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Short Communication

Formulation, Development of Mucoadhesive Placebo Buccal Patches: Physical Characterization

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ABSTRACT

The purpose of present work was to design and evaluate mucoadhesive placebo buccal devices. These patches are composed of mixture of mucoadhesive polymer Methyle cellulose and water in combination with Polyvinylpyrollidone and glycerin. The patches were fabricated by solvent casting techniqu and were evaluated for its physical properties. The patches were evaluated for film weight uniformity, thickness, swelling index, surface pH, mucoadhesive time and folding endurance. A combination of Methyle cellulose with Polyvinylpyrollidone K30, glycerin with water as solvent gives promising results.

INTRODUCTION

The buccal mucosa lines the inner cheek, and buccal formulations are placed in the mouth between the upper gums and cheek to treat local and systemic conditions. The buccal route provides one of the potential route for typically large, hydrophilic and unstable proteins, oligonucleotides and polysaccharides, as well as conventional small drug molecules. The oral cavity has been used as a site for localand systemic drug delivery[1].

Amongst the various routes of drug delivery, oral route is perhaps the most preferred to the patient and the clinician alike. However, peroral administration of drugs has disadvantages such as hepatic first pass metabolism and enzymatic degradation within the GI tract, that prohibit oral administration of certain classes of drugs especially peptides and proteins. Consequently, other absorptive mucosae are considered as potential sites for drug administration. Transmucosal routes of drug delivery offer distinct advantages over peroral administration for systemic drug delivery. These advantages include possible bypass of first pass effect, avoidance of presystemic elimination within the GI tract, and, depending on the particular drug, a better enzymatic flora for drug absorption[2].

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There are two permeation pathways for passive drug transport across the oral mucosa: paracellular and transcellular routes. Permeants can use these two routes simultaneously, but one route is usually preferred over the other depending on the physicochemical properties of the diffusant. Since the intercellular spaces and cytoplasm are hydrophilic in character, lipophilic compounds would have low solubilities in this environment. The cell membrane, however, is rather lipophilic in nature and hydrophilic solutes will have difficulty permeating through the cell membrane due to a low partition coefficient. Therefore, the intercellular spaces pose as the major barrier to permeation of lipophilic compounds and the cell membrane acts as the major transport barrier for hydrophilic compounds. Since the oral epithelium is stratified, solute permeation may involve a combination of these two routes. The route that predominates, however, is generally the one that provides the least amount of hindrance to passage[2].

Advantages of buccal drug delivery system[1],

1) It is richly vascularized and more accessible for the administration and removal of a dosage form.
2) Buccal drug delivery has a high patient acceptabilitycompared to other non-oral routes of drug administration.

3) Harsh environmental factors that exist in oraldelivery of a drug are circumvented by buccal delivery.
4) Avoids acid hydrolysis in the gastrointestinal tract and by passing the first-pass effect.
5) Moreover, rapid cellular recovery and achievement of a localized site on the smooth surface of the buccal mucosa.

Disadvantages of buccal drug delivery system[1],

1) Low permeability of the buccal membrane: specifically when compared to the sublingual membrane.
2) Smaller surface area. The total surface area of the membranes of the oral cavity available for drug absorption is 170 cm^2 of which ~50 cm^2 represents non-keratinized tissues, including the buccal membrane.
3) The continuous secretion of saliva (0.5–2 l/day) leads to subsequent dilution of the drug.
4) Swallowing of saliva can also potentially lead to the loss of dissolved or suspended drug and, ultimately, the involuntary removal of the dosage form. These are some of the problems that are associated with buccal drug delivery.

MATERIALS AND METHOD

For carrying out the work, Methyle cellulose, Polyvinylpyrolidone (PVP) K30, were purchased from Central Drug House (P) Ltd. New Delhi, CDH Laboratory and glycerin was the institutional purchase.

The patches were prepared (Table 1) by solvent casting technique[3,4]. The weighed and measured quantity of Methyle Cellulose, Polyvinyl pyrollidone and Glycerin were taken in solvent i.e. Water in beaker and the mixture was stirred for about 15 minutes. Then dispersion was kept untouched for about 2 hours, then poured it into Petri dish and kept it in oven at 40 ^{0}C to 45 ^{0}C for about 6 to 8 hours.

Table 1: Buccal patch formulation

Composition	Unit	Formulation(F)
Methyle cellulose	(mg)	500
P.V.P. K30	(mg)	180
Distilled water	(ml)	20
Glycerin	(ml)	01

P.V.P.- Polyvinylpyrollidone

RESULTS AND DISCUSSION

Evaluation of prepared mucoadhesive placebo buccal patches has been performed with following physical characteristics.

Film weight[4,5]

For evaluation of film weight, 8 films of (2×2cm^2) from formulation were taken and weighed individually on a digital balance. The results were analyzed for mean and standard deviation. (Table 2)

Thickness[4,5]

For evaluation of thickness, 8 films (2×2cm^2) of formulation were taken and the film thicknesses were measured by digital thickness gauze. The results were analyzed for mean and standard deviation. (Table 3)

Folding endurance[4,5]

8 films from formulation (2×2cm^2) were cut by using sharp blade. Folding endurance was determined by repeatedly folding a small strip of film at the same place till it brakes. The number of times, the films could be folded at the same place without breaking will give the value of folding endurance. The results were analyzed for mean and standard deviation. (Table 4)

Surface pH[4,5],

The surface pH of the patches were determined in order to investigate the possibility of any side effects, in-vivo. An acidic or alkaline pH may cause irritation to the buccal mucosa. It was our attempt to keep the surface pH as close to neutral as possible. For the determination of surface pH, 1 patch (2×2cm^2) from formulation were taken and with the help of pH paper, surface pH have been observed. (Table 5)

Swelling index(S.I.)[4,5],

For the determination of swelling index (S.I) the pre-weighed 1 patch (2×2cm^2) from formulation was placed in a beaker (containing 20 ml of water). After particular interval of time patches were removed and wiped with tissue paper and weighed.

$$S.I. = (W\,2 - W\,1 / W\,1) \times 100$$

Where, S.I. is swelling index, W1 is weight of buccal patch before dipping into beaker and W2 is weight of buccal patch after dipping in beaker and wiped. (Table 6)

Table 2: Patches weight

Formulation	1st	2nd	3rd	4th	5th	6th	7th	8th	Mean ± S.D.
F	60	90	60	70	50	70	50	60	63.75±13.02

S.D.:- standard deviation, all the weights are in mg.

Table 3: Patches thickness of formulation

Formulation	1st	2nd	3rd	4th	5th	6th	7th	8th	Mean ±S.D.
F	0.16	0.19	0.17	0.15	0.16	0.17	0.14	0.26	0.17±0.037

S.D.:- standard deviation, all the thickness are in mm.

Table 4: Folding endurance of formulations

Formulation	1st	2nd	3rd	4th	5th	6th	7th	8th	Mean ±S.D.
F	290	294	280	293	297	287	290	288	289.87±5.166

S.D.:- standard deviation

Table 5: Surface pH

Formulation	pH range
F	6- 7

Table 6: Swelling Index(S.I.)

Time (min)	F (%)
5	4.45
10	5.55
15	11.13
20	18.10

Table 7: Mucoadhesive time

Formulation	1st	2nd	3rd	4th	5th	6th	7th	8th	Mean ±S.D.
F	260	278	260	280	310	265	282	289	278±16.826

S.D.:- standard deviation, all the time are in second.

Mucoadhesive time[4,5],

The in- vitro mucoadhesive time was determined using disintegration apparatus. The disintegration medium was 800 ml of phosphate buffer (pH 7.4) maintained at 37±2 ^{0}C. The segment of buccal mucosa of sheep was glued to the surface of glass slab, which was then vertically attached to the apparatus. Three mucoadhesive films of formulation were hydrated on one surface with Phosphate buffer (pH 7.4) and the hydrated surface was brought into contact with the mucosal membrane and allowed the apparatus to move up and down. The time required for complete detachment of the film from surface was recorded. The results were analyzed for mean and standard deviation. (Table 7)

CONCLUSION

A new formulation of mucoadhesive placebo buccal patch has been developed and all the physical characteristics of the prepared

mucoadhesive placebo buccal patches were observed carefully which shows that formulation **F** (Table 1) gives the prominent results. This buccal patch has been evaluated for weight, thickness, folding endurance, surface pH, swelling index, and mucoadhesive time.

Working under placebo conditions definitely nullify the wastage of so called potent drugs which have their greater importance. On considering the research and industrial level, on the part of economy it will surely be considered as economy efficient work as it saves thousands of dollers spend on the purchase of drugs which was used with the trials of formulations or with novel drug delivery system.

Buccal lining is supposed to be more advantageous for drug delivery as bypass of the gastrointestinal tract and hepatic portal system, increasing the bioavailability of orally administered drugs that otherwise undergo hepatic first-pass metabolism. In addition the drug is protected from degradation due to pH and digestive enzymes of the middle gastrointestinal tract. Improved patient compliance due to the elimination of associated pain with injections, administration of drugs in unconscious or incapacitated patients, convenience of administration as compared to injections or oral medications have been observed. So, the prepared buccal patches shows the increased ease of drug administration.

Future aspects,

- In mucoadhesive placebo buccal patches we can use any potent drugs which fulfill the criteria for buccal patch as drug delivery system.
- We can perform the dissolution of medicated mucoadhesive buccal patch for drug release profile studies.
- We can further perform the *in-vivo* studies for the prepared mucoadhesive buccal patches.
- We can perform the stability test for the prepared mucoadhesive buccal patches.

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