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Technical Note on Buccal Patch



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ABSTRACT

The buccal patch is an ideal drug delivery system, it is placed on the oral cavity to deliver a specific dose of medication through the internal jugular vein. Since they provide quick onset of action by oral mucosal absorption of the drug and also reduce the dose size with minimal adverse effect. This dosage form is very useful in an emergency case. The buccal patch is provides a controlled release of the medication. Buccal patch formulation can be a constant and prolonged drug level. The review article covers advantages, methods for the preparation of buccal patches, and evaluation parameters of buccal patches.



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INTRODUCTION

The buccal route is an alternative to the oral route for drug administration. Oral administration is the most common and preferable route for delivery of most therapeutic agents, but some drugs show the drawback and problem in this route viz., First pass metabolism, Gastric irritation, Enzymatic degradation of the drug in GI tract.^[1,2]

Buccal mucosa has a rich blood supply and acts as an ideal site for drug absorption. Drugs directly enter into the systemic circulation through the internal jugular vein.^[3,4]

Various mucoadhesive devices are available in the market, including tablets, films, patches, disks, strips, ointments and gels. However, the buccal patch provides greater flexibility and comfort than other devices.^[5]

The buccal patch is categorized as an oral route of administration. The buccal patch is a non-dissolving thin matrix modified release dosage form composed of one or more polymer films or layers containing the drug and/or other excipients.^[6]

The patch is laminated with an impermeable backing layer and a drug containing layer from which the drug is released in a controlled manner.^[7]

TYPES OF BUCCAL PATCH^[6,8]

1. **Matrix type (bi-directional)** –

Drug, adhesive, and additives mixed together and this mixture is designed in the form of patches.

2. **Reservoir type (unidirectional)** –

The buccal patch designed in a reservoir system contains a cavity for the drug and additives separated from the adhesive. An impermeable backing is applied to control the direction of drug delivery; to reduce patch deformation and disintegration while in the mouth, and to prevent drug loss.

ADVANTAGES – ^[9,10,11,12]

1. Self-medication
2. The quick onset of action by oral mucosal absorption of the drug.

3. Very useful in the emergency case.
4. Reduce the dose size with a minimum adverse effect.
5. Longer residence time.
6. Excellent accessibility.
7. Low enzymatic activity.
8. Painless administration.
9. Drugs direct entry into systemic circulation.
10. Passive diffusion.
11. If a patient suffered from vomiting, a buccal patch can be preferred because it prevents drug degradation due to gastrointestinal enzymes.
12. In adverse effect conditions, drug action can be terminated by removing the buccal patch from the site of application.

DISADVANTAGES – [13,14]

1. Drugs that are unstable at buccal pH cannot be administered.
2. Eating and drinking may become restricted.
3. Those drugs which are absorbed by passive diffusion can only be administered by this route.
4. Drugs that have a bitter taste or unpleasant taste or an obnoxious odor or irritate the mucosa cannot be administered by this route.
5. Drugs required with a small dose can only be administered.

POLYMER –

To protect the drug from the physiological environment and prolong the release of drugs to improve its stability is the main role of the polymer.^[15]

Various natural and synthetic polymers are available.

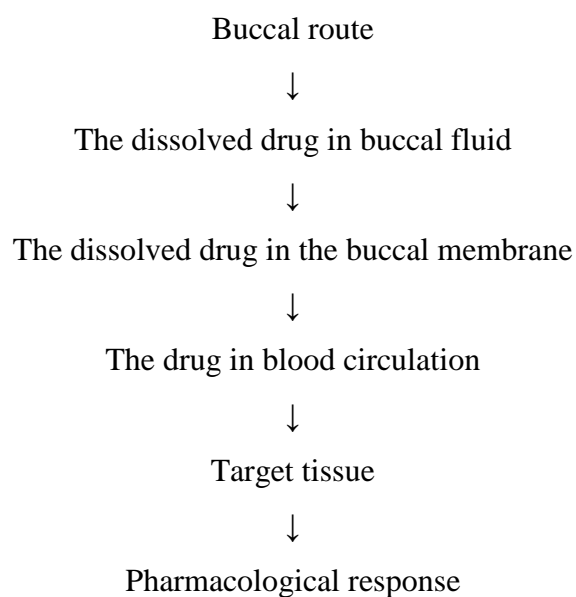
Table No. 1: LIST OF POLYMER^[13,16]

Sr. No.	NATURAL POLYMER	SYNTHETIC POLYMER
1	Chitosan	Cellulose derivatives – hydroxylpropyl methylcellulose, sodium carboxymethyl cellulose, methylcellulose/ethyl cellulose.
2	Sodium alginate	Polyvinyl alcohol
3	Tragacanth	Polyethylene oxide
4	Guar gum	Polyvinylpyrrolidone
5	Gelatin	Poly hydroxyl ethyl methyl acrylate
6	Soluble starch	
7	Xanthan gum	

Characteristics of ideal polymer – ^[17]

1. Non-toxic and non absorbable.
2. Not irritated to the mucous membrane.
3. Adhere quickly to moist tissue.
4. Easy incorporated of the drug and should offer no hindrance to its release.
5. Not decomposed on storage.

Mechanism of buccal absorption^[8]



COMPOSITION^[8,13,14,18,19]

1. Active ingredient
2. Polymer (adhesive layer) – HPMC (hydroxypropyl methylcellulose), hydroxypropyl cellulose, hydroxyethylcellulose, polyvinylpyrrolidone, polyvinyl alcohol, carbopol, etc.
3. Diluents – lactose CD
4. Flavoring agent – clove oil, menthol, vanillin, etc.
5. Sweetening agent – mannitol, sucralose, aspartame etc.
6. Backing layer – ethylcellulose, etc.
7. Plasticizer – propylene glycol, propylene glycol-100, 400, etc.
8. Penetration enhancer – PEG-400, cyanoacrylate, etc.

Method of preparation – ^[14,18,19]

Solvent casting method

↓
Excipients including drug codispersed in organic solvents with continuous stirring and coated onto a sheet of a release liner.

↓
Clear viscous solution

↓
Solvent evaporation

↓
A thin layer of protective backing material is laminated onto the sheet of coated release liner to form a laminate.

↓
Die cut to form patches of the desired size.

Direct milling



Patches are manufactured without the use of solvent.



Drug and excipients are mixed by direct milling or by kneading without using any liquid.



After the mixing process, the material is rolled on the release liner until the desired thickness is achieved.



The backing material is then laminated.

Table No. 2: EVALUATION OF BUCCAL PATCH^[9,10,11,12,14,18,19,20]

Sr. No.	Parameter	Significance	Technique used
1	Weight	Determine average weight variation	Digital balance
2	Thickness	Determine average thickness value	Screw gauge
3	Surface pH	Determine the surface pH of the buccal patch	pH meter and pH paper
4	Folding endurance	Determine by repeatedly folding 1 patch at the same place till its breaks and average value reported	--
5	Swelling index	Determine swelling index using agar gel and phosphate buffer	Petri dish
6	Drug content uniformity	Determine drug content	Beaker
7	Tensile strength	Measure the strength of the patch	Tensile strength tester
8	In vitro drug release	Determine drug release	Diffusion cell
9	Ex vivo	Determine drug release by using animal mucosa	Diffusion cell

CONCLUSION –

The buccal patch is an ideal drug delivery system. It is painless, convenient, and potentially effective. The buccal patch improves the therapeutic efficacy of drugs thereby reduce both no. and size of the dose. It is a unique alternative to conventional drugs by virtue of its ability

in overcoming hepatic metabolism, frequencies, and enhancing bioavailability. This article provides valuable information regarding the type, composition, method of preparation, evaluation of buccal patch.

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