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Formulation and Evaluation of Famotidine Buccal Tablets

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ABSTRACT

Famotidine is a Histamine H_2- receptor antagonist used in the treatment of peptic ulcer disease and Gastroesophageal reflux disease. The aim of the present work is to formulate and evaluate famotidine buccal tablets by increasing drug solubility and permeability. Solid dispersions were prepared by solvent evaporation method to increase the drug solubility using guargum, SSG and HPMC as carriers, and methanol as solvent in different drugs to polymer ratio, in which optimised formulation is for the preparation of buccal tablets. Tablets were prepared by direct compression method using sodium alginate, sodium carboxy methylcellulose and carbopol as bioadhesive polymers. Prepared famotidine buccal tablets were evaluated and based on dissolution studies F2 is considered as optimized formulation of improving solubility of drug. Again solid dispersions were prepared with drug, guar gum and sodium lauryl sulphate (as penetration enhancer) in 0.5, 1, and 1.5% to increase drug permeability. By using solid dispersion containing SLS, buccal tablets were prepared and evaluated for Weight variation, Thickness, Hardness, Swelling studies, Bioadhesive strength, *invitro* Dissolution and Ex-*vivo* Diffusion studies. The sustained drug release and permeation was obtained for the formulation containing 1% SLS as permeation enhancer, sodium alginate and carbopol 1:2 ratio as bioadhesive polymers and the % release was 93.58%, diffusion was 89.92% after 8 hours. The developed buccal drug delivery of famotidine buccal tablets was one of the alternative routes of administration to avoid first pass metabolism and to improve bioavailability through buccal mucosa. It is capable of releasing the drug for sustained action to reduce the need of frequent administration and improve patient compliance.

Keywords: Bioadhesion strength, Ex-vivo Permeation, *In vitro* Dissolution.

INTRODUCTION

The aim and objective of the present work is to formulate and evaluate famotidine buccal tablets and to enhance the solubility and permeability of drug. It is also focused on the selection of bioadhesive polymers and its activity in various combinations and ratios. The first approach is to improve the drug solubility by solid dispersion technique (Rajeshree Panigrahi *et al*., 2011). The optimized solid dispersion containing guar gum 1:6 ratios is selected for the formulation of buccal tablets using three bioadhesive polymers *i.e*., sodium carboxy methyl cellulose, sodium alginate and carbopol 934P. The next approach is to improve the permeability of the drug. Hence, the optimized formulation is further formulated and evaluated by the addition of permeation enhancer (SLS) in solid dispersions in different concentrations (Alagusundaram M *et al*., 2010).

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MATERIALS AND METHODS

Famotidine (SMS pharmaceuticals Ltd., Hyderabad), Guargum, Sodium lauryl sulphate (HiMedia Pvt, Ltd. Mumbai), Sodium carboxy methyl cellulose, Sodium alginate, Carbopol 934P (HiMedia Pvt, Ltd. Mumbai), Talc (Otto chemicals, Mumbai), Magnesium stearate (Sd fine chemicals Ltd., Mumbai) and Ethyl cellulose (HiMedia Pvt, Ltd. Mumbai)

Preparation of famotidine buccal tablets

Accurately weighed quantity of optimized famotidine solid dispersions ($\cong$ 20mg of drug), bioadhesive polymers were blended homogeneously for 15 mins by triturating using glass mortar and pestle.

Magnesium stearate and talc were added and triturared for 2 mins. The powder blend was compressed using 8 mm round face punch with low compression force which acts as a core layer. Ethyl cellulose was blended for 15 mins and added on the surface of the core layer and compressed under tablet punching machine (Table No 1) (Harshal Narkhede *et al*., 2011, Vivekanand Prajapati *etal.*, 2012).

Preparation of buccal tablets containing permeation enhancer

Solid dispersions were prepared with optimized formulation *i.e.*, with 1:6 ratio of drug and guargum. In addition to it permeation enhancer (SLS) is added in 0.5, 1, 1.5% using methanol as solvent. It is then evaporated using a water bath at 45^0C followed by grounding, sieving through a sieve no 60 and stored in air tight containers. From this 20mg equivalent drug is weighed along with bioadhesive polymers and blended homogeneously for 15 mins by triturating using glass mortar and pestle. Magnesium stearate and talc were added and triturared for 2 mins. The powder blend was compressed by adding Ethyl cellulose as backing membrane (Table No 2) (Sumanjali Dodla *et al*., 2012).

Evaluation of famotidine buccal tablets

Post compression studies

Thickness: (Lachman L *et al*., 1987)

Tablet thickness of three randomly selected tablets was measured using digital vernier callipers. The average thickness for each tablet was calculated.

Hardness

It is the force required to break a tablet by compression in the radial direction. The crushing strength of the tablet was measured using Monsanto hardness tester. An average of three observations is calculated.

Friability

Friability of the tablets was determined using Roche friabilator. Pre-weighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. Conventional tablets that lose less than 1% of their weight are acceptable.

$$\% \text{ Friability} = \frac{W1 - W2}{W1} \times 100$$

Weight variation

The weight variation test is done by weighing 10 tablets individually, calculating average weight and comparing the individual tablet weights to the average. The tablets meet the USP test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

$$\%\text{weight variation} = \frac{\text{Avg Wt} - \text{Initial Wt}}{\text{Avg Wt}} \times 100$$

Drug content

Five tablets were taken and powdered; the powder ≅20 mg of famotidine was dissolved in 100 ml of phosphate buffer pH 6.8, filtered, diluted suitably to 20µg/ml concentration and analyzed at 272nm using UV-Visible spectrophotometer.

Surface pH

10ml of phosphate buffer pH 6.8 was taken and one tablet was kept in contact with the phosphate buffer solution pH 6.8 for 2hrs. The pH of the tablet was checked by placing the electrode of pH meter on the tablet for one minute.

Swelling studies

The swelling studies of the buccal tablets were evaluated in phosphate buffer pH 6.8. The initial weight of the tablet (W_1) was determined and then a tablet was placed in 6ml phosphate buffer pH 6.8 in a petridish and then was incubated at 37 ± 1^0C. The tablet was removed at different time intervals (0.5, 1, 2, 3, 4, 5, 6, 7 and 8hr) blotted with filter paper and reweighed (W_2). The swelling index was calculated by the formula:

Swelling index=$100(W_2-W_1)/W_1$

Where, $W_{1=}$ Initial weight of the tablet

$W_{2=}$ Final weight of the tablet

***Ex-vivo* bioadhesion strength**

A modified physical balance was used for determination of the *exvivo* bioadhesion strength. Fresh sheep buccal mucosa obtained from local slaughterhouse was cut into pieces, washed with distilled water followed by phosphate buffer pH 6.8. A piece of buccal mucosa was fixed to the apparatus with instant adhesive. The tablet was fixed on the sheep buccal mucosa using few drops of phosphate buffer pH 6.8. The other side tablet was attached to a pan that is attached to a pulley. To the pulley a pan was fixed which is used to keep the weights. A beaker was weighed initially and placed to balance the weight of physical balance on both sides. Water was poured drop wise on the other side of the balance until the tablet detached from the mucosal surface, after detachment the weight of the beaker was noted and from this the weight Of water is calculated. This detachment force gave the bioadhesion strength of the buccoadhesive tablet in grams (Tekade B.W *et al*., *2013*).

***In vitro* dissolution studies**

In vitro dissolution studies of famotidine buccal tablets were conducted with the USP type II apparatus. Phosphate buffer pH 6.8 was used as dissolution medium at 37 ± 0.5^0C with 50 rpm speed (G.Dinesh Babu *et al*., 2012).

***Ex-vivo* drug Permeation**

In vitro drug permeation was performed using Franz diffusion cell at 37±0.5°C. The sheep buccal membrane obtained from local slaughter house was mounted between the donor and receptor compartments. The tablet was placed on the membrane and the receptor compartment (15 ml capacity) was filled with phosphate buffer pH 6.8, and stirred by a magnetic stirrer at 50 rpm. 1 ml aliquot was withdrawn at predetermined time intervals (1, 2, 3, 4, 5, 6, 7 and 8hr) and replaced with

fresh medium. The aliquots were analyzed after appropriate dilution by UV spectrophotometer at 272 nm (Shital K.Thombre *et al*., 2013).

Drug release kinetics

To investigate the possible mechanisms of drug release from the prepared tablets, the drug permeated data were fitted to various kinetic models such as zero order, first order, Hixson Crowell's cube root model, higuchi and korsmeyer's peppas drug release kinetics (Chime Salome A *et al*., 2013).

Characterization of famotidine buccal tablets

Drug polymer interaction (FTIR) Study

FTIR study is useful to identify drug excipient interaction. FT-IR spectral measurements for famotidine buccal tablets were recorded using analytical 2202 FTIR spectrophotometer. About 2-3 mg of sample was mixed with KBr to prepare the pellets under a hydraulic pressure of 1000-1500 psi and samples were scanned from 5500-500 cm^{-1} spectral resolution.

Stability studies

The optimized formulation was closely packed in aluminium foils and then stored at 40^0 C ± 2^0 C /75% RH ± 5% in stability chamber for 3 months and evaluated for their physical appearance, drug content, *in-vitro* drug release and *Exvivo* studies at intervals of 1 month (Jasvir Singh *et al*., 2013).

RESULTS AND DISCUSSION

For tablets without permeation enhancer

The bulk density of all the formulations was found to be 0.453 to 0.542gm/ml whereas the tapped density was observed between 0.568 to 0.659gm/ml. From the values of bulk density and tapped density the values for compressibility index and hausner's ratio were calculated. The values for Carr's index were found between 18.36 to 20.89%. The values for hausner's ratio were found in between 1.220 to 1.226. All these values are within the specified limit. Angle of repose was found to be less than 33. Overall these values indicate good flow properties of powder blend, uniform die fill and better compression ability (Table.3).

The thickness of all formulations was found to be uniform as it was obtained in the range of 4.04 to 4.35 mm. Hardness test for all formulations was carried out and observations obtained were in the range of 5.52 to 7.28 kg/cm^2. Hardness for all formulations was observed to be proper, which signify that crushing strength of all formulations was maintained after direct compression. % Friability test of all formulations was found to be in the range of 0.42 to 0.75. % friability of all formulations indicated that it was less than 1%, which showed the I.P specification and reveals that all formulations have possessed good physical strength and can withstand the mechanical shocks that can be observed during handling, shipping and transportation. The % weight variation of all formulations was found to be less than 4.57%. None of the tablet was found to deviate from the average weight of tablets (variation with deviation less than ± 7.5, which complies with USP specification) signifies that there is uniformity in flow of powder blend which leads to uniform die fill. Drug content of all formulations was observed between 90.68 to 96.03%. Drug content of all the formulations was uniform, which indicated that there was uniform flow and uniform distribution of drug. The surface pH of all the formulations was determined. The pH was maintained between 6.43-6.77 (Table.4).

The swelling studies for all nine formulations were performed and it was observed that as the polymer concentration increased, there was a marked increase in the swelling index up to some extent. This was observed in all the formulations. The maximum swelling index was observed in formulation F6 containing sodium CMC and carbopol with 86.36% in 8 hrs (Table.5).

The bioadhesive strength of the tablets was found to be a function of nature and concentration of polymer. The tablets with sodium alginate and carbopol 934P showed bioadhesive strength between 20.32to 25.74 gm. The tablets with Sodium CMC and carbopol 934P showed bioadhesive strength between 20.28 to 25.57 gm. Tablets with Sodium CMC and sodium alginate gave bioadhesive strength between 20.10 to 24.21 gm. The bioadhesive strength exhibited by the tablets containing Carbopol 934P and Sodium alginate in 1:2 ratios were considered satisfactory for maintaining them in the oral cavity. The force of adhesion for all the formulations was found to be in the range of 1.971-2.525N (Table.6).

In *invitro* drug release studies, formulations F1 to F3 containing sodium alginate and carbopol, an increase in concentration of Carbopol 934P was found to sustain the drug release over an extended period of time. In formulations F4 to F6 containing sodium CMC and carbopol, an increase in concentration of carbopol, extended the drug release over a period of 8 hours. Formulations F7 to F9 showed quick release as the concentration of polymer increased tablets containing sodium CMC and sodium alginate. So, F2 is considered as optimized formulation of improving solubility of drug (Table.7).

For tablets with permeation enhancer

The thickness of all formulations was found to be uniform. Hardness test for all formulations was carried out and observations obtained were in the range of 6.76 to 7.20 kg/cm^2. Hardness for all formulations was observed to be proper, which signify that crushing strength of all formulations was maintained after direct compression. % Friability of all formulations was found to be in the range of 0.54 to 0.97. Friability test for all formulations indicated that % friability was less than 1%, which showed the I.P specification and reveals that all formulations have possessed good physical strength and can withstand the mechanical shocks that can be observed during handling, shipping and transportation. The % weight variation of all formulations was found to be in the range of less than 4.57%. None of the tablet was found to deviate from the average weight of tablets (variation with deviation less than ±7.5, which complies with USP specification) signifies that there is uniformity

in flow of powder blend which leads to uniform die fill. Drug content of all formulations was observed between 93.89 to 96.03%. The drug content of all the formulations was even, which indicated that there was uniform flow and distribution of drug (Table.8).

The swelling studies for all three formulations were performed and it was observed that D1 and D2 having swelling index of 78.18 and 81.81 and it may also increase further. The maximum swelling index was observed in formulation D3 containing 1.5% SLS in 7 hrs and there was no further increase in swelling index (Table.9).

The bioadhesive strength of the tablets was found to be a function of nature and concentration of polymer. The tablets with sodium alginate and carbopol 934P and 0.5% SLS showed 25.68 gm, 1% SLS showed 24.74 gm and 1.5% SLS gave 20.42 gm of bioadhesive strength. The bioadhesive strength exhibited by the tablets containing Carbopol 934P and Sodium alginate in 1:2 ratios and 0.5% SLS were considered satisfactory for maintaining them in the oral cavity. The force of adhesion for all the formulations was found to be in the range of 2.003-2.519 N (Table.10).

In *invitro* drug release studies formulations D1 to D3 containing sodium alginate and carbopol was used, in which D1 and D2 showed a sustain release drug permeation. D3 was found that complete release takes place in 7 hrs (Graph.1).

Ex-vivo permeation studies revealed that famotidine buccal tablet formulations D1 containing 0.5% SLS showed 74.52% drug permeation. D2 containing 1% SLS showed a sustain release drug permeation of 89.92% at the end of 8 hours. D3 containing 1.5% SLS showed a maximum drug permeation of 97.75% *i.e*., almost complete diffusion in 8 hrs, hence D3 is not suitable for sustained release formulation. In all the formulations as the concentration of permeation enhancer increased the rate of drug permeation also increased which was evidenced from the results (Graph.2).

The parameters such as DE at 30 and 60 minutes were found to be 29.79 and 40.58. Half-life of drug *i.e*., T50 was found to be 3.82 min for optimized D2 formulation containing sodium alginate, carbopol as bioadhesive polymers and 1% SLS as permeation enhancer. The drug release patterns of famotidine buccal tablets had followed the zero order kinetic models predominantly followed by higuchi model. This release patterns are evident with the correlation coefficient 'r' values which are nearer to 1 (Graph.3).

FT-IR spectra of pure famotidine showed principal absorption peaks at 601.82 cm^{-1} (C-S stretching), 690.55 cm-1 (C-H Aromatic bending), 775.43cm-1(=C-H bending), 1284.66 cm-1 (C-N stretching), 1601.00 cm-1 (N-H bending), 2935.82 cm-1 (C-H stretching) and 3375.61 cm^{-1} (N-H bending). The identical peaks of C-S stretching, C-H Aromatic bending, =C-H bending, C-N stretching, N-H bending, C-H stretching and N-H bending, vibrations were also noticed in the spectra of drug with carbopol 937P and sodium alginate. FT-IR spectra revealed that there was no interaction between the drug and the excipients used for famotidine buccal tablets (Graph.4, 5, 6).

The optimized D2 formulation is kept for stability studies. Accelerated stability studies were carried out at 40^0C/75%RH for 3 months. The tablets were then evaluated for hardness, friability and weight variation, Drug content and *Exvivo* bioadhesion, *In-vitro* drug release studies and *Ex-vivo* drug Permeation studies for initial, 1 month, 3 months, the results indicated that there was no significant change in physical evaluation.

The accelerated stability study was performed as per ICH guidelines for optimized buccal tablets for a period of 3 months. The evaluated parameters did not show any significant change during storage period. Hence, it is confirmed that the prepared tablets were stable.

Table.1 Composition of famotidine buccal tablets

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Optimized solid dispersion formulation ≃20mg	135	135	135	135	135	135	135	135	135
Sodium CMC	-	-	-	30	20	15	30	20	15
Sodium alginate	30	20	15	-	-	-	30	40	45
Carbopol 934P	30	40	45	30	40	45	-	-	-
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Mg. Stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Ethyl cellulose	20	20	20	20	20	20	20	20	20
Total	220	220	220	220	220	220	220	220	220

Table.2 Composition of tablet for buccal tablets containing permeation enhancer

Ingredients (mg)	D1	D2	D3
Optimized solid dispersion formulation(≃20 mg)	135mg (0.5% SLS)	135mg (1% SLS)	135mg (1.5% SLS)
Sodium CMC	-	-	-
Sodium alginate	20	20	20
Carbopol 934P	40	40	40
Talc	2.5	2.5	2.5
Mg. Stearate	2.5	2.5	2.5
EC	20	20	20
Total	220	220	220

Table.3 Physical parameters of powder blend

Formulation code	Bulk density (gram/ml)	Tapped density (gram/ml)	Carr's index (%)	Hausner's ratio	Angle of repose (^{0})
F1	0.528±0.002	0.650±0.006	18.43±0.469	1.22±0.01	28.17±0.43
F2	0.534±0.003	0.657±0.005	18.74±0.17	1.226±0.005	28.03±0.24
F3	0.542±0.004	0.659±0.006	17.79±0.406	1.213±0.005	26.82±0.45
F4	0.480±0.023	0.611±0.013	19.73±0.342	1.243±0.005	29.60±0.56
F5	0.487±0.006	0.601±0.005	18.96±0.325	1.226±0.005	28.34±0.3
F6	0.505±0.001	0.618±0.002	18.36±0.51	1.22±0.01	29.05±0.54
F7	0.453±0.001	0.572±0.002	20.89±0.309	1.26±0	32.36±0.82
F8	0.455±0.003	0.570±0.004	20.17±0.03	1.25±0	30.79±0.28
F9	0.458±0.003	0.568±0.002	19.45±0.291	1.226±0.005	29.36±0.53

Table.4 Physical parameters of famotidine buccal tablets

Formulation code	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Weight variation	% Drug content	Surface pH
F1	4.06±0.011	6.76±0.114	0.47±0.03	0.219±0.0005	93.28	6.70
F2	4.09±0.013	7.12±0.164	0.46±0.02	0.219±0	91.90	6.77
F3	4.04±0.02	7.24±0.151	0.42±0.01	0.219±0	90.99	6.67
F4	4.21±0.013	6.78±0.130	0.54±0.03	0.218±0.005	93.58	6.43
F5	4.16±0.021	6.84±0.089	0.58±0.005	0.218±0.005	94.50	6.63
F6	4.18±0.008	7.28±0.192	0.59±0.11	0.218±0.11	95.72	6.60
F7	4.35±0.028	5.52±0.083	0.75±0.055	0.217±0.01	96.03	6.67
F8	4.30±0.021	5.72±0.130	0.74±0.01	0.217±0.11	93.89	6.43
F9	4.32±0.025	5.82±0.083	0.63±0.11	0.217±0.01	90.68	6.57

Table.5 Swelling index

Formulation code	Percentage swelling index							
	1 hr	2 hr	3 hr	4 hr	5 hr	6 hr	7 hr	8 hr
F1	31.36	41.81	50	57.27	64.09	70	74.09	80
F2	27.27	38.18	47.72	55.45	62.72	68.18	74.09	75.90
F3	37.27	46.81	54.54	60	66.81	71.81	72.72	72.72
F4	30.90	40.90	49.54	57.27	64.09	70.90	76.81	78.18
F5	43.63	54.09	63.63	70.90	76.81	82.27	83.63	83.63
F6	37.72	48.63	57.27	65	71.81	76.81	81.81	86.36
F7	41.81	52.27	60.90	67.72	74.09	79.09	82.27	82.27
F8	40.90	50.90	59.09	66.81	73.18	78.18	84.09	84.09
F9	45.45	54.54	64.09	71.81	77.27	84.09	85.90	85.90

Table.6 *Ex vivo* bioadhesion strength for prepared tablets

Formulation code	Ex-vivo bioadhesive strength (g)	Force of adhesion (N)
F1	25.68±0.014	2.519±0.001
F2	25.74±0.028	2.525±0.002
F3	20.32±0.014	1.993±0.001
F4	25.57±0.007	2.508±0.0007
F5	24.16±0.028	2.370±0.002
F6	20.28±0.014	1.989±0.001
F7	24.21±0.007	2.375±0
F8	24.02±0.028	2.356±0.002
F9	20.10±0.014	1.971±0.001

Table.7 Comparative dissolution data famotidine tablets

Time (hrs)	% Cumulative drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	21.53±0.62	16.18±1.68	21.17±0.84	20.29±0.83	23.87±1.23	24.71±0.81	24.06±0.60	25.20±0.82	29.42±0.86
1	25.50±0.83	20.18±1.49	29.18±1.28	26.60±1.25	30.43±1.65	32.93±0.82	34.84±0.81	35.92±0.41	39.33±0.43
2	33.34±1.05	27.50±0.85	36.62±2.58	35.60±0.62	39.37±0.83	43.21±1.64	41.35±0.81	43.48±0.83	53.25±1.50
3	40.04±1.68	34.56±2.13	44.11±3.45	44.35±0.63	48.35±0.42	53.54±1.23	53.08±1.22	56.07±1.04	67.25±1.08
4	48.54±0.85	42.86±1.51	53.46±1.54	53.74±1.05	57.38±1.25	63.93±1.64	65.74±0.83	68.73±1.88	81.32±1.30
5	56.80±1.06	51.81±0.87	59.51±1.76	62.89±1.48	66.46±2.29	74.38±1.66	79.33±0.83	82.34±1.06	95.47±1.31
6	63.92±0.86	60.51±1.09	65.60±1.34	71.79±0.44	75.30±0.85	84.88±0.85	91.84±1.44	95.43±1.27	--
7	70.34±0.86	66.74±1.52	73.08±0.91	80.59±0.85	84.01±0.85	95.84±0.65	--	--	--
8	79.72±1.28	74.46±0.67	82.38±0.90	89.39±1.06	92.73±0.44	--	--	--	--

Table.8 Physical parameters of famotidine buccal tablets

Formulation code	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Weight variation	% Drug content
D1	4.12±0.03	6.76±0.05	0.54±0.04	0.219±0.0005	96.03±0.155
D2	4.09±0.01	7.20±0.04	0.97±0.01	0.219±0	94.50±0.305
D3	4.04±0.04	7.10±0.06	0.73±0.04	0.218±0.0005	93.89±0.460

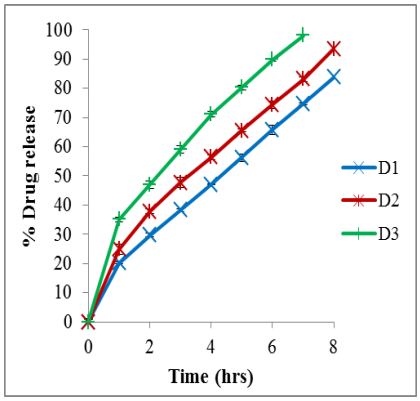
Table.9 Swelling studies for famotidine buccal tablets

Code	Percentage swelling index							
	1 hr	2 hr	3 hr	4 hr	5 hr	6 hr	7 hr	8 hr
D1	37.72	47.72	55.45	62.72	68.18	72.72	75.90	78.18
D2	38.18	48.63	57.27	64.09	70	74.09	77.27	81.81
D3	41.81	50	59.09	67.72	74.09	78.18	84.09	84.09

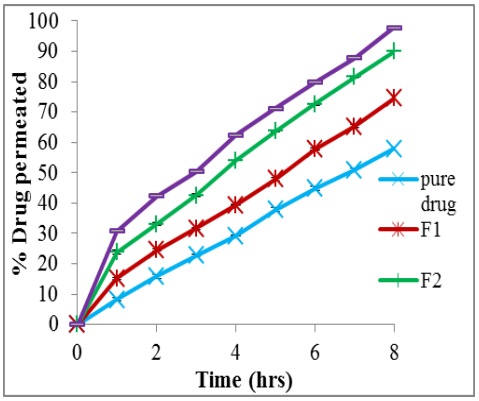
Table.10 Bioadhesive strength, Force of adhesion and Drug content of famotidine buccal tablets

Formulation code	Bioadhesive strength (g)	Force of adhesion (N)
D1	25.68±0.01	2.519±0.001
D2	24.74±0.055	2.426±0.005
D3	20.42±0.04	2.003±0.004

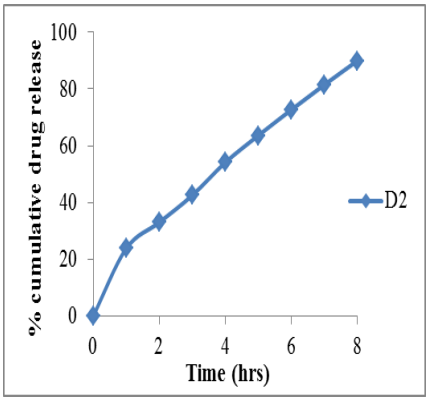
Graph.1 Dissolution profile of famotidine tablets



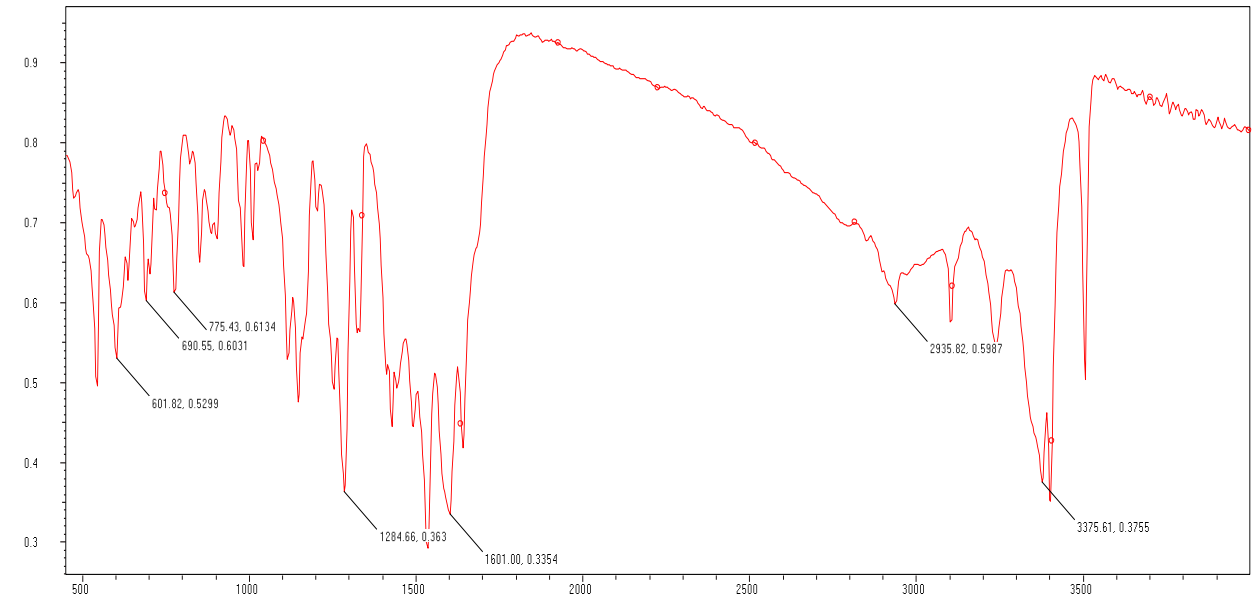
Graph.2 *Ex vivo* drug diffusion of famotidine buccal tablets



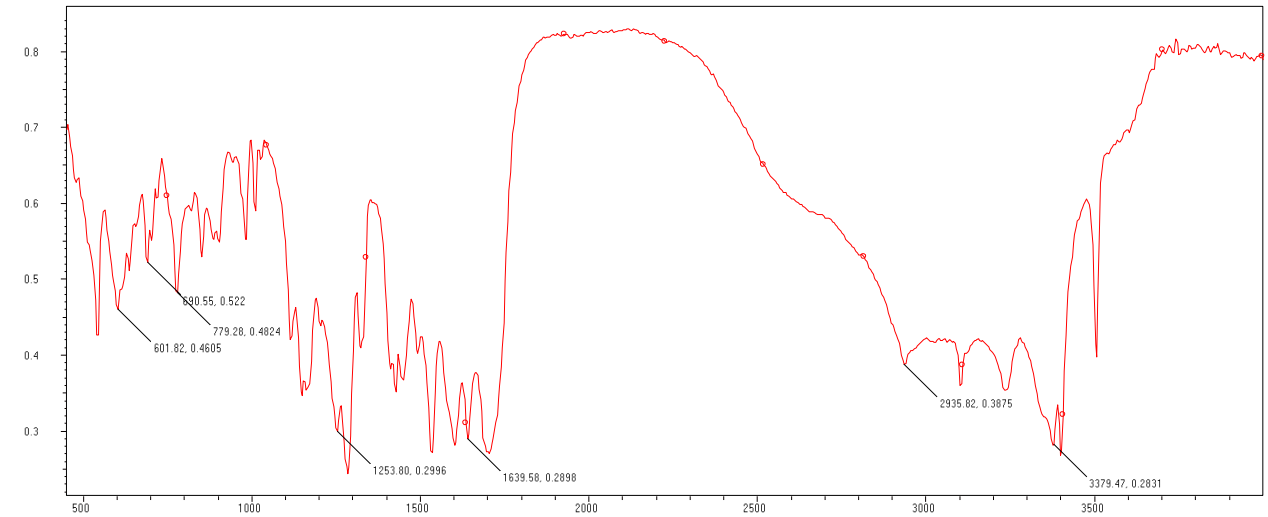
Graph.3 Zero order plots of buccal tablets



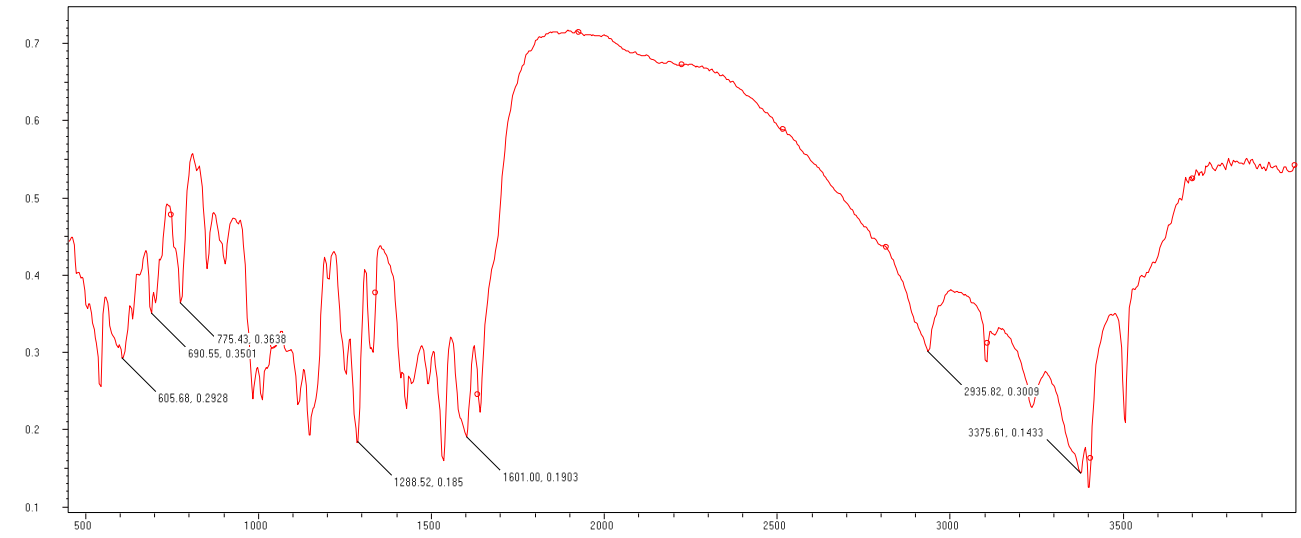
Graph.4 FTIR spectra of famotidine



Graph.5 FTIR spectra of famotidine with carbopol



Graph.6 FTIR spectra of famotidine with sodium alginate



CONCLUSION

Famotidine solubility was improved by solid dispersion technique using guar gum. Using optimized SD (S3), famotidine buccal tablets were prepared by direct compression method. Nine formulations (F1-F9) were prepared by using bioadhesive polymers such as sodium carboxy methyl cellulose, sodium alginate and carbopol 934P in different concentrations and different combinations. Among all the formulations F2 formulation containing sodium alginate and carbopol 934P in 1:2 ratio was considered as optimized formulation having 74.46% in 8hrs showing sustained release based on *invitro* drug release, swelling and *Exvivo* bioadhesive strength. Using optimized famotidine buccal tablet formulation (F2), further formulated by the addition of sodium lauryl sulphate as permeation enhancer in three formulations (D1-D3) in different concentrations of SLS. The sustained release of drug through diffusion was observed in D2 formulation having 89.92% in 8 hrs, containing sodium alginate and carbopol 934P as bioadhesive polymers and 1% SLS as permeation enhancer. Hence, D2 was considered as optimized formulation. FT-IR study reveals that their no interaction between drug and excipients and can be used for preparation of famotidine buccoadhesive tablets. The stability studies were carried out at $40^0C \pm 2^0C$ / 75% ± 5% RH for 3 months. There was no significant change in the physical property and drug content during the study period.

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