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Research Article

Formulation and Evaluation of Buccal Patches of Diclofenac Sodium as a Model Drug

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Abstract



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The present study was concerned with the formulation and evaluation of buccal patches of Diclofenac Sodium. Here, Diclofenac sodium is used as a model drug. Buccal patches of Diclofenac Sodium were prepared by solvent casting method using PEG 400, Glutaraldehyde, Glycerin, HPMC, Gelatin and required quantity of distilled water. Weight variation, thickness, drug content and release studies were assessed.

Keywords: Buccal patch, Diclofenac sodium, oral mucosa, HPMC, PEG-400, Glutaraldehyde.

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INTRODUCTION

A drug can be given via various pathways in order to have pharmacological effects. Since centuries it has been understood that the drugs which are administered through buccal route quickly enter the reticulated vein (lying below oral mucosa). The oral mucosa cavity is the main pathway for drug administration to the systemic circulation. Drug delivery via buccal cavity has highly patient acceptability than the other non-oral routes of drug administration. It is more accessible for the administration and removal of dosage form. Basically, it bypasses the liver's 1st pass metabolism.¹



Now a days novel drug delivery system plays an important role to ameliorate the bioavailability of drugs by reducing absorption on gastrointestinal tract. This drug delivery system is defined as drug administration through the mucosal membranes lining the buccal mucosa. The buccal mucosa is placed in the mouth between the upper gums and cheek. This route is mainly used to deliver the unstable drug to prevent the drug degradation in acidic or alkaline environment and also prevent the enzyme degradation. These patches also

cover the wound surface, reducing pain and it increases the effectiveness of the oral disease treatment.

Diclofenac Sodium is a powerful non-steroidal anti-inflammatory drug (NSAID) used to treat rheumatoid and osteoarthritis, bursitis, ankylosing spondylitis, toothache, dysmenorrhea, quick relief of pain and wound edema. Long-term use causes inflammation and ulcers in the GI tract. It is a good choice for buccal drug delivery for its physicochemical properties and half-life.²

MATERIALS AND METHODS

MATERIALS: - Diclofenac Sodium (Yarrow Chem Products), Gelatin (Loba Chem), PEG 400 (MERCK), HPMC (Loba Chem), Glutaraldehyde (Loba Chem), Glycerin (New Bengal Drug House).

PREPARATION: - Gelatin, PEG 400, and Diclofenac Sodium are dissolved in purified water and heated in a water bath. Glass slides were coated with the molten gelatin mixture, which was left to cool and solidify at ambient temperature. A vacuum desiccator was used to dry the slides for 24 hours. Dry patches were picked up from the slide, and 2 x 2-centimeter² portions were cut with scissors. The patches were inserted into a 100ml beaker that had been prepared with an aqueous solution of glutaraldehyde (1%w/v). The patches were vacuum-dried at ambient temperature after being cleaned with distilled water to eliminate glutaraldehyde. Glycerin and HPMC were stirred until it completely distributed with water and cooling in the refrigerator to create a transparent viscous solution. Patches were covered in a coating of HPMC and left to dry overnight at ambient temperature.

Table 1: Formulations of buccal patches

Ingredients	F1	F2	F3
Diclofenac Sodium	10 mg	10 mg	10 mg
Gelatin	1 g	1 g	1g
PEG 400	0.5 g	1 g	0.5 g
Distilled water	3ml	3ml	3ml
Glutaraldehyde	1%	1%	1%
Glycerin	0.5 g	0.5 g	0.5 g
HPMC	0.5g	0.5g	0.5g
Time of cross-linking	4 min	4 min	4 min

EVALUATION OF PATCHES BY PHYSICAL TESTS

Physical appearance: - The patches were observed for color, transparency and smoothness.⁴

Weight uniformity: - The patches were dried in vacuum desiccators at ambient temperature. For measuring the weight uniformity of patches, an area of 2cm × 2cm was cut. Three patches of each formulation were individually weighted on a digital balance and then the mean weight was calculated.^{2,3}

Moisture Content: - Three patches of each formulation were weighted and kept in desiccators containing calcium chloride at room temperature for 24 hours. The patches were weighed after 24 hours and determined the percentage of moisture absorbed.⁵

Thickness: - At first, the patches were set aside for measuring it's thickness by a micrometer screw gauge. One side from the center and two sides from the corner. Each patch was placed between the two sides and the thickness (D1) was measured. Then the thickness of the two slides (D2) was measured with a screw gauge after removing the patch. Finally, the thickness of each patch is calculated from the given equation, and then the average value was recorded.⁶

$$D = D1 - D2$$

Drug Content estimation: -Each patch had a specific area cut out of it and then liquefied in 10 ml of phosphate buffer solution. The solution was then filtered after 24 hours. A test tube was used to transfer the filtrate. The absorbance of the solution was measured using a UV Spectrophotometer at 276 nm, and the drug content was estimated.⁷

In-vitro release study of Diclofenac Sodium across the semi-permeable membrane

A patch of 1 cm × 1 cm was cut and the side containing HPMC was put on a semi-permeable membrane followed by a slight press. The membrane was fitted with the opening of a Keshary-Chien apparatus in a way that it was facing toward the receptor chamber. The receptor chamber was filled with 50 ml of distilled water (receptor medium). The semi-permeable membrane just touched the medium. The temperature was kept constant by circulating water from a precision water bath possessed at 37±0.5°C. Samples of 5ml each were taken out through the port of the apparatus and fresh 5ml medium was replenished to retain the volume of the receptor medium. The medium was constantly stirred with a magnetic stirrer. Then the samples were settled in a UV spectrophotometer to assess the absorbance at 276 nm against a blank sample of distilled water.⁶

Physical appearance

Take a photograph of dried patches that resembled transparent membranes that looks thin and pale yellow in color. (Figure 1)



Figure 1: Buccal Patches of Diclofenac Sodium

Weights of patches

Weights of the patches (2cm × 2cm) were measured in triplicate and the average weight was reported in Table 2.

Table 2: Results of weight uniformity measurements of the buccal patches

Formulation	Weight (gm)[MEAN]	
	Reading 1	Reading 2
F1	0.1833	0.1762
F2	0.1767	0.1886
F3	0.1632	0.1753

Moisture content study

The initial and final weights of each patch were taken after maintaining a condition of 30°C, RH 80-90% for 24hrs, and the percentage of moisture absorbed was tabulated by the following formula:⁸

$$\% \text{ Moisture absorbed} = \frac{\text{Final Weight} - \text{Initial Weight}}{\text{Initial Weight}} \times 100\%$$

Table 3: Results of Moisture content measurements of the buccal patches

Formulation	Mean
F1	4.02±0.01
F2	4.80±0.026
F3	5.41±0.01

(Mean ±SD, n = 3)

RESULTS AND DISCUSSION

Thickness

At three different locations on each patch, the thickness was assessed using a screw gauge and the average value of the patches was determined.

Table 4: Thickness of buccal patches (Diclofenac Sodium, n=3)

Formulation No.	Thickness $\pm$ SD(mm)
F1	0.41 $\pm$ 0.010
F2	0.36 $\pm$ 0.026
F3	0.39 $\pm$ 0.050

(Mean $\pm$ SD, n = 3)

Drug release study from the buccal patches across semi-permeable membrane

The release of Diclofenac Sodium from the buccal patches was determined. All other formulations underwent the same method for calculating the release of the drug. The release data of all the patches were plotted (Fig. 4).

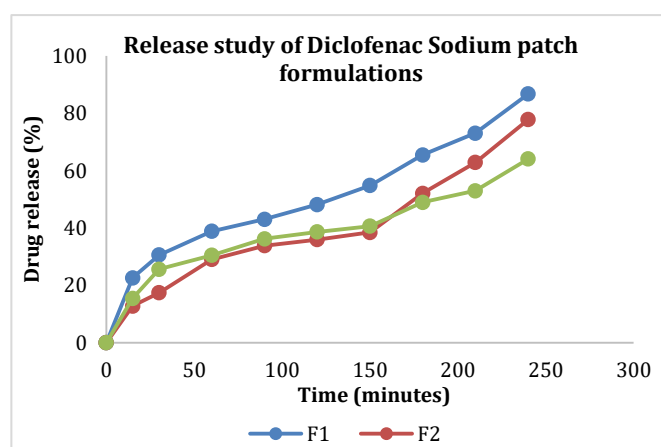


Figure 2: Percentage drug release of various formulations of Diclofenac Sodium Patch

CONCLUSION

The buccal patch containing Diclofenac Sodium (selected as a model drug) was effectively manufactured and assessed for different factors, such as weight uniformity, physical appearance, moisture content, thickness, drug content

estimation, and *in-vitro* drug release. Among the three formulations, F1 revealed a percentage drug release after 4 hours of 86.724%. From the research mentioned above, it can be supposed that such a buccal patch covers the surface of the wound area, hence reducing discomfort and also being able to treat mouth disease more efficiently. However, for the future development of this dosage form, more research and clinical testing are needed.

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