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A Review Article on Buccal Patches: Formulation and Evaluation

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ABSTRACT: 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. In buccal drug delivery the drug is placed between your gums and cheek, where it gets dissolved and absorbed into blood. Buccal drugs come in tablet, films, or sprays.
KEYWORDS: Buccal mucosa; First pass metabolism; Drug plasma concentrations.

I. INTRODUCTION

Buccal drug delivery a highly effective way to improve bioavailability, where buccal mucosa facilitates direct entry of drug molecules into systemic circulation as it has a rich blood supply. Buccal cavity is easily accessible for self-medication so it is well accepted by patients. Buccal dosage forms are available in formulations like adhesive tablets, gels, and patches of which patches are preferred in terms of flexibility and comfort. A buccal patch provides good penetration of drug, a large contact surface area and a unidirectional drug release.

IDEAL CHARACTERISTICS OF BUCCAL PATCHES

- The drug should get released in a controlled fashion.
- 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.

ADVANTAGES OF BUCCAL PATCHES

1. First pass metabolism is avoided.
2. Inhibits acid /enzyme metabolism.
3. In case of toxicity, administration and removal of drug is easy.
4. With respect to parental, patient compliance is good.
5. With respect to skin and TDDS (4-4000), permeation is faster.
6. Compared to sub lingual mucosa surface area is large.
7. Blood supply is rich.
8. Metabolic activity is low.
9. Robust.
10. An alternative to intestine.
11. Easy usage and low variability.
12. Controlled release zero order.
13. Low enzymatic activity.
14. High bioavailability.
15. Excellent accessibility.
16. Sustained drug delivery.

DRAWBACKS

1. Not suitable for children.
2. Difficulty in drinking and eating.
3. Surface area is less compared to skin.
4. Drugs which have bitter taste or which cause irritant to mucosa or having noxious smell.
5. These can cause salivary erosion which enter GIT and choke oesophagus.
6. Unstable at buccal pH (6.5 to 7) cannot be administered.

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

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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.

Buccal patches composition:

1) Active pharmaceutical ingredient (API): A large number of active pharmaceutical ingredient are used in buccal patches delivery system.
2) Polymers: Hydroxy ethyl cellulose, Hydroxy propyl cellulose, Poly vinyl pyrrolidine, 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.

Mechanism Of Permeation Enhancers:
The following are the mechanisms of permeation enhancers:

1. Changing mucus rheology: permeation enhancers decreases the viscosity of the mucus.
2. Increasing the fluidity of lipid bilayer membrane: penetration enhancers increases 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: penetration enhancers increase the drug absorption at tight junctions.
4. By overcoming the enzymatic barrier: by varying the enzymatic activity membrane fluidity varies incidentally. Penetration enhancers act by obstructing the various peptidases and thereby disabling the enzymatic barrier.

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.
2. ENVIRONMENTAL FACTORS: a) saliva, b)salivary glands, c)movement of buccal tissues.

MANUFACTURING METHODS OF BUCCAL PATCHES

Solvent Casting method:

In this method mucoadhesive polymers in required quantity are treated with solvent and polymer swell after vertexing. In this method measured quantity of plastic is added in mixture and vortexed. The drug liquified in small volume of solvent system and added to the polymer solution and mixed well. The air which is entrapped is removed and the blend is taken in to a petri plate. The patched are stored in desiccator for the evaluation.

Direct milling method:

Direct milling or kneading methods are used for mixing drug and excipients without any liquified solution. Rolling procedure is used to achieve desired thickness. The backing material is laminated.

Hot melt extrusion method:

In this method the blend of pharmaceutical ingredients aremolten and then forced to through an orifice to get different shapes. The hot melt is used for the fabrication of controlled release matrix tablets, pellets, granules, disintegrating films.Finally dies are used to get the desired shaped films.

Semi solid casting:

Initially a solution of water-soluble film forming polymer is organised in this method. The solution formed above added to a solution of acid insoluble polymer which was prepared in ammonium for sodium hydroxide. Desired amounts if plasticizer is added to a gel mass. The gel mass is casted into films or ribbons finally.

Rolling method:

In rolling method, solution or suspension containing drug is rolled on a carrier. The solvent is mixture of water and alcohol. The film is allowed to dry and cut in to desired shapes and sizes.

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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, then by employing pHpaper on the surface of swollen patch pH was determined.
2. Thickness measurements: For measuring thickness screw gauge with a least count of 0.01 thickness is used. At five different places thickness is measured and average value was determined.
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±1º 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.
5. Thermal analysis study: Using differential scanning calorimeter thermal analysis can be executed.
6. Buccalpatches 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.

II. CONCLUSION:

Buccal drug delivery systems provide numerous advantages in terms of accessibility, administration and withdrawal, retentivity, low enzymatic activity, economy, high patient compliance. Adhesion of buccal patches to mucosal membranes leads to an increased drug concentration gradient at the absorption site which improve bioavailability of systematically delivered drugs. Buccal drug delivery systems are also used for local disorders at mucosal membranes like mouth ulcers, to reduce overall required dose and minimize side effects. the usage of buccal patches can be stopped in case any adverse effects are seen. So it is concluded that buccal patches are one of the vital dosage forms in pharmaceutical industries.

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