Introduction

The mucosa is considered as potential sites for drug administration. Transmucosal routes of drug delivery (i.e., the mucosal linings of the nasal, rectal, vagina, ocular and oral cavity) offer distinct advantages over peroral administration for systemic drug delivery [1]. These Advantages includes possible bypass of the first pass effect, avoidance of presystemic elimination of gastrointestinal tract and depending on the particular drug. A better enzymatic flora for drug absorption [2].

Components or structural features of oral cavity:

Oral cavity is that area of mouth delineated by the lips, cheeks, hard palate, soft palate and floor of mouth. The oral cavity consists of two regions [3].

- Outer oral vestibule, which is bounded by cheeks, lips, teeth and gingival (gums).

- Oral cavity proper, which extends from teeth and gums back to the fauces (which lead to pharynx) with the roof comprising the hard and soft palate.

The tongue projects from the floor of the cavity.

Buccal patches are the type of drug formulation which has a drug administration through the buccal mucosa for drug delivery. These patches tend to enter the drug directly to systemic circulation escaping hepatic first pass metabolism. Buccal drug delivery systems are advantageous in increasing drug plasma concentrations and also therapeutic drug activity [4].

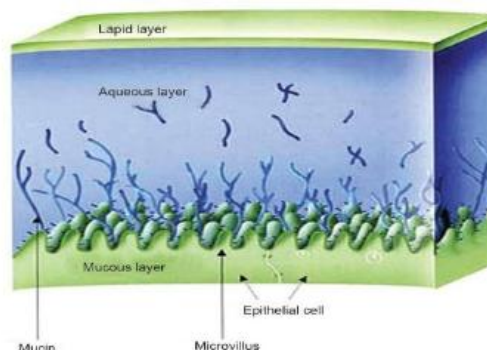


Figure 2: Mucus membrane structure.

Ideal characteristics of buccal patches

- The drug should get released in a controlled fashion [5].
- Normal functions should not be disturbed like talking and drinking.
- The patch should get attached to the site of application for few hours.
- The patch should not cause irritation at the site of application.
- The patch should provide drug release in a unidirectional way towards mucosa.
- Should provide the rate and extent of drug absorption [6].

Limitations in buccal patches:

- The area of absorptive membrane is relatively smaller [7].
- Saliva is continuously secreted into the oral cavity diluting drugs at the site of absorption
- Resulting in low drug concentrations at the surface of the absorbing membrane.
- There is risk that the delivery system itself would be swallowed.
- Drug characteristics may limit the use of the oral cavity as a site for drug delivery. Taste.
- Irritancy, allergy and adverse properties such as discoloration or erosion of the teeth may limit the drug candidate list for this route.
- Conventional type of buccal drug delivery systems did not allow the patient to concurrently eat, drink or in some cases, talk.

Types of buccal patches

1. Matrix type: In matrix type, the drug is consistently mixed with the hydrophilic or lipophilic polymer matrix for fabricating buccal patches. By moulding the medicated polymer, the therapeutic disc is formed.

2. Reservoir type: In reservoir system, the drug loss is reduced by attaching a water-resistant backing. It comprises of a cavity for drug and additives other than adhesives [9].

Buccal patches composition:

1) Active pharmaceutical ingredient (API): A large number of active pharmaceutical ingredient are used in buccal patches delivery system [10].

2) Polymers: Hydroxy ethyl cellulose, Hydroxy propyl cellulose, Poly vinyl pyrrolidone, polyvinyl alcohol, Carbopol.

3) Diluents: Lactose, microcrystalline starch & starch.

4) Sweetening agents: sucralose, Aspartame, mannitol.

5) Flavouring agents: Menthol, clove oil, peppermint oil, cinnamon oil, spearmint oil, vanilla, vanillin, cocoa, coffee, chocolate.

6) Backing layer: Ethyl cellulose, poly vinyl alcohol.

7) Penetration enhancer: EDTA, citric acid, cyanoacrylate, PEG 100, 400, propylene Glycol [11].

Mechanism of Permeation Enhancers:

The following are the mechanisms of permeation enhancers:

1. Changing mucus rheology: permeation enhancers decrease the viscosity of the Mucus [12].

2. Increasing the fluidity of lipid bilayer membrane: permeation enhancers increase the fluidity by the interaction of lipid or protein components with the lipid packing and eventually increasing the fluidity.

3. Action at tight junction's components: permeation enhancers increase the drug absorption at tight junctions.

4. By overcoming the enzymatic barrier: by varying the enzymatic activity membrane fluidity varies incidentally. Permeation enhancers act by obstructing the various peptidases and thereby disabling the enzymatic barrier [13].

Factors affecting buccal absorption:

1. Membrane Factors: Surface area available for absorption, degree of keratinization, intercellular lipids of epithelium, basement membrane, lamina propria, mucus layer of salivary pellicle, blood supply/lymph drainage, cell renewal and enzyme content, absorptive membrane thickness [14].

2. Environmental Factors:

- saliva,
- salivary glands,
- movement of buccal tissues.

Methods of Preparation of Buccal Patch

(a). Solvent casting technique:

In this technique the required quantity of mucoadhesive polymer is treated with required volume of solvent system and vortexed to allow polymer to swell. After swelling, mixture is treated with, measured quantity of plasticizer (propylene glycol or glycerin or dibutyl phthalate) and vortexed. Finally the required quantity of drug is dissolved in small volume of solvent system and added to the polymer solution and mixed well. Then set aside for some time to remove any entrapped air and transferred into a previously cleaned petri plate. The formed patches were stored in a desiccator till the evaluation tests were performed [15].

(b). Hot melt extrusion technique:

The Hot-melt extrusion (HME) technique is an attractive alternative to traditional processing methods and offers many advantages over the other pharmaceutical processing techniques. Molten polymers during the extrusion process can function as thermal binders and act as drug depots and/or drug release retardants upon cooling and solidification. Since solvents and water are not necessary, the numbers of processing and time-consuming drying steps are reduced. A matrix can be massed into a larger unit independent of compression properties. The intense mixing and agitation imposed by the rotating screw cause de-aggregation of suspended particles in the molten polymer resulting in a more uniform dispersion and the process is continuous and efficient. Bioavailability

of the drug substance may be improved when it is solubilized or dispersed at the molecular level in HME dosage forms. Pharmaceutical Hot-Melt Extrusion processes can be categorized as either ram extrusion or screw extrusion [16].

(c). Solvent evaporation method

In this technique the required quantity of mucoadhesive polymer is treated with required volume of solvent system and heat on water bath to dissolve polymer properly than dissolved the drug in that solution by heating and add plasticizer in required quantity. Then set aside for some time to remove any entrapped air and transferred into a previously cleaned petri plate. The formed patches were stored in a desiccator till the evaluation tests were performed [17].

Evaluation parameters of buccal patches:

1. Surface pH: On the surface of the previously prepared agar media buccal patches are applied for about one hour, and then by employing pH paper on the surface of swollen patch pH was determined [18].

2. Thickness measurements: For measuring thickness screw gauge with a least count of 0.01 thicknesses is used. At five different places thickness is measured and average value was Determined [19].

3. Folding endurance: Number of times patches could be doubled repetitively till it broke folding endurance can be accomplished.

4. Swelling study: In 1.5% agar gel plate previously weighed buccal patch is placed and is incubated at $37 \pm 1^\circ$ C. the patch is removed from the petri dish for one-hour intermissions up to 3h then by using filter paper surface water is desiccated. The swollen patch is removed and finally swelling index is estimated [20].

5. Thermal analysis study: Using differential scanning calorimeter thermal analysis can be Executed [21].

6. Buccal patches morphological characterization:

Morphological characterization of buccal patches can be done by scanning electron microscopy.

7. Permeation evaluation of buccal patch: For permeation evaluation, phosphate buffer is Filled in a receptor compartment, the hydrodynamics of receptor compartment is sustained by mixing at 50rpm with a magnetic bead. Samples are withdrawn at predetermined time intermissions and drug content is evaluated [22].

Conclusion

The buccal mucosa is abundant in both vascular and lymphatic system through which drugs are straightforwardly delivered systematically. Also, patches avoid the first- pass digestion in liver and pre-systemic end in gastrointestinal tract. Furthermore, buccal medication can be ended at any point of time in cases of toxicity enabling patches a safe and simple method of application of drugs in the buccal space. Thus, buccal drug delivery has emerged to be assuring area for continued

research with the aim of systemic delivery and attractive alternative for delivery of potent peptide and protein drug molecules.

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Conflict of Interest Statement

No conflict of interest.

Ethics Approval and Consent to Participate

Not applicable.

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