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Formulation and Evaluation of Oral Mucoadhesive Buccal Films of Famotidine

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ABSTRACT
The goal in formulating oral mucoadhesive buccal films of selective H2 receptor antagonist of famotidine is to increase the bioavailability, minimize the dose and reduce the side effects and to improve the patient compliance. Buccal drug delivery is an alternative method of systemic drug delivery that offers several advantages over both injectable and enteral methods. Buccal and sublingual sectors are the most commonly used routes for drug delivery and they may be used for the treatment of local or systemic diseases. The Aim of the study is related to the formulation and evaluation of oral mucoadhesive buccal films of famotidine by solvent casting technique. The Preparation contains 15 formulations by using different polymers like Hydroxy Propyl Methyl Cellulose - 15 cps (HPMC), Carbopol (CP) and Poly vinyl pyrrolidone (PVP). The prepared batches of oral mucoadhesive buccal films of famotidine were evaluated for the physico chemical evaluations like surface pH, PMA, PML, swelling percentage, WVT, thickness, weight, folding endurance and drug content, the ex-vivo bucco adhesive strength, Ex-vivo permeation studies, in-vitro release studies and in-vivo release studies in rabbits were performed. The satisfactory results were obtained in all prepared formulations and based on the results F14 (150mg) +CP (25mg) +PVP (25mg) was the best one when compared to other.

Key Words: Hydroxy Propyl Methyl Cellulose (HPMC), Poly vinyl pyrrolidone (PVP) Percentage Moisture Absorption (PMA) Percentage Moisture Loss (PML) and Water Vapour Transmission Rate (WVT).

I. INTRODUCTION

Buccal drug delivery is an alternative method of systemic drug delivery that offers several advantages over both injectable and enteral methods. The parenteral route may give excellent bioavailability but suffers from poor patient compliance and various risks such as anaphylaxis and extravasation infection. Peroral administration of pharmaceutical compositions has some drawbacks. For instance, it is difficult to keep the medicament at the desired location so that it can be absorbed, distributed and metabolized easily. These limitations have driven the development of alternative routes of administration. Absorptive mucosa has been attracting extensive research, as they offer many benefits, such as noninvasive administration, rapid onset of action, good bioavailability, avoiding of hepatic first pass metabolism and reduced side effects[1].

Buccal and sublingual sectors are the most commonly used routes for drug delivery and they may be used for the treatment of local or systemic diseases. The permeability of the oral mucosa is probably related to the physical characteristics of the tissues. The sublingual mucosa is more permeable and thinner than the buccal mucosa and because of the considerable surface area and high blood flow; it is a feasible site when a rapid onset is desired. The sublingual route is generally used for drug delivery in the treatment of acute disorders, but may not be always useful as its surface is constantly washed by saliva and tongue activity which makes it difficult to keep the dosage form in contact with the mucosa.

Advantages

1. It is richly vascularized and more accessible for administration and removal of dosage forms[2].
2. High patient accessibility.
3. An expanse of smooth muscle and relatively immobile mucosa, suitable for administration of retentive dosage forms.
4. Direct access to systemic circulation through the internal jugular vein bypasses drugs from hepatic first pass metabolism, leading to high bioavailability.
5. Bypass exposure of the drugs to the gastrointestinal fluids.
6. More rapid cellular recovery and achievement of a localized site on smooth surface of buccal mucosa.
7. Low enzyme activity, suitability for drugs/ excipients that mildly and reversibly damages or irritates the mucosa.
8. Non-invasive method of drug administration.
9. Facility to include permeation enhancer or enzyme inhibitor or pH modifier in the formulation.

Disadvantages

1. Low permeability of buccal membrane[2].
2. Small surface area (170 cm^2).
3. Subsequent dilution of the drug due to continuous secretion of saliva.
4. Inconvenience of patient when eating or drinking.

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Limitations

1. Effect of salivary scavenging and accidental swallowing of delivery system.
2. Barrier property of buccal mucosa.
3. Relatively small absorption area.

II. MATERIALS AND METHODS

Famotidine was obtained as a gift sample from Richer pharmaceuticals, Hyderabad. Hydroxy Propyl methyl cellulose K4M from Richer pharmaceuticals, Poly vinyl pyrrolidine, Carbopol were obtained as a gift sample from Drugs India, Hyderabad.

Table 1 : The Composition of Buccal Films Prepared Using Famotidine

Formulation code	Polymers in mg			Solvents in ml	
	HPMC	CP	PVP	Ethanol (70 % v/v)	PG
F1	200	0	-	9	1
F2	190	10	-	9	1
F3	180	20	-	9	1
F4	170	30	-	9	1
F5	160	40	-	9	1
F6	150	50	-	9	1
F7	190	-	10	9	1
F8	180	-	20	9	1
F9	170	-	30	9	1
F10	160	-	40	9	1
F11	150	-	50	9	1
F12	150	35	15	9	1
F13	150	30	20	9	1
F14	150	25	25	9	1
F15	150	15	35	9	1

Famotidine: 20 mg

FABRICATION OF DRUG FREE BUCCAL FILMS

The buccal mucoadhesive films were prepared by the method of solvent casting technique[3,4] employing 'O' shape ring placed on a glass surface as substrate by using different polymerslike Hydroxy Propyl Methyl Cellulose - 15 cps (HPMC), Carbopol(CP) and Poly vinyl pyrrolidone (PVP).

The calculated quantities of polymers were dispersed inethanol (70 %). The carbopol polymeric solution was neutralized using triethanolamine. The polymeric solutions are levigation with 30 % w/w propylene glycol which served the purpose of plasticizer as well as penetration enhancer. The solution was mixed occasionally to get semisolid consistency. Then the solution was subjected to sonication in a bath sonicator to remove the air bubbles Then this were casted on a glass surface employing 'O' shape ring having 3.6 cm in diameter is covered with funnel to controlling the evaporation of solvent and allowed to dry at room temperature over night. The dried films were separated and the backing membrane used

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was aluminium foil. Then the formulations were stored in desiccators until further use.

CONSTRUCTION OF CALIBRATION CURVE

An accurately weighed 100 mg of Famotidine was dissolved in pH 7.4 phosphate buffer as per I.P and make up the volume up to 100 ml in a volumetric flask, (Stock Solution: I, 1000 µg/ml) . From this 5 ml of solution were pipette out and make up the volume up to 100 ml (Stock Solution: II, 50µg/ml). Then the aliquots were prepared, whose concentration ranging from 0 to 30 µg/ml and the absorbance were measured at 272 nm[3] by using UV Spectrophotometer Labomed, (Model No: 2602) against the reagent blank.

PHYSICO - CHEMICAL EVALUATION

1. SURFACE pH

Buccal films were left to swell for 2 h on the surface of an agar plate, prepared by dissolving 2 % (w/v) agar in warmed isotonic phosphate buffer of pH 6.8 under stirring and then pouring the solution into a petridish till gellig at room temperature. The surface pH[31] was measured by means of a pH paper placed on the surface of the swollen patch. The mean of two reading was recorded.

2. PERCENTAGE MOISTURE ABSORPTION (PMA)

The percent moisture absorption test[6] was carried out to check the physical stability of the buccal films at high humid conditions. In the present study the moisture absorption capacity of the films were determined as follows. Three 1cm diameter films were cut out and weighed accurately then the films were placed indesiccators containing saturated solution of aluminium chloride, keeping the humidity inside the desiccators at 79.5 %. After 3 days the films were removed, weighed and percentage moisture absorption was calculated. Average percentage moisture absorption of three films was found.

$$\text{Percentage Moisture Absorption} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \text{X10}$$

3. PERCENTAGE MOISTURE LOSS (PML)

This test was also carried to check the integrity of filmsat dry condition. Three 1cm diameter films was cut out and weighed accurately and kept in desiccators containing fused anhydrous calcium chloride. After 72 hours the films were removed and weighed. Average percentage moisture loss of three films wasfound out.

$$\text{Percentage Moisture Loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \text{X100}$$

4. SWELLING PERCENTAGE (%S)

A drug loaded films were placed in a thoroughly cleaned petridish having 50 ml of pH 6.8 phosphate buffer. An increase in the weight of the patch was noted in 15 min intervals for 60 min and the weight was calculated. The swelling percentage was calculatedby using the following formula,

$$\% S = \frac{X_t - X_0}{X_0} X100$$

Where, % S - swelling percentage

Xt - the weight of swollen film after time t, X0 -weight of film at zero time.

5. WATER VAPOUR TRANSMISSION RATE (WVT)

For this study vials of equal diameter were used as transmission cells. These cells were washed thoroughly and driedin an oven. About 1 g of calcium chloride was taken in the cell and the polymeric films measuring 1 cm^2 area were fixed over the brim with the help of an adhesive. The cells were weighed accurately and initial weight was recorded, and then kept in a closed desiccators containing saturated solution of potassium chloride. The humidity inside the desiccators was found in between 80 – 90 % RH. The cells were taken out and weighed after 18, 36, 54 and 72hrs. From increase in weights the amount of water vapour transmitted and the rate at which water vapour transmitted were calculated by using the following formula.

W V T = WL/S

Where, W is water vapour transmitted in mg, L is thickness of thefilm in mm, S is exposed surface area in cm^2.

6. THICKNESS

The thickness of each film was measured by using a digital vernier caliper at six different positions of the film and the average thickness was calculated.

7. WEIGHT OF FILMS

The weights of three films were taken and the weight variation was calculated.

8. FOLDING ENDURANCE

Folding endurance of the film was determined by repeatedly folding one patch at the same place till it broke or folded upto 300 times manually, which was considered satisfactory to reveal good film properties. The number of times of film could be folded at the same place without breaking gave the value of the folding endurance. This test was done for three films.

9. DRUG CONTENT ESTIMATION

A film was cut into three pieces of equal diameter weretaken in separate 100 ml of pH 6.8 phosphate buffer was added and continuously stirred for 24 h. The solutions were filtered, suitably diluted and analyzed at 272 nm in a UV Spectro photometer. The average of drug content of three films was takenas final reading.

MEASUREMENT OF BUCCOADHESIVE STRENGTH

A modified balance method was used for determining the ex-vivo buccoadhesive strength. Fresh sheep buccal mucosa was obtained from a local slaughterhouse and used within 2 h of slaughter. The mucosal membrane was separated by removing the underlying fat and loose tissues. The membrane was washed with distilled water and then with isotonic phosphate buffer (IPB) pH 6.8 as

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moistening fluid. Sheep Buccal mucosa was fixed on the plane surface of glass slide attached (with adhesive tape) to bottom of smaller beaker, kept inverted in 500 ml beaker attached to the bigger beaker. Isotonic phosphate buffer pH 6.8 was added to the beaker up to the upper surface inverted beaker with buccal mucosa. The buccal film was stuck to the lower side of the upper clamp with cyanoacrylate adhesive. The exposed patch surface was moistened with IPB and left for 30 s for initial hydration and swelling. Then the platform was slowly raised until the film surface came in contact with mucosa. Two sides of the balance were made equal before study by keeping a weight on the right hand pan. A weight of 5 g was removed from the right hand pan, which lowered the pan along with the patch over the mucosa. The balance was kept in this position for 5 minutes contact time. Then weights were slowly added to the right hand pan until the film detached from the mucosal surface. This detachment force gave the buccoadhesive strength of the buccal film in grams. The following parameters were calculated from the bioadhesive strength.

Force of adhesion (N) = (Bioadhesive strength (g) ×9.8)/1000

Bond strength (N m–2) = Force of adhesion / surface area

EX-VIVO PERMEATION STUDIES

An ex-vivo diffusion study of Famotidine was carried out using a fresh sheep buccal mucosa[11] using modified diffusion cell at 37 ± 1°C. Fresh sheep buccal mucosa was mounted between the donor and receptor compartments. Sheep Buccal mucosa was tied to one end of an open-ended cylinder, which acts as a donor compartment. The film should be placed in such a way that it should be stuck on the mucous membrane.

The receptor compartment was filled with isotonic phosphate buffer pH 6.8. The assembly was maintained at 37 ºC and stirred magnetically. Samples were withdrawn at predetermined time intervals and analyzed using UV - Spectrophotometer at 272 nm.

IN-VIVO DRUG RELEASE STUDY

Selection of Animals

Rabbits of 10 – 12 weeks old weighing 2.5 to 3 kg was selected.

Method

A healthy rabbit[12] weighing 2.5 to 3 kg was taken which was already checked for absence of any diseases. The fore limbs and hind limbs were tied into the iron rod of the mini operation

III. RESULTS AND DISCUSSION

Table; so that rabbit was in dorsal position (Fig.7.). The dose of famotidine was adjusted based on the rabbit weight i.e the optimized formulation F14 were cut to several pieces containing about 1 mg of drug was placed in the buccal membrane with the help of a clip. Dextrose solution was transfused continuously throughout the period of study. Periodically 1ml of blood sample was taken by syringe, which already contained 1 ml of heparin solution to prevent blood clotting. These blood samples were subjected for centrifuging at 2,500 rpm for about 30 minutes. 1 ml of supernatant was taken, and after suitable dilution, analyzed at 272 nm using UV spectrophotometer.

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Table 2: Calibration Curve Data Of Famotidine

Concentration In µg/Ml	Absorbance At 272 Nm
0	0
2	0.067
4	0.135
6	0.203
8	0.272
10	0.340
12	0.407
14	0.475
16	0.550
18	0.611
20	0.680
22	0.747
24	0.815
26	0.883
28	0.950
30	1.020

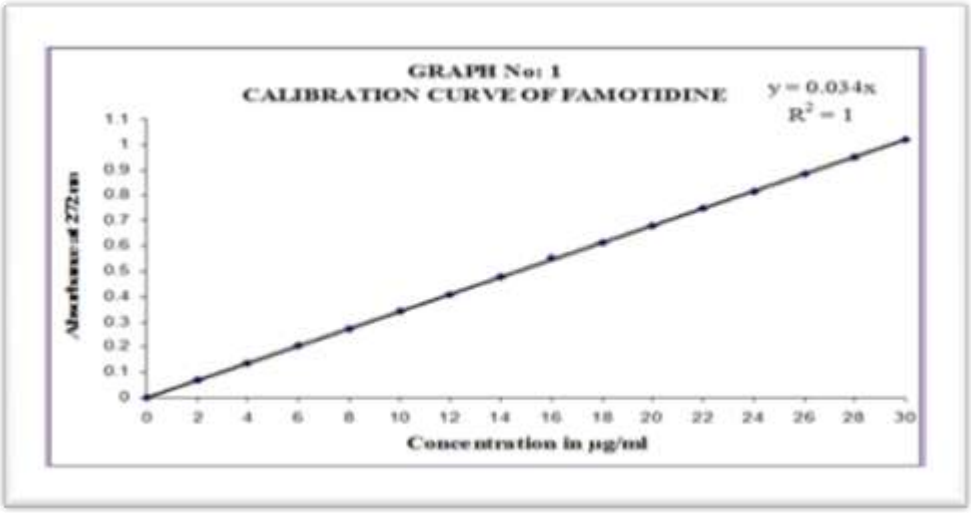

Figure 1: Calibration Curve Data of Famotidin

Table 3 : Physicochemical Evaluation of Buccal Films of Famotidine

Formulation Code	Surface pH ± SD	PMA ± SD	PML ± SD	Swelling Index ± SD
F1	6.73±0.005	5.21±0.07	5.97±0.12	69.4±1.04
F2	6.79±0.005	7.32±0.04	5.14±0.72	99.67±0.69
F3	6.71±0.015	9.24±0.09	4.74±0.1	118.4±0.72
F4	6.64±0.050	10.32±0.11	4.14±0.2	124.15±0.99
F5	6.6±0.015	12.13±0.09	4.08±0.03	132.36±0.61
F6	6.52±0.03	14.21±0.06	3.88±0.02	138±0.85
F7	6.7±0.03	7.86±0.27	6.44±0.1	67.53±0.65
F8	6.8±0.015	6.18±0.13	7.13±0.08	69.7±0.72
F9	6.77±0.005	5.34±0.12	9.12±0.07	71.6±0.62
F10	6.8±0.001	4.12±0.13	10.06±0.06	78.6±1.07

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F11	6.81±0.001	3.56±0.25	11.21±0.06	82.6±1.1
F12	6.71±0.001	13.02±0.23	4.84±0.08	86.9±0.9
F13	6.67±0.005	11.26±0.24	5.72±0.01	77.4±0.7
F14	6.63±0.005	9.89±0.22	6.13±0.02	72.53±0.6
F15	6.61±0.017	7.02±0.06	7.45±0.52	69.56±0.65

Table 4: Physicochemical Evaluation of Buccal Films of Famotidine

Formulation Code	WTR SD	Thickness (mm) SD	Weight of films in mg SD	Drug Content in mg
F1	10.58±0.35	0.24±0.01	180.93±1.55	19.7
F2	7.67±0.34	0.62±0.01	163.18±0.9	18.9
F3	7.17±0.34	0.47±0.01	171.53±0.81	18.1
F4	6.4±0.35	0.59±0.01	186.31±0.58	19.76
F5	5.98±0.08	0.85±0.02	191.37±0.85	18.76
F6	5.39±0.32	0.31±0.01	210.12±1.06	18.43
F7	10.87±0.35	0.22±0.02	181.17±1.79	19.7
F8	11.48±0.52	0.2±0.01	172.35±1.11	18.6
F9	11.58±0.43	0.23±0.01	172.31±1.11	19.1
F10	12.3±0.59	0.25±0.01	174.37±1.11	18.2
F11	12.44±0.48	0.31±0.01	174.94±1.66	19
F12	5.69±0.2	0.48±0.02	172.23±0.91	18.6
F13	5.91±0.38	0.43±0.01	170.37±0.65	18.9
F14	6.32±0.2	0.36±0.01	171.07±0.93	19.9
F15	6.94±0.31	0.32±0.01	182.43±0.5	19.3

Table 5: Measurement of Buccoadhesive Strength of Buccal Films of Famotidine

Formulation code	Buccoadhesive strength in gm
F1	15.4
F2	15.5
F3	16.6
F4	20.5
F5	27.8
F6	32.5
F7	15.3
F8	17.4
F9	19.8
F10	24.8
F11	26.7
F12	34.2
F13	34.8
F14	35.6
F15	33.4

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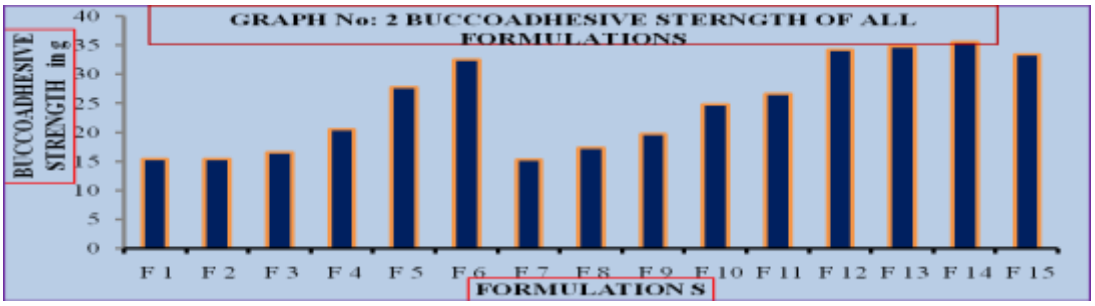

Table 6: In-Vitro Drug Release Data for Buccal Film F1-F15

TIME IN Hrs	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
1	18	24	19	14	9.8	7.2	16	14
2	28.2	30.1	29.6	22.4	20	17.2	24.6	22.1
3	35.2	37.6	36.1	33.9	29.4	25.6	33.2	32.6
4	47.2	49.6	48.6	44	41.6	39.2	44	43
5	55.4	57.1	55.6	52.4	50.1	48.6	50.4	49
6	67.2	70.1	68.1	64.2	62.4	59	58.2	57.4
7	74.6	77.9	75.4	71.6	69	67.2	70	68
8	83.2	85.6	84	79.2	76.4	73.1	75.2	74
9	88.6	90.2	89.6	84	81.2	79.6	82	81.2
10	95.2	96	95.6	92	89	87.2	90	88.9
11	-	-	-	98.1	96.2	94.4	96.6	95.2

TIME IN Hrs	F9	F10	F11	F12	F13	F14	F15
0	0	0	0	0	0	0	0
1	11	9	7.2	3.12	4.62	6.62	5.21
2	20	18.4	15.2	10.2	11.1	15.6	13.2
3	30	29.2	24.9	16	18.1	23.6	20.1
4	42.2	40.4	35.9	28.2	29.6	30.6	29.9
5	47.2	46	44.9	40.1	41.4	43.2	42.9
6	55.2	54.8	52	46.2	47.9	50.2	48.9
7	65	63	61	54	56.2	61.4	58.9
8	73.2	71	69	67	68	70.2	69.2
9	80	79	78	76.6	77.4	79.2	78.1
10	87.1	86.2	85	83.2	84	86.4	85
11	94	93.2	91	89.4	90.6	92.2	91
12				94.4	96.2	98.2	97

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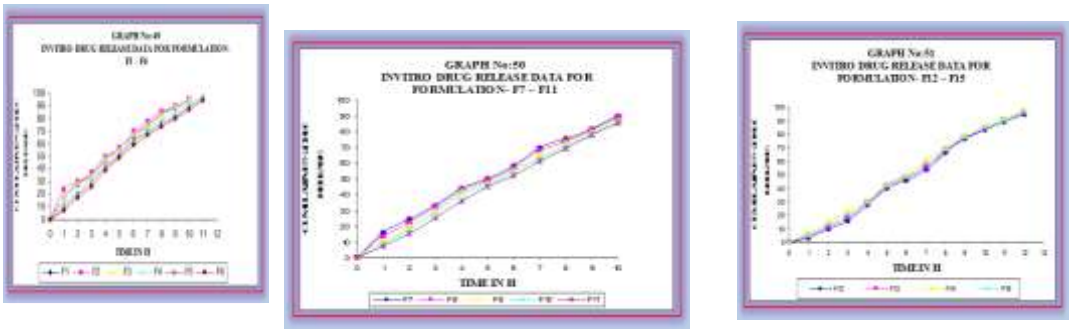
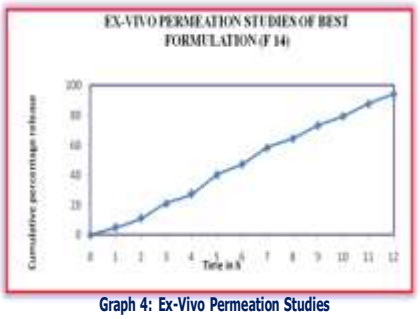


Graph 3: In-Vitro Drug Release Data For Buccal Film F1-F15 Table No: 7 Ex-Vivo Permeation Studies of Best Formulation (F 14)

Time (h)	Cumulative % Drug Release
0	0
1	5.16
2	11.12
3	21.02
4	27.41
5	40.23
6	47.42
7	58.31
8	64.4
9	73.2
10	79.4
11	87.6
12	94.23



Graph 4: Ex-Vivo Permeation Studies

Table 8: In-Vivo Drug Release Data For Best Formulation F 14 [HPMC (150 Mg) + CP (20 Mg) + PVP (30 Mg)]

Time in hours	Amount of drug release (mg)	Cumulative percentage drug release
1	0.84	4.23
3	4.178	20.89
6	8.956	44.37
9	13.29	66.45
12	18.08	90.4

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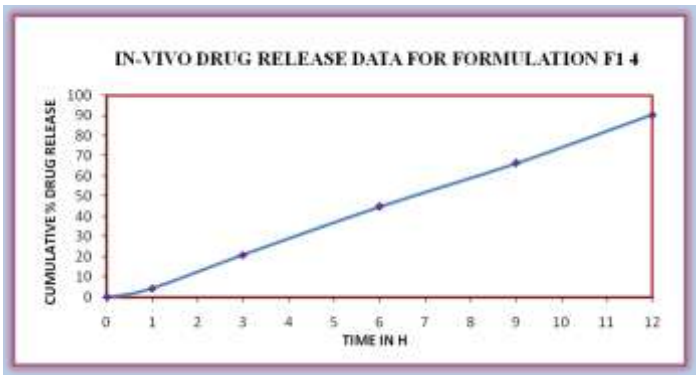
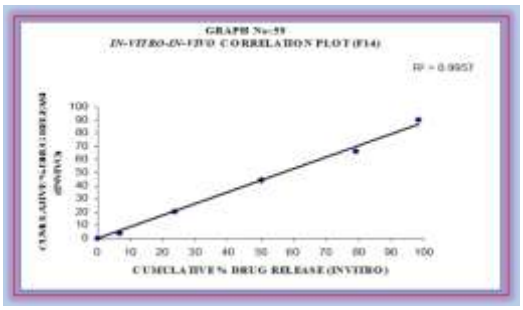


Graph 5: In-Vivo Drug Release Data For Best Formulation F 14 Table 9: In-Vitro In-Vivo Correlation Data

Time in hours	Cumulative % drug release in-vivo	Cumulative % drug release in-vitro
1	4.23	6.62
3	20.89	23.6
6	44.37	50.2
9	66.45	79.2
12	90.4	98.2



Graph 6: In-Vitro In-Vivo Correlation Data

IV. DISCUSSION

The Famotidine buccal mucoadhesive films were prepared by the method of solvent casting technique employing 'O' shape ring placed on a glass surface as substrate by using different polymers such as Hydroxy Propyl Methyl Cellulose - 15 cps (HPMC), Carbopol-P 934 (CP) and Poly vinyl pyrrolidone (PVP). Ethanol (70

% v/v) is used as the solvents. Propylene glycol serves as the plasticizer as well as penetration enhancer. Triethanolamine was used to neutralize the carbopol polymeric solution.

In-vitro drug release studies

Distinguishable difference was observed in the release of Famotidine in all formulations. The resultsand data of in vitro studies are shown in the Table and the individual graphs were shown. Formulations F1, F2, F3 containing HPMC alone and Combination of carbopol and HPMC gave a reasonable Famotidine release up to 10 h.

Formulations F4, F5 and F6 containing Combination of carbopol and HPMC gave a reasonable Famotidine release up to 11 h.

The formulations F1, F2, F3, F4, F5 and F6 has shown release 95.2%, 96%, 95.6 %, 98.1 %, 96.2 % and 94.4 % respectively the drug release was Non fickian release in case of formulations F1 and F2 and Super case II transport type in of case of formulations F3, F4, F5 andF6.

Formulations F7, F8, F9, F10 and F11 containing Combination of HPMC and PVP gave a reasonable Famotidine release up to 11 h.

The formulations F7, F8, F9, F10, F11 and F12 has shown release 96.6 % , 95.2 % ,94 %, 93.2 %, and 91 % respectively The in-vitro drug release was Non fickian release in case of formulations F7 and Super case II transport type in

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of case of formulations F8, F9, F10 and F11.

Formulations F12, F13, F14 and F15 containing Combination of HPMC, CP and PVP gave a reasonable Famotidine release up to 12 h.

Formulations F12, F13, F14 and F15 has shown release 94.4% , 96.2% ,98.2% and 97% respectively The *in-vitro* drug release was Non fickian release in case of formulations F14 and Super case II transport type in of case of formulations F12, F13 and F15.

At pH 6.8, carbopol is present in ionized state and as a result the polymeric network gets loosened comparatively, attributing for the higher drug release. The addition of PVP decreases the Famotidine release may be due to enhancement in swelling of the polymer, which in turn increases the barrier effect and decreases the drug release, there by controlling the drug release approximately 12 h.

The incorporation of carbopol and PVP into HPMC films, the drug release was found to maximum at the end of 12th h.

***Ex-vivo* permeation studies**

The oral mucosa represents a barrier to drug permeation and it is intermediate between skin epidermis and the gut in its permeability characteristics. The effectiveness of the buccal barrier and whether buccal absorption could provide means for Famotidine administration can be determined by *Ex-vivo* permeation studies. Permeation studies were carried out on formulation F 14. The cumulative amount of drug permeated was 94.23 % maximum in 12 h.

***In-vivo* studies**

In-vivo buccal diffusion studies were conducted for the Famotidine buccal film F 14 in rabbits showed zero order release pattern. The *in-vivo* studies of buccal films of Famotidine in rabbits did not show any inflammation or any other sensitization reactions at the administration site.

SUMMARY AND CONCLUSION

The Famotidine buccal films were prepared by solvent casting technique using ethanol (70%v/v) as a solvent, employing o shape ring placed on a glass surface as substrate and by using different polymers like Hydroxy Propyl Methyl Cellulose-15cps (HPMC), Carbopol (CP) and Poly Vinyl Pyrrolidine (PVP).The polymeric solutions are levigated with 30%w/w propylene glycol which served the purpose of plasticizer as well as penetration enhancer. The prepared famotidine buccal films were characterized based upon their physico-chemical characteristics like surface PH, PMA, PML, swelling percentage, WVT, thickness, weight, folding endurance and drug content. the ex-vivo bucco adhesive strength, Ex-vivo permeation studies, in-vitro release studies and in-vivo release studies in rabbits were performed.

The satisfactory results were obtained in all prepared formulations and based on the results F14 (150mg) +CP (20mg) +PVP (30mg) was the best one when compared to other. Good correlation was observed between in-vitro and in-vivo profile, revealed the ability of the formulation to reproduce the in-vitro release pattern through the biological membrane. Hence famotidine oral mucoadhesive buccal films could be promising one as they increase bioavailability, minimize the dose reduces the side effects and improve patient compliance and also famotidine might be a right and suitable candidate for oral controlled drug delivery via mucoadhesive buccal films.

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CONFLICT OF INTEREST

Authors declare no Conflict of Interest

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