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Formulation and Evaluation of Biopolymer Based Buccal Film of Diclofenac Sodium

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Abstract: Buccal drug delivery gives easier and safe method of drug administration because in case of toxicity it can be terminated by simply removing the dosage form from buccal cavity. The buccal film of diclofenac sodium was prepared for systemic delivery by solvent casting method using sodium alginate and Ocimum Basilicum mucilage. Then film was evaluated for parameter like physical appearance, surface texture, mass uniformity, thickness, folding endurance, drug content and *in vitro* drug release. The results of evaluation test reveals that prepared film was smooth, have adequate folding endurance. The film shows percentage cumulative drug release of 67.57% at the end of 4 hrs.

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INTRODUCTION

Among the various routes of drug delivery, transmucosal drug delivery offers distinct advantages over per oral administration for systemic effect. Among various transmucosal routes, buccal mucosa is the most suited for local, as well as systemic delivery of drugs. The unique physiological features make the buccal mucosa as an ideal route for mucoadhesive drug delivery system. These advantages include bypass of hepatic first-pass effect and avoidance of presystemic elimination within the gastrointestinal tract (Akbari et al., 2004; Veuillez et al., 2001).

Amongst the various routes of drug delivery, oral route is perhaps the most preferred to the patient. However, per oral 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. Drug buccal administration, on the other hand, is highly acceptable by patients. Oral mucosa is relatively permeable with a rich blood supply. Furthermore, oral transmucosal drug delivery avoids first pass effect and provides facile removal of dosage form in case of need (Chein et al., 2005).

Diclofenac sodium is used as Non-steroidal anti-inflammatory drug because of their outstanding analgesic, and antipyretic effects it is used for long term therapy which is effective in patients having severe joint pain i.e. Rheumatoid arthritis, mayalgia, myasthenia gravis like diseases. Diclofenac sodium is subject to hepatic first pass metabolism, the 50–60% of the drug reaches the systemic circulation in the unchanged form. Moreover, per oral administration of diclofenac sodium results in gastrointestinal disturbances ranging from abdominal discomfort, nausea, vomiting to serious gastrointestinal bleeding or peptic ulcers.

Hence, the buccal film of diclofenac sodium can be prepared for easy administration through buccal mucosa which provides direct entry of drug into the systemic circulation hence avoiding hepatic first pass metabolism.

In the present investigation buccal film was prepared by solvent casting method by using sodium alginate and Ocimum Basilicum mucilage. The main objective in this work is to formulate diclofenac sodium buccal film that could be applied to the buccal mucosa giving systemic effects to decrease gastric irritation and avoid the first pass effect (Devaranjan et al., 1997).

MATERIALS AND METHODS

Diclofenac sodium was obtained as a gift sample from . All other chemicals and reagents were of analytical grade.

Preparation of buccal film

The buccal film of Diclofenac sodium was prepared by solvent casting method. The composition of film was shown in the table 1.

Backing layer was prepared by forming homogeneous paste of sodium alginate in water and then this mixture was poured into a petriplate and dried using hot air oven at 50^0c.

Accurately weighed 400 mg of mucilage was taken in a 50 ml beaker containing 15 ml of distilled water and stirred vigorously until transparent mass was obtained. In another beaker 20 mg of diclofenac sodium was dispersed in 5 ml of distilled water properly. Then it is added in beaker containing mucilage and finally glycerine was added which was used as a plasticizer. Then this mixture was poured onto the dried backing layer.

Finally dried in hot air oven at 50^0c until it becomes dry.

Table 1: Composition of Buccal film

Sr. No	Ingredients	Quantity
1	Diclofenac Sodium	20 mg
2	Mucilage	400 mg
3	Sodium Alginate	300 mg
4	Glycerin	2 ml

Calibration curve of Diclofenac sodium

Preparation of stock solution

Accurately weighed 10 mg of diclofenac sodium was transferred to the 100 ml volumetric flask and dissolved in phosphate buffer pH 6.8. Finally volume was made upto 100 ml.

Preparation of working solutions

From the stock solution, aliquots of 0.5, 1, 1.5, 2, 2.5 and 3 ml are transferred to the 10 ml volumetric flask and final volume was made with phosphate buffer pH 6.8 to get concentrations of 5, 10, 15, 20, 25 and 30µg/ml respectively. Finally the absorbances of prepared solutions were measured against blank (Phosphate buffer pH 6.8) at 276 nm by using UV visible spectrophotometer and calibration curve was plotted.

Evaluation of Buccal Film

The prepared film was evaluated for following parameters -

1. Physical appearance:

The film observed visually for their physical appearance such as color and transparency.

2. Surface texture:

The surface texture of the film was evaluated by simply touching the surface of the patch.

3. Mass uniformity:

For the mass uniformity three patches were taken and weighed individually on electronic balance. The average weights were calculated in table.

4. Thickness:

Three films were selected randomly and the thickness of the each film was measured at different places using vernier calliper. The average film thickness and standard deviation performed in triplicate was computed in table.

5. Folding endurance test

The folding endurance of the film was determined by repeatedly folding one film at same place till it broke. The number of times the film could be folded at the same place without breaking gives the value of the folding endurance.

6. Drug content

For drug content determination we have taken 1 x 1cm film and then it was placed into 10 ml of phosphate buffer 6.8 for 12 hrs on magnetic stirrer then solution was sonicated for 30-40 mins. Then it was filtered, diluted suitably and analyzed on a U.V. Spectrophotometer.

7. In-Vitro Drug Release

In-vitro release studies were carried out by using dialysis membrane. The dialysis membrane was placed into dissolution media over night for soaking, after soaking the membrane was filled with dissolution media then film was placed into same, this was act as donor comportment. The receptor comportment was filled with phosphate buffer pH 6.8. A magnetic bead was placed in receptor comportment and the whole assembly was placed on magnetic stirrer and the temperature maintained at 37±0.5°c. Buffer was stirred samples of 1 ml were withdrawn at regular intervals, suitably diluted and absorbance was measured at 276 nm. The volume of the receptor comportment was maintained constant by replacing equal volume of buffer.

RESULTS

The calibration curve of Diclofenac sodium was constructed in phosphate buffer pH 6.8 at 276 nm using UV visible spectroscopy. Table 2 shows the absorbance of Diclofenac sodium solution containing 5-30 µg/ml of Diclofenac sodium in phosphate buffer pH 6.8. Figure 2 shows the calibration curve of Diclofenac sodium with regression value 0.997 and slope 0.02652. The calculations for drug content and in vitro drug release are based on calibration curve.

Table 2: Absorption data of Diclofenac sodium in phosphate buffer pH 6.8

Sr. No.	Conc. (µg/ml)	Absorbance
1	5	0.1429
2	10	0.2668
3	15	0.3811
4	20	0.5300
5	25	0.6821
6	30	0.7924

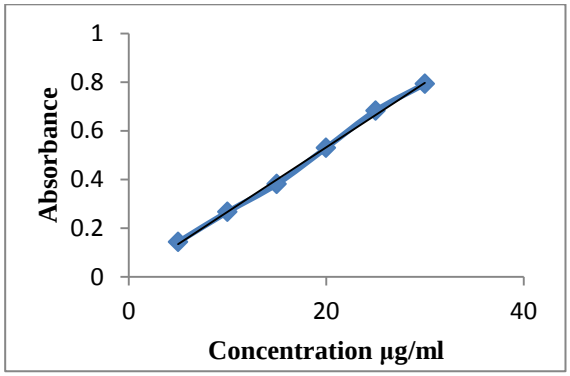

Figure 2: Calibration curve of Diclofenac sodium in phosphate buffer pH 6.8

The physical appearance of film was evaluated by visual observations. Film was transparent and has slight cream color. Then the surface texture was found to be very smooth.

The results of physical evaluation of buccal film were shown in the table 3. Average weight of film was found to be 54 mg. The thickness of film was found to be 0.45 mm. The folding endurance of the film was measured manually and they were folded between 123 times without breaking or cracking.

Table 3 Evaluation of Diclofenac sodium buccal film

Mass Uniformity (mg)	Thickness (mm)	Folding endurance	Drug content (%)
54	0.45	123	70.30

The drug content determination was done to ensure uniform distribution of drug within the film. The drug content was estimated for three films using standard method and mean was given in table 3. The drug content of prepared buccal film was found to be 70.30%.

The result of *In-vitro* drug release studies was shown in table 4, the Drug release profile for buccal film was shown in Figure 3. It was observed that the drug release at the end of 4 hrs is about 67.56 %.

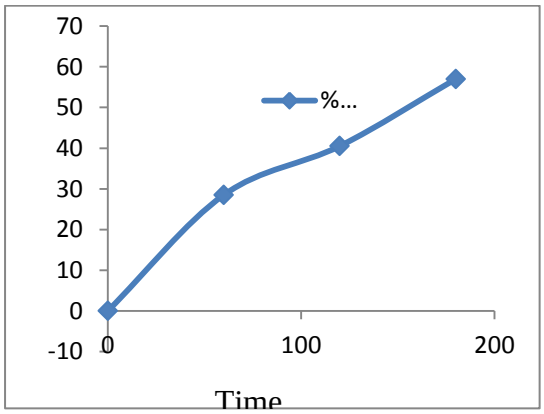

Figure 3: *In-vitro* Drug Release of film

DISCUSSION

On the basis of obtained results (table 2 and figure 2) it was concluded that Diclofenac sodium, obeys Beer- Lambert's law in the range of 5-30 µg/ml.

The slight cream color of film was may be due to sodium alginate. From the results of physical evaluation of buccal film we may conclude that, there was no any significant difference in weights of prepared films hence there is uniformity in mass for different films.

The thickness of film was found to be 0.45 mm, which was acceptable. From the result of folding endurance test we can conclude that the prepared film has good flexibility and thus, the prepared films were suitable for large scale manufacture to produce long, continuous film without breaking or tearing. The folding endurance of film was due to glycerin which was used as plasticizer and which imparts better flexibility to film.

From the results of drug content we can say that here is no any significant difference between drug content of all the films, which indicates that the drug was distributed uniformly throughout the film.

By looking towards results of *in-vitro* drug release of film it was observed that the drug release at end of 4 hrs, is 67.56%, it might be due to the presence of *Ocimum Basilicum* mucilage which absorbed the surrounding fluid, swelled and released the drug.

CONCLUSION

The buccal film of Diclofenac sodium was successfully formulated by using natural polymer and evaluated for various parameters like physical appearance, surface texture, thickness, mass uniformity, folding endurance, drug content and *in-vitro* drug release.

Thus, the Ocimum Basilicum mucilage showed a good gelling property and it can be concluded that, *Ocimum Basilicum* mucilage is suitable for formulation of buccal films.

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Table 4: *In-Vitro* Drug Release of Film

Time (Mins)	Abs	Conc. (µg/ml)	Conc. (mg/ml)	Error	DR	CDR	%CDR
60	0.0101	0.3107	0.000316	0.00158	0.057	0.0570	28.50
120	0.0131	0.4298	0.000429	0.0021	0.077	0.0810	40.52
180	0.018	0.6184	0.000618	0.0030	0.113	0.1180	57
240	0.0201	0.6938	0.000693	0.0034	0.1248	0.1352	67.56

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