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Formulation and evaluation of Naproxen buccal films by using solvent casting method

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ABSTRACT:
The idea of mucoadhesion has attracted significant attention in the pharmaceutics community in recent decades. Mucoadhesive buccal medication administration provides a number of benefits, including extending the dose's residence duration at the application site. The main aim of the study is to formulate and evaluate naproxen buccal films by using HPMCK15 as rate controlling polymer and poly vinyl pyrollidone as an adhesive agent. Buccal films where prepared by using solvent casting method. The drug and drug-polymer compatibility was studied using FTIR studies. The results represents that the naproxen buccal films bypasses first-pass metabolism and reduce desirable side effects with desired adhesive properties. These films are proposed for the use of naproxen drug in buccal and dental inflammatory diseases.

I.INTRODUCTION

The situation in which two materials, at least one of which is biological in nature, are kept together for an extended amount of time by means of interfacial forces is known as bioadhesion or mucoadhesion. This idea started to be used with medicine delivery devices in the 1980s. Mucosal drug deliveries for drug transport are as follows:

- Buccal/oral
- Nasal
- Ocular
- Vaginal
- Rectal

Buccal delivery is the administration of medications through the mucosal membrane lining the cheeks. Buccal mucosa is suitable for delivering less permeable molecules and peptide medicines and considered to be the absolute route of mucoadhesive drug delivery system.

Naproxen is a non-steroidal anti-inflammatory drug meant for reducing ongoing inflammation, pain and fever. The aim of the study is to develop a buccal film containing a small dose of naproxen meant for local delivery that can be easily applied and removed by the patient itself for the treatment of buccal inflammatory diseases such as periodontitis, stomatitis.

Mechanism Of Mucoadhesion

- ✓ Contact stage
- ✓ Consolidation stage

Contact stage: During this stage an intimate wetting, spreading and swelling of the mucoadhesive material creates a close contact between a bio adhesive and a mucosal membrane.

Consolidation stage: Moisture breaks molecules and causes attractive interaction between the two surfaces.

II. MATERIALS AND METHODS

$HPMCK_{15}$ was obtained as gift sample from colorcon asia pvt.ltd. Goa, Poly vinyl pyrollidone was brought from Bangalore fine chemicals, Poly ethylene glycol was brought from Bangalore fine chemicals, Ethylcellulose, Glycerol, Propylene glycol were brought from isochem laboratories.

FORMULATION OF NAPROXEN FILMS BY SOLVENT CASTING METHOD

Solvent casting method is the most widely used method for the manufacture of buccal films.

The steps involved are as follows

- Hydrophilic polymers are dissolved in water to form a homogenous viscous solution.
- API and other lipophillic excipients are dissolved in suitable solvent to form a clear viscous solution.
- Both the solutions are mixed to form a clear homogenous mixture.
- The plate is lubricated evenly with glycerin and the mixture is poured in it.
- Then the resulting solution is allowed to dry and once it is dried the films are cut into needed size.

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Formulation	Ingredients									
	Naproxen (mg)	HPMC K_{15} (mg)	PVP (mg)	PEG (mg)	Ethyl cellulose (mg)	Glycerol (ml)	Propylene glycol (ml)	Ethanol	Menthol	Sucrose
F_1	100	200	100	20	20	1	-	q.s	q.s	q.s
F_2	100	250	100	20	20	1	-			
F_3	100	200	100	20	20	-	1			
F_4	100	250	100	20	20	-	1			

Table 01: Formulation flow chart

EVALUATION OF NAPROXEN BUCCAL FILMS:

1. Weight of the film

Buccal film is weighed by calibrated weighing balance. Individual weight of each film is calculated. Average weight is calculated and analyzed.

2. Thickness

Thickness of buccal film is evaluated by calibrated micrometer screw gauge. The thickness is measured at five different points of the film and means value is calculated. This is done to ensure the uniformity in the thickness of the film as it is directly correlated with accuracy of dose in the film and supports the reproducibility of the method used for the formulation.

3. Film clarity

Examine the buccal film visually for any defects such as cracks, discoloration, or uneven distribution of the film material.

4. Light transmission test

Hold the buccal film against a light source to assess its transparency. Clarity is often associated with the film's ability to transmit light uniformly

5. Surface smoothness

Run your fingers over the surface of the buccal film to check for smoothness. A rough or uneven surface may indicate a lack of clarity.

6. Folding endurance

The test is performed by folding the films numerous times repeatedly until the films begin to crack or break. The test is occasionally limited to a maximum of 300 folds, and the value is stated as the number of folds the film can withstand before rupturing.

7. FTIR spectral analysis

FTIR study was carried out to check the identity of drug and to determine the drug and excipient compatibility studies. Infrared spectrum of Naproxen was determined using brucker's spectrophotometer. It involves passing light through a sample and measuring the intensity of the transmitted light at different wavelengths. This information is used to create a spectrum, which reveals details about the sample's composition.

III.RESULTS AND DISCUSSION

Weight of the film

The films are weighed individually and the average is taken.

Formulation	Individual weight (mg)	Average (mg)
F_1	102.3	102.8
F_2	101.8	
F_3	105.9	
F_4	101.4	

Table 02: Weight measurement of films

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Thickness

The thicknesses of the films are calculated individually and the mean are taken into consideration.

Formulation	Individual thickness	Average
F_1	0.1	0.1
F_2	0.1	
F_3	0.1	
F_4	0.1	

Table 03: Thickness measurement of films

Film clarity

The films are evaluated under visual inspection and the results are declared.(Table – 4)

Light transmission test

The films are placed in front of light and the transmitted light is observed and the results are declared. (Table – 4)

Surface smoothness

The films are evaluated for their surface smoothness and the results are declared. (Table – 4)

Folding endurance

The films are folded for numerous times repeatedly and the time in which crack or braking of films occurs is recorded.

(Table – 4).

Formulation	Film clarity	Light transmission test	Surface smoothness	Folding endurance
F_1	Clear	Clear	Smooth	250<
F_2	Clear	Clear	Smooth	250<
F_3	Clear	Clear	Smooth	250<
F_4	Clear	Clear	Smooth	250<

Table 04: Physical properties of films

ANALYTICAL METHODS:

Determination of λmax by using methanol

The maximum absorption for naproxen standard solution (250 µg/ml) was measured between 200 – 400 nm by using methanol was found to be 230 nm and it is shown in the following figure

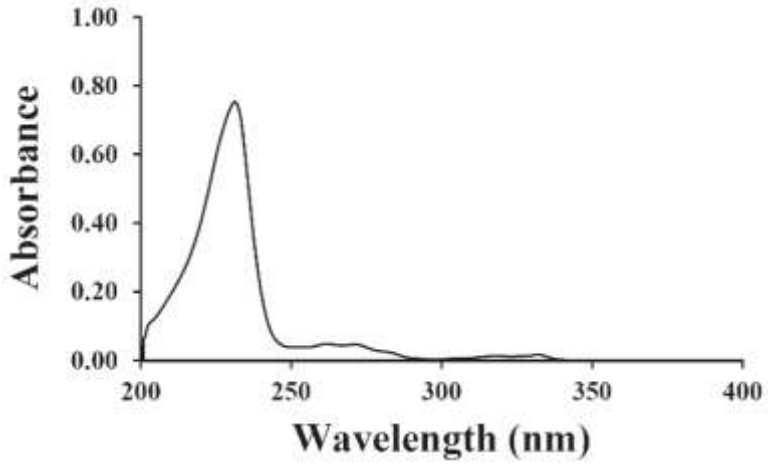

Figure 01: Absorption spectrum of Naproxen standard solution against Methanol blank.

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Preparation of standard curve of naproxen in Methanol

UV absorption spectrum of naproxen in methanol showed λmax at 230 nm. Absorbance obtained for various concentration of naproxen in methanol are given in table. The graph of absorbance vs concentration for naproxen was found to be linear in the concentration range of 10 - 40 µg/ml. The drug obeys Beer – Lambert's law in the range of 10 - 40 µg/ml.

S.No	Concentration (µg/ml)	Absorbance (nm)
1	10	1.15
2	20	1.96
3	30	2.81
4	40	3.68

Table 05: Data of absorbance vs concentration for naproxen

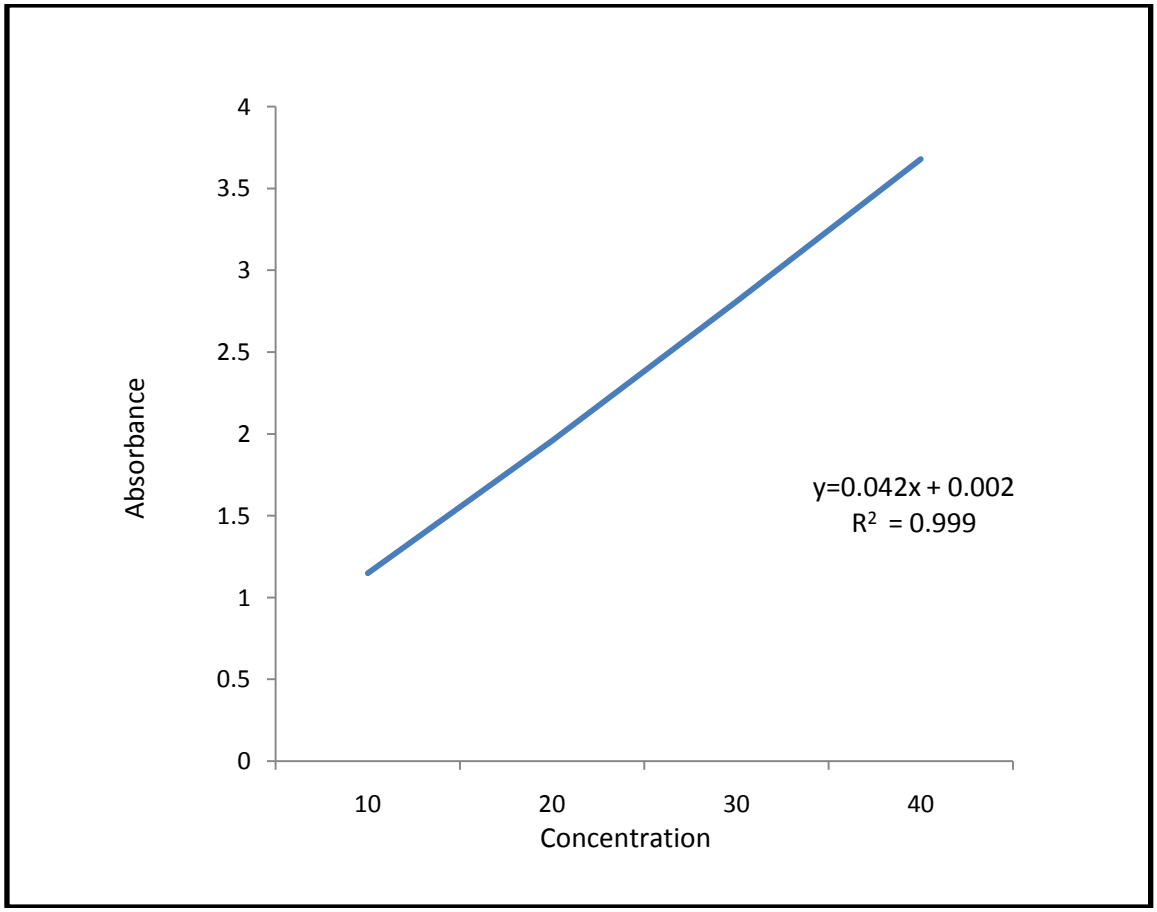

Figure 2: Standard graph of Naproxen in methanol

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FTIR Spectral Analysis:

Identification Of Naproxen By FTIR Spectroscopy:

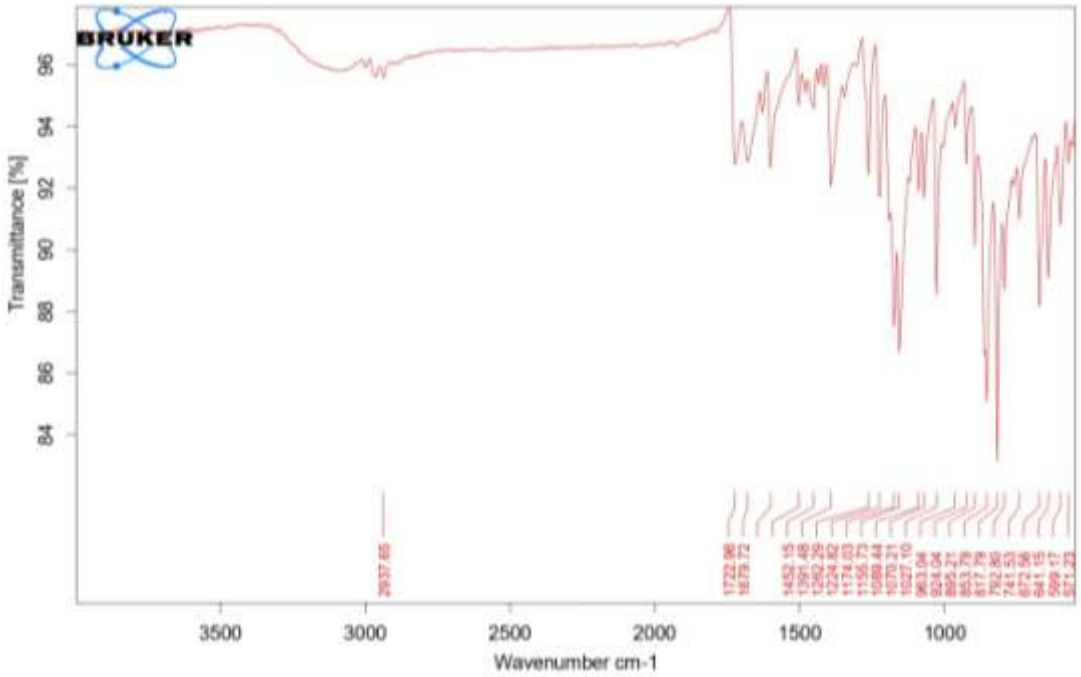

Figure: FTIR spectrum of pure drug Naproxen

Drug Excipient Compatability Studies

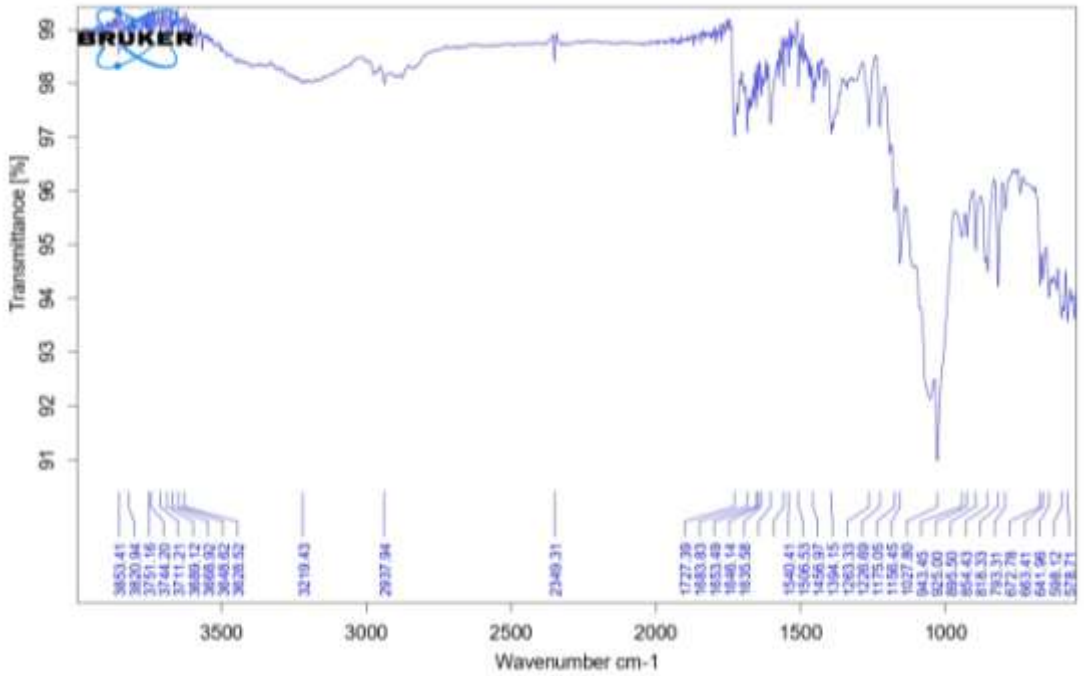

Figure FTIR spectrum of pure drug Naproxen and HPMC K15

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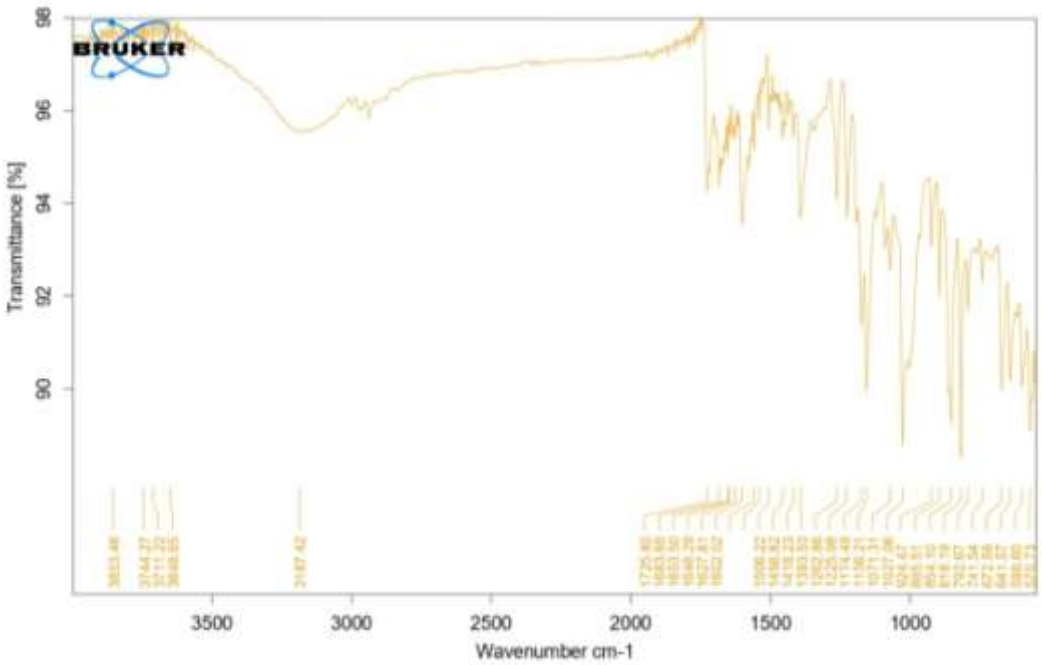

Figure : FTIR spectrum of pure drug Naproxen and ethyl cellulose

IV.CONCLUSION

The developed Naproxen mucoadhesive film containing HPMC polymer is satisfied in terms of good bioadhesive characteristics and contolled drug release thereby reducing the dosing frequency and prevents hepatic metabolism. In comparison of the formulations F_2 and F_4 shows extended drug release time.

REFERRENCE

[1]. M.A. Hassan, N.S. Barakat, M. El-Badry, S.M. Shehata Formulation and in vitro/in vivo evaluation of naproxen

[2]. mucoadhesive buccal patches for local effect J. DRUG DEL. SCI. TECH., 21 (5) 423-431 2011

[3]. Dipak Malpure Rajaram, Sharada Deore Laxman, and Buccal Mucoadhesive Films: A Review. Sys Rev Pharma. 2017;8(1):31–38

[4]. Singh, Sharma, and Garg, "Review on Mucoadhesive Drug Delivery System Emphasis on Buccal Route: An Important Tool in Designing of Novel Controlled Drug Delivery System for the Effective Delivery of Pharmaceuticals." J Dev Drugs 2017; 6:1.

[5]. Vyas Heli Rajeshkumar, Dr. Darshit Ram, and Sheetal Buddhadev, Recent Trends and Advances in Buccal Film Drug Delivery System: An Innovative Pharmaceutical Dosage Form Technology. International Journal of Pharmaceutical Sciences, 74(1), May–June 2022; Article No.27, 161–172.

[6]. Tochukwu C. Okwuosa, Laxmi Kerai-Varsani, Lewis Shipp, Fang Liu, and Buccal films: A review of therapy options, formulations, and pertinent assessment methodologies. 2022; 1071-1092.

[7]. Vishakha Dhananjay Jagtap Buccal Film - A Review on Novel Drug Delivery System Vol.7; Issue: 6; June 2020.

[8]. Radha Madhavi , Varanasi SN Murthy, Prameela Rani and Dileep Kumar Gattu Buccal Film Drug Delivery System-An Innovative and Emerging Technology J Mol Pharm Org Process Res 2013, 1:3

[9]. Venkatalakshmi R., SudhakarY., Madhu C., Varma M. (2012), Buccal Drug Delivery System Using Adhesive Polymeric Patches, Int. J. Of PharmSci and Res., 3(1):35-41.

[10]. Mishra S. A Review article: Recent Approaches in buccal patches. The Pharma Innovation 2012; 7(2):12.

[11]. Swathi E., Swapna D., Konasree S.D., Sindhu R. K., and Narasimha R. R. formulation and assessment of fast dissolving buccal patches. 2011; 1(3):145-

159 in International Journal of Pharma and Bio Sciences.

[12]. Ragvendra NG, Shravani B, Reddy MS. Overview on buccal drug delivery systems. Journal of pharmaceutical science and research.2013;5(4):80-88

[13]. Mahajan A, Chhabra N, Aggarwal G. Formulation and characterization of fast dissolving buccal film. Scholars Research Library.2011;3(1):152-165.

[14]. Tayal S, Jain N.Buccal conrol drug delivery system:a review. International journal of Pharmaceutical science and research. 2011; 2(1):13-24.

[15]. Akhter H. A comprehensive review on buccal drug delivery. Int. J of Pharmaceutical Research and development. 2011; 3(1):59-77.

[16]. Chinna RP, Chaitanya KSC, Madhusudan RY. A review on bio adhesive Buccal drug delivery systems: current status of formulation and evaluation methods. Daru. 2011; 19(6):385-403.

[17]. Gilhotra RM, Ikram M, Srivastava S, Gilhotra N. A clinical perspective on mucoadhesive Buccal drug delivery systems. J Biomed Res. 2014; 28(2):81-97.

[18]. Hyma P., Sakeena Fatima formulation and evaluation of oral fast dissolving films of naproxen sodium int j curr pharm res, vol 14, issue 2, 48-53original article