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Research Article

OFLOXACIN BUCCOADHESIVE TABLETS FOR TREATMENT OF PERIODONTITIS

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Abstract:

Periodontal diseases are recognized as the major public health problem throughout the world affecting about 750 million people as on 2010. Periodontal diseases are group of infections and inflammatory conditions, including gingivitis and periodontitis that affect teeth-supporting structures. A solution for these problems could be the local administration of the drug formulated in a controlled release delivery system to be placed directly on the action site. Ofloxacin is a synthetic fluorinated carboxy quinolone that has a broad spectrum of activity against both gram-negative and gram-positive bacteria. Nine formulations of ofloxacin buccoadhesive tablets were prepared using chitosan and co-polymers gaur gum, sodium alginate and HPMC K-15M. These tablets were evaluated by physical parameters like thickness, hardness, % friability, weight variation, drug content, surface pH, buccoadhesive strength, swelling index and In-vitro drug release. All the formulations showed compliance with pharmacopeial standards, FTIR studies showed no evidence of interaction between ofloxacin and buccoadhesive polymers. Among all the formulations F6 showed greater in-vitro drug release of 99.755 % in 8 hours and sufficient buccoadhesive strength. The surface pH of all the formulations was found to be well within the limit of acceptable salivary pH range. The results indicate that the buccoadhesive tablets of ofloxacin are good choice for treatment of periodontal diseases.

Keywords: *Ofloxacin, chitosan, sodium alginate, mucoadhesion, In-vitro drug release.*

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INTRODUCTION [1-4]:

Periodontal diseases are recognized as the major public health problem throughout the world. Daily oral hygiene plays a vital role in maintaining healthy teeth and gums. Periodontal disease can do occur in all age groups, ethnicities, races, genders and socioeconomic levels. Periodontal diseases are group of infections and inflammatory conditions, including gingivitis and periodontitis that affect teeth-supporting structures. These diseases occur when bacteria from dental plaque invade surrounding tissues and accumulation of plaque at the gingival margin induces inflammatory response. The result is the formation of pockets between gingiva and tooth that causes gingival margin retraction and the development of an ideal environment for anaerobic bacteria growth responsible for the disease. The progression of this destruction process can cause tooth loss. The therapeutic goal is the removing of bacteria responsible for the infection by mechanical cleaning and topical application of antimicrobial agents such as Tetracycline, Ofloxacin, Metronidazole, Clindamycin, Chlorhexidine and Cetylpyridinium. Antimicrobial agents are orally administered to produce a systemic effect, but this application induces some side effects like hypersensitivity, gastrointestinal intolerance, and development of bacterial resistance. Furthermore, it is reported that this kind of administration does not guarantee concentration at the action site because the active product is not retained locally for a sufficient period of time. A solution for these problems could be the local administration of the drug formulated in a controlled release delivery system to be placed directly on the action site.

Mucoadhesive drug delivery systems are delivery systems, which utilize the property of bioadhesion of certain polymers. Bioadhesion is defined as an ability of a material to adhere a particular region of the body for extended period of time not only for local targeting of drugs but also for better control of systemic delivery. Buccal region has epithelium of 40–50 cell layers thick, sub mucous tissue with racemose, mucous, serous glands and lamina propria rich with blood vessels and capillaries that open to the internal jugular vein as shown in Figure 1. Mucoadhesive buccal drug delivery systems offer many advantages over conventional systems such as ease of administration, rapid termination of therapy and administration to unconscious patients. Drug which are destroyed by the enzymatic/alkaline environment of the intestines are unstable in the acidic environment of the stomach can be administered by this route. From technical point of view, an ideal buccal dosage form must have three

properties. It must maintain its position in the mouth for a few hours, release the drug in a controlled fashion and provide the drug release in a unidirectional way towards the mucosa. In regard to the first requirement, strong adhesive contact to the mucosa is established by using mucoadhesive polymers as recipients. If the mucoadhesive recipients are able to control drug release, the second requirement can be fulfilled by preparing a system have uniform adhesiveness and impermeable backing layer. Various mucoadhesive devices such as include tablets, film, patches, discs, strips, ointments and gel have been recently developed. Most of the mucoadhesive materials are either synthetic or natural hydrophilic or water insoluble polymers and are capable of forming numerous hydrogen bonds because of presence of the carboxyl, sulphate or hydroxyl functional groups. Various materials were tested for mucoadhesion. The synthetic materials include Carbopol-934, Hydroxyl propel methyl cellulose (HPMC), Hydroxyl ethyl cellulose (HEC), Sodium carboxyl methyl cellulose, Polymethylmethacrylates and polycarboxophil, while natural polymers include xanthium gum, sodium alginate, gelatin, acacia and tragacanth. The bioadhesive polymers can not only cause the adhesion effects but can also control the release rate of drug.

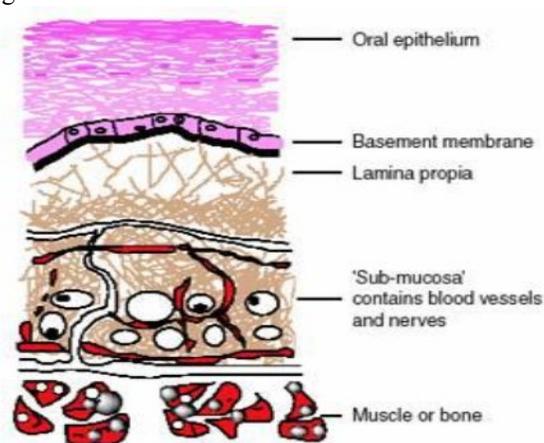


Fig 1: Cross-section of buccal mucosa

Ofloxacin is a synthetic fluorinated carboxyquinolone that has a broad spectrum of activity against both gram-negative and gram-positive bacteria. It is indicated for uncomplicated skin infections, complicated urinary tract infection, respiratory tract infections and some sexually transmitted diseases. Normal dosage regimen varies from 200-600 mg administered twice or thrice a day, depending on severity of infection. Biological half-life of drug is from 5-6 hrs.

The present study is to prepare site specific buccoadhesive tablets of Ofloxacin. The polymer that is being used in this study is chitosan and copolymers are gaur gum, sodium alginate and HPMC K15M.

MATERIALS AND METHODS:

Ofloxacin was received as gift sample from Aurobindo Pharma, Hyderabad. Chitosan was obtained from CIFTRI, Kerala. Guar gum, sodium alginate and HPMC K15M were procured from Himedia, Mumbai. All other reagents used were of analytical grade.

1.Preformulation Studies [5,6]

a. Compatibility studies:

I.R spectroscopy can be used to investigate and predict any physiochemical interaction between different polymers. Infrared spectra matching approach was used for detection of any possible chemical interaction between the drug and polymer. The drug-excipient compatibility studies were carried out using Fourier Transform Infrared Spectrophotometer (FTIR). Infra red spectra of pure drug and mixture of drug and polymer were recorded.

b. Flow property measurement:

(i) Angle of repose:

Angle of repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose (θ) was calculated using the following formula:

$$\tan \theta = h/r$$

h = height of the heap of pile,

r = radius of base of pile

(ii) Bulk density:

Apparent bulk density (ρ_b) was determined by pouring the blend into a graduated cylinder. The bulk

volume (V_b) and weight of the powder (M) was determined. The bulk density was calculated using following formula

$$\text{Bulk density}(\rho_b) = \text{Mass of the blend (M)} / \text{Normal volume (V}_b)$$

(iii) Tapped density:

The measuring cylinder containing a known mass of blend (M) was tapped for a fixed time (100 tapping). The minimum volume occupied in the cylinder and weight of the blend was measured. The tapped density was calculated using following formula

$$\text{Tapped density} = \text{Mass of the blend} / \text{tapped volume}$$

(iv) Hausner's ratio (H):

This is an indirect index of ease of powder flow. It is calculated by the following formula

$$\text{Hausner's ratio} = \text{Tapped density} / \text{Bulk density}$$

(v) Compressibility index or Carr's Index:

The simplest method of measurement of free flow of powder is compressibility. An indication of the ease with which material can be induced to flow is given by compressibility index (C.I) which is calculated as follows

$$\text{Carr's Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}}$$

2.Preparation of Ofloxacin Buccoadhesive Tablets [7,8]:

Buccal tablets were prepared by direct compression method. All the ingredients were weighed accurately according to the batch formula as described in Table 1. Except lubricant, all ingredients were screened through sieve no 100. All the ingredients were thoroughly blended in a glass motor with pestle for 5min, after sufficient mixing lubricant was added and again mixed for additional 2-3 min. The mixture is then compressed using tablet compress machine.

Table 1: Formulation of Ofloxacin buccoadhesive tablets

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug	100	100	100	100	100	100	100	100	100
Chitosan	75	50	25	75	50	25	75	50	25
Guar gum	25	50	75	-	-	-	-	-	-
Sodium alginate	-	-	-	25	50	75	-	-	-
Hpmc K15M	-	-	-	-	-	-	25	50	75
Lactose	90	90	90	90	90	90	90	90	90
Sod. saccharin	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Mag.stearate	3	3	3	3	3	3	3	3	3
Talc	6	6	6	6	6	6	6	6	6
Total weight (mg)	300	300	300	300	300	300	300	300	300

Evaluation of Buccoadhesive Tablets [9-12]:**Thickness:**

The thickness of three randomly selected tablets from each formulation was determined in mm using a Digital Vernier Calipers.

Hardness:

The Monsanto hardness tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger is placed in contact with the tablet, and zero reading is taken. The upper plunger is then forced against a spring by turning threaded bolt until the tablets break. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of break is recorded and zero force reading is deducted from it. It is expressed in kg/cm^2 .

Weight Variation Test:

Weight variation was determined to know whether different batches of tablets have uniformity. 20 tablets weighed individually, calculated the average weight and compared the individual tablet weights to the average. The tablets meet the test if not more than two tablets are outside the percentage limit and none of the tablet differs by more than two times the percentage limit. The weight variation tolerance for uncoated tablets differs depending on average weight of the tablets and it is expressed in %.

Friability:

The tablets were tested for friability using Roche friabilator. 20 tablets were weighted initially and transferred to the friabilator. The instrument was set to 25 rpm for 4 min the resulting tablets were reweighed and percentage loss was calculated using the formula.

$\% \text{ Friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{initial weight}} \times 100$

Drug Content:

Ten tablets from each formulation were powdered individually and a quantity equivalent to 100mg drug was accurately weighed and is dissolved in 50ml of 6.8phosphate buffer from this further dilutions was done by taking 1ml of sample and diluting with 6.8 phosphate buffer. The absorbance was measured at 299.64nm by UV spectrophotometer to calculate percentage of drug content.

Surface PH:

The microenvironment pH of the prepared mucoadhesive tablets was determined to evaluate the possible irritation effects on the mucosa. The tablets were left to swell in 10 ml of distilled water in small beakers and the pH was measured at time intervals of 1, 2, 3, 4 up to 8 hrs by placing the electrode in

contact with the microenvironment of the swollen tablets.

Buccoadhesive Strength:

Buccoadhesive strength was measured by modifying physical balance in which left pan has been replaced by two vials. One vial is attached to the base and other vial is hanged with the thread. Goat buccal mucosa is attached to the two vials in between two vials tablet is placed. Weights are added to the right pan till the tablet detaches and that weight is considered as buccoadhesive strength.

Swelling Studies:

The tablets of each formulation were weighed individually (W1) and placed separately in petridishes containing 15ml of phosphate buffer (PH 6.8). At regular intervals (0.5, 1, 2, 3, 4, 5, 6, 7, 8hrs) the tablets were removed from petridishes and excess water removed carefully using filter paper. The swollen tablets were re-weighed (W2) the swelling index of each formulation calculated by using the formula

$$\text{Swelling index (S.I)} = \frac{W1 - W2}{W1}$$

W1= Initial weight W2= final weight

In vitro Drug Release Study:

The drug release rate from buccal tablets was studied using the USP type-II dissolution test apparatus. The assembly is kept in a jacketed vessel of water maintained at $37 \pm 0.5^\circ\text{C}$. Buccal tablets were made to stick on bottom of the flask. The beaker is filled with 900ml of phosphate buffer pH 6.8. The paddle rotation speed was maintained at 50 rpm, at various time intervals samples were withdrawn and analyzed by U.V spectrophotometer at 288nm. Experimentation was carried out up to 8 hrs.

Drug release Kinetic studies

The dissolution data was fitted into the following mathematical models

Zero order equation $Q = SQ_0 - k_0t$

Where Q is the concentration at time t, Q_0 is the initial concentration and K_0 is zero order rates constant.

First order equation $\ln Q = \ln Q_0 - k_1t$

Where Q is the concentration at time t, Q_0 is the initial concentration and K is first order rate constant.

Higuchi equation $Q = k_2t^{1/2}$

Where Q is the concentration at time t, k_2 is the rate constant.

Korsmeyer-Peppas equation $Q/Q_0 = kt^n$

Where k_0 , k_1 , k_2 were release rate constants, Q/Q_0 was fraction of drug released at time t, k was constant, n is the release exponent indicates

mechanism of release. 'n' value between 0.43 and 0.5 indicating Fickian (case I) diffusion-mediated release, non-Fickian (Anomalous) release, coupled diffusion and polymer matrix relaxation, occurs if $0.5 < n < 0.89$, purely matrix relaxation or erosion-mediated release occurs for $n=1$ (zero-order kinetics), and super case II type of release for $n > 0.89$.

RESULTS:

Drug-Excipient compatibility

The pure drug of ofloxacin and the solid admixture of drug and various polymers used in the preparation of mucoadhesive tablet formulation were characterized by FT-IR spectroscopy to know the compatibility as shown in Figure 2. There was no significant difference and characteristic peaks of pure drug were unchanged in spectrum of tablet formulation.

Characteristic of powder blend:

Powder blend prepared for compression of mucoadhesive tablets were evaluated for their flow properties, results were tabulated in Table 2. Angle of repose was in the range of $19.6 \pm 2.1^\circ$ to $23.3 \pm 2.4^\circ$, which indicates excellent flow of powder for all formulation. The bulk density of the powder formulation was in the range of 0.50 ± 0.02 to 0.56 ± 0.09 g/ml; the tapped density was in the range of 0.62 ± 0.13 to 0.69 ± 0.16 g/ml, which indicates that the powder was not bulky. The hausner's ratio values ranged from 1.14 ± 0.25 to 1.25 ± 0.19 ; compressibility index was found to be in the range of 13.1 ± 1.25 to 15.9 ± 1.23 %, indicating compressibility of the tablet blend is good. This value indicates that the prepared powder blend exhibited good flow and compression properties.

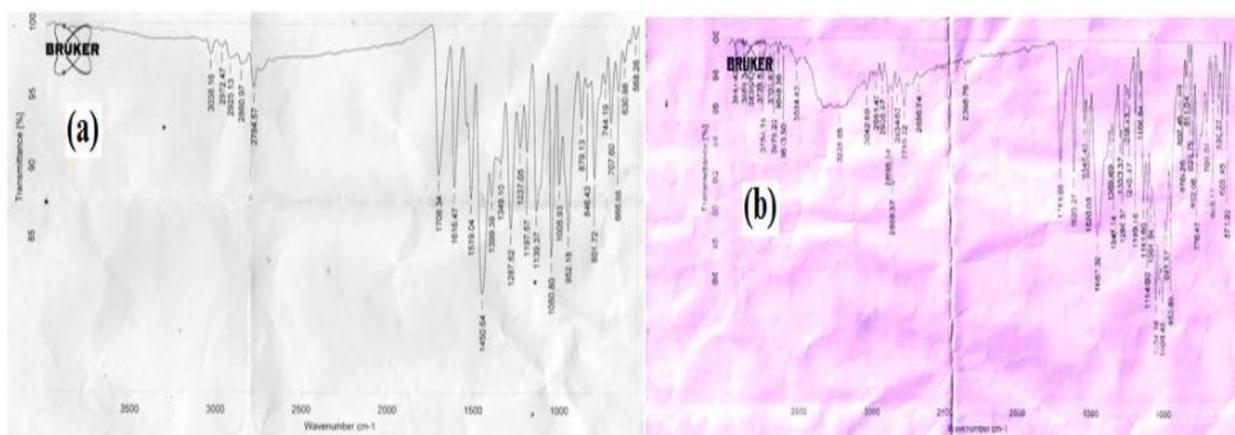


Fig 2: FTIR Spectral comparison of (a) Ofloxacin (b) Ofloxacin buccoadhesive tablet formulation-F6

Table 2: Precompression parameters of the powder blend

Formulation	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index (%)	Hausner's ratio	Angle of repose ($^\circ$)
F1	0.56 ± 0.09	0.64 ± 0.15	15.1 ± 0.21	1.21 ± 0.18	23.3 ± 2.4
F2	0.54 ± 0.06	0.62 ± 0.13	14.1 ± 1.19	1.17 ± 0.16	22.6 ± 1.7
F3	0.55 ± 0.08	0.65 ± 0.17	13.1 ± 1.25	1.14 ± 0.25	22.4 ± 2.9
F4	0.53 ± 0.04	0.64 ± 0.09	15.9 ± 1.23	1.15 ± 0.18	20.7 ± 2.3
F5	0.50 ± 0.02	0.67 ± 0.17	15.1 ± 1.24	1.23 ± 0.22	20.8 ± 1.7
F6	0.54 ± 0.04	0.63 ± 0.12	13.2 ± 1.12	1.16 ± 0.11	19.6 ± 2.1
F7	0.56 ± 0.08	0.68 ± 0.11	13.2 ± 1.12	1.17 ± 0.17	22.6 ± 2.5
F8	0.52 ± 0.06	0.69 ± 0.16	14.1 ± 1.3	1.18 ± 0.23	21.7 ± 1.9
F9	0.51 ± 0.03	0.67 ± 0.13	14.2 ± 1.24	1.25 ± 0.19	20.8 ± 1.8

Table 3: Post Compression Parameters of Ofloxacin buccoadhesive tablets

Formulations	Weight variation (%)	Thickness (mm)	Hardness (kg/cm ³)	Friability (%)	Drug content (%)	Surface pH	Buccoadhesive strength (gm)
F1	0.63	3.00±0.03	4.03±0.09	0.46±0.01	99.0±2.4	5.73	9.7
F2	0.62	3.01±0.04	4.02±0.10	0.56±0.02	98.3±1.7	5.83	10.2
F3	0.83	3.12±0.02	5.05±0.10	0.66±0.04	98.9±2.8	6.5	10.8
F4	0.52	3.81±0.03	4.61±0.08	0.67±0.01	99.4±2.3	6.73	11.1
F5	0.63	2.91±0.02	4.03±0.10	0.65±0.02	98.7±1.7	6.87	12.2
F6	0.65	3.41±0.05	5.04±0.04	0.78±0.05	97.6±2.4	6.2	13.5
F7	0.63	3.52±0.03	5.06±0.05	0.47±0.03	99.5±2.4	5.79	6.8
F8	0.77	3.60±0.04	4.51±0.08	0.58±0.01	97.3±1.7	6.63	7.5
F9	0.53	3.61±0.02	5.02±0.10	0.35±0.02	98.9±2.8	6.83	8.2

Post Compression Parameters

Post compression parameters like thickness (3.51 to 3.8 mm), hardness (4.02 to 5.04 kg/cm²), weight variation (0.52-0.63%), friability (0.56 to 0.78%), Drug content (98.7- 99.4%) observed were within specified limits. The values of post compression parameters were shown in Table 3.

SurfacepH:

Surface pH of all formulations F1 to F9 was found to be 5.73-6.83 range, which is well within the limit of acceptable salivary pH range. The results are illustrated in Table 3.

Buccoadhesive strength:

The bioadhesion characteristics were affected by the concentration of the bioadhesive polymers. Increase

in concentration of polymer increases bioadhesive strength of formulation. The tablets exhibited mucoadhesive strength of 6.8-13.5g. Results represent that formulation F6 containing chitosan and sodium alginate has high mucoadhesive strength of 13.5g. The results are illustrated in Table 3.

Swelling study:

The swelling studies were conducted for all the formulations i.e. F1 to F9 and the results were shown in the table 4 and figures 3, 4. All the formulations were hydrated generally by keeping the tablets in contact with the water for 1 to 8 h. The highest hydration (swelling) i.e. 71.57% was observed with the formulation F3. This may be due to quick hydration of polymers (chitosan & guar gum).

Table 4: Swelling studies of ofloxacin buccoadhesive tablets

Time (hrs)	%Swelling index of Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	2.80	5.33	12.43	9.04	16.20	21.21	14.40	29.32	42.68
2	6.40	12.67	23.14	10.98	18.97	25.76	22.01	46.18	60.84
4	14.60	27.00	38.57	13.02	23.57	30.81	23.95	48.32	62.28
6	22.20	39.67	57.86	16.72	29.33	37.97	27.12	48.32	63.96
8	28.20	50.67	71.57	17.42	29.73	39.99	29.76	52.69	68.77

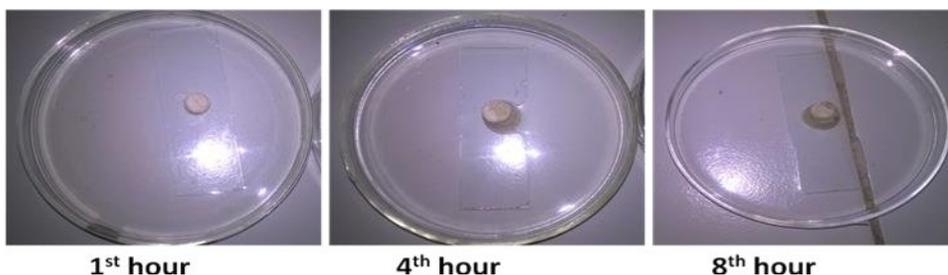


Fig 3: Swelling studies of ofloxacin Formulation F3

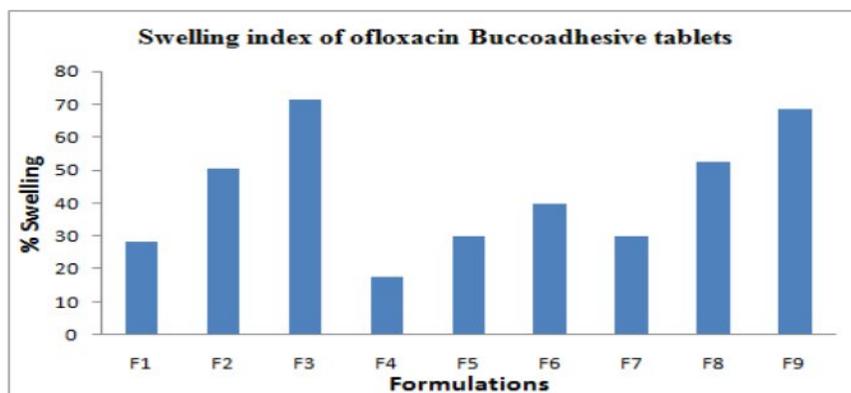


Fig 4: Swelling index of ofloxacin buccoadhesive tablets F1-F9

***In-vitro* drug release:**

In present study, *in-vitro* drug release results followed the predictable behavior as shown in Figure 5, 6, 7. Tablets of F1, F2, F3 (guar gum as a secondary polymer) batches showed drug release 64.688 %, 83.909%, 90.667% in 8 hours respectively. The formulations F1-F3 does not have the desired extended drug release up to 8 hrs. Tablets of F4, F5, F6 (sodium alginate as a secondary polymer) batches

showed drug release 62.196 %, 78.782 %, 99.755 % in 8 hours respectively. Tablets of F7 F8, F9 (HPMC K15M as a secondary polymer) batches showed drug release 59.183 %, 67.701 %, 87.654 % in 8 hours. The formulations F7-F9 have extended drug release up to 8 hrs, but the percentage drug release was less. Among these formulations, F6 has desired highest percentage drug release at the end of 8 hrs and was selected as the best formulation.

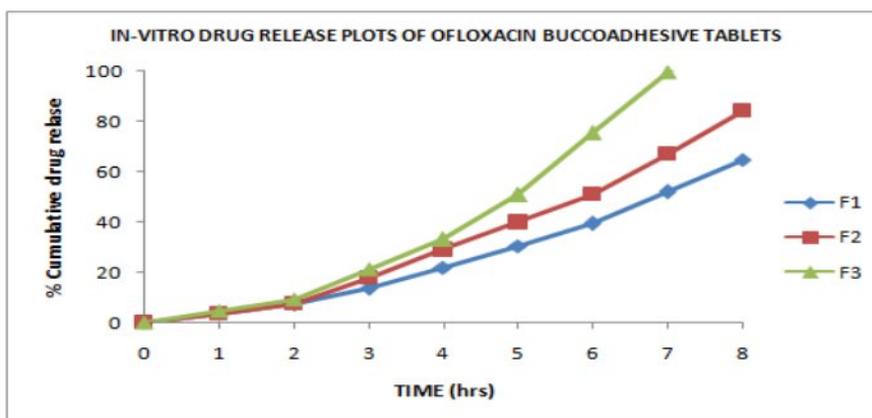


Fig 5: *In-vitro* Drug release of Ofloxacin Buccoadhesive tablets formulation F1-F3

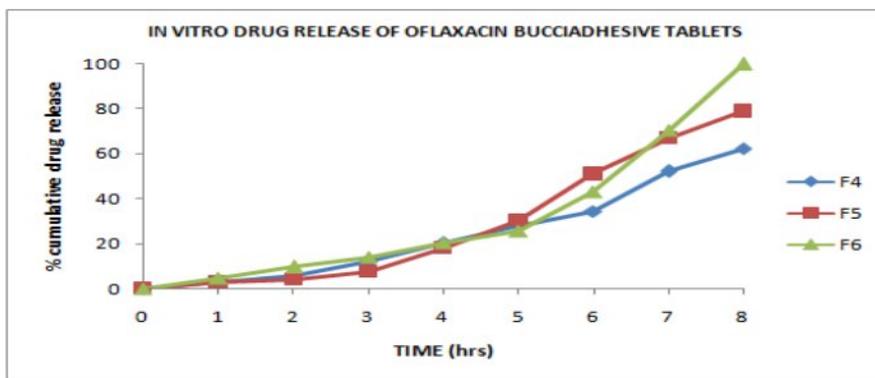


Fig 6: *In-vitro* Drug release of Ofloxacin Buccoadhesive tablets formulation F4-F6

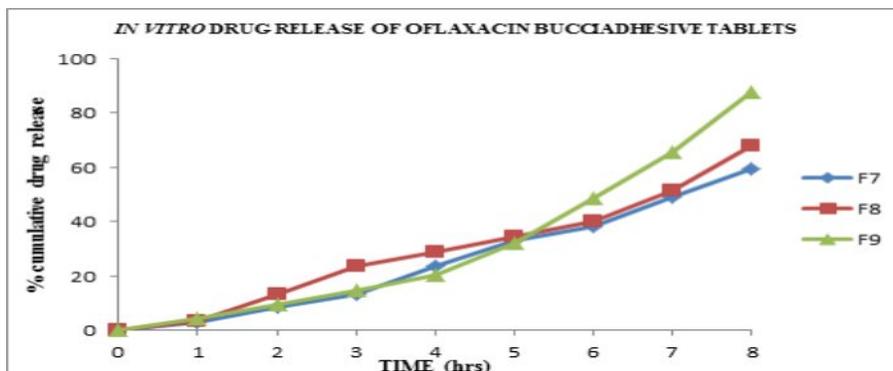


Fig 7: *In-vitro* Drug release of Ofloxacin Buccoadhesive tablets formulation F7-F9

Drug Release Kinetics

The results of dissolution data were fitted to various kinetic equations to analyze the release mechanism. All the formulations F1-F9 followed zero order kinetics. The prepared formulations exhibited anomalous non-fickian type of release, as the values

of release exponent 'n' lies between 0.55-0.881. Anomalous transport (Non Fickian) refers to the summation of both diffusion and polymer matrix relaxation controlled release. Results are showed in Table 5 and Figure 8-11.

Table 5: Kinetics of drug release from Ofloxacin Buccoadhesive tablets

Formulation Code	Zero order (r^2)	First order (r^2)	Higuchi (r^2)	Korsmeyer-peppas	
				(r^2)	(n)
F1	0.964	0.895	0.991	0.961	0.712
F2	0.962	0.835	0.990	0.957	0.738
F3	0.928	0.811	0.930	0.967	0.826
F4	0.945	0.880	0.964	0.962	0.601
F5	0.911	0.826	0.906	0.985	0.55
F6	0.947	0.730	0.948	0.922	0.78
F7	0.980	0.940	0.830	0.919	0.726
F8	0.975	0.903	0.857	0.924	0.881
F9	0.917	0.734	0.723	0.944	0.787

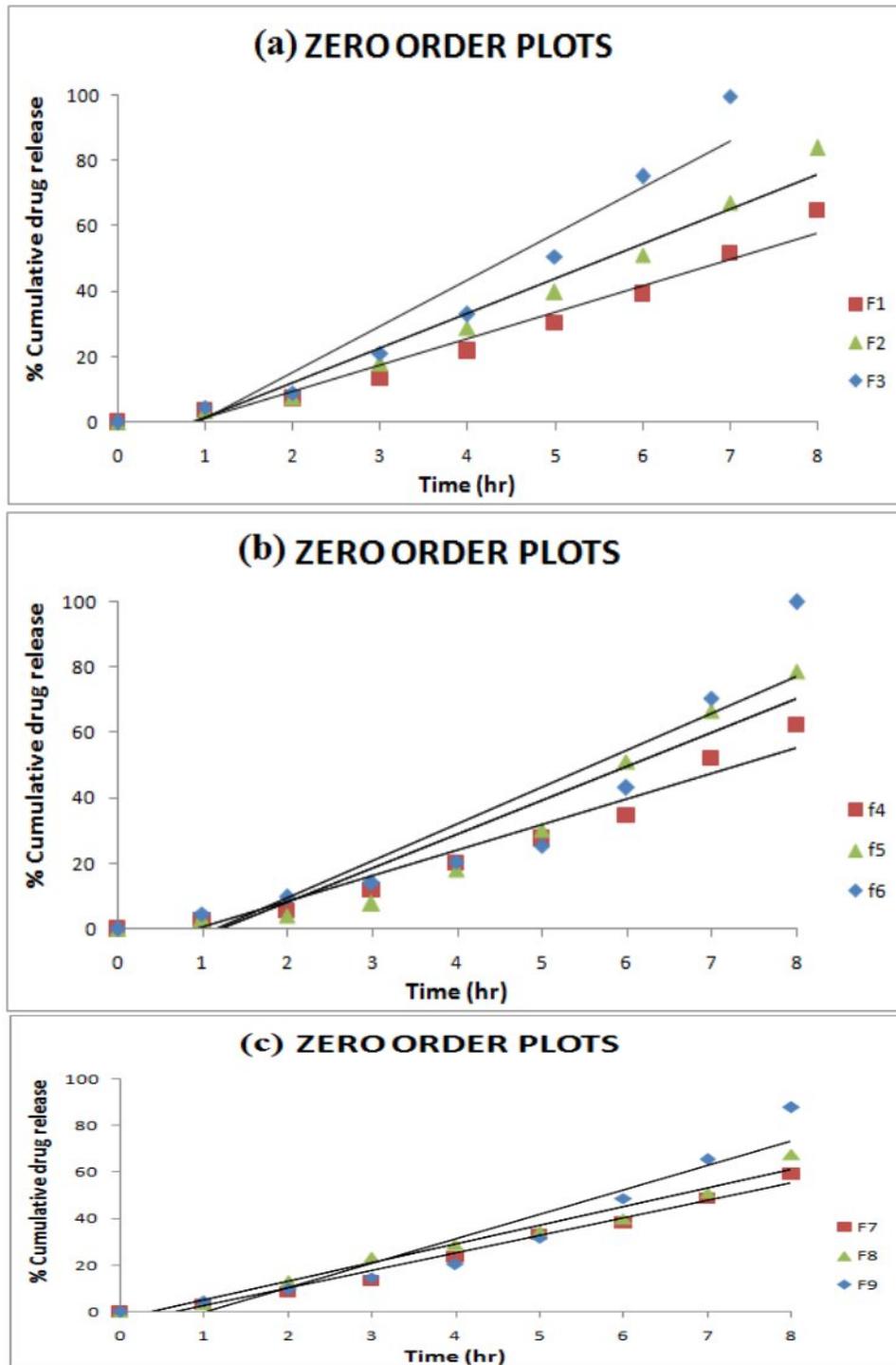


Fig 8: Zero order kinetic plots of Ofloxacin Buccoadhesive tablets (a) F1 to F3, (b) F4 to F6, (c) F7 to F9

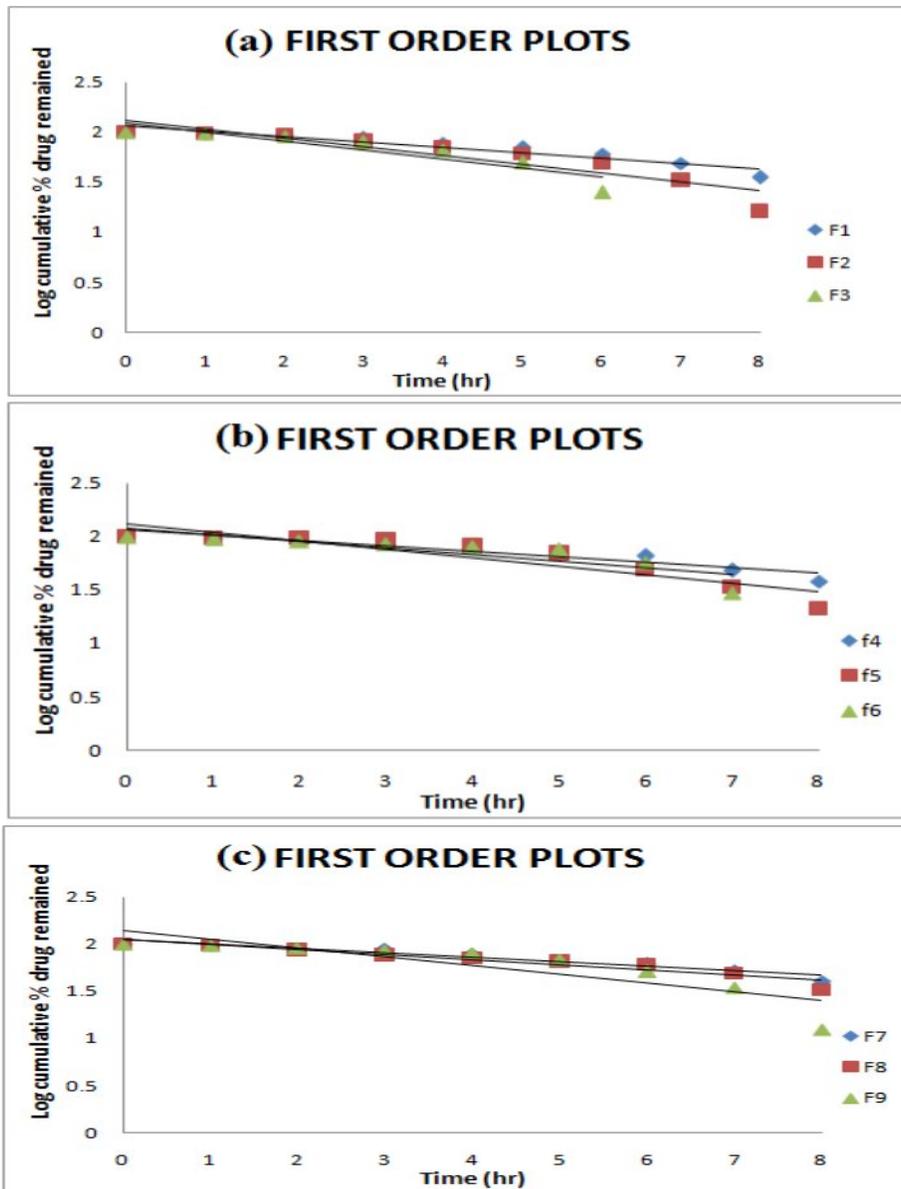
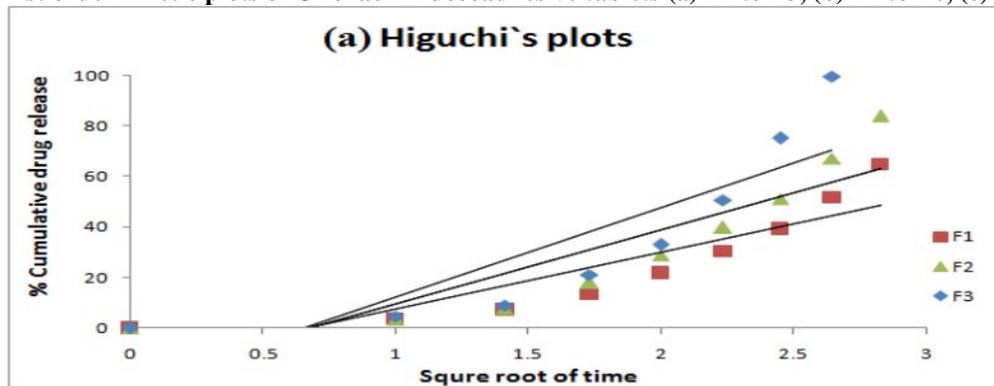


Fig 9: First order kinetic plots of Ofloxacin Buccoadhesive tablets (a) F1 to F3, (b) F4 to F6, (c) F7 to F9



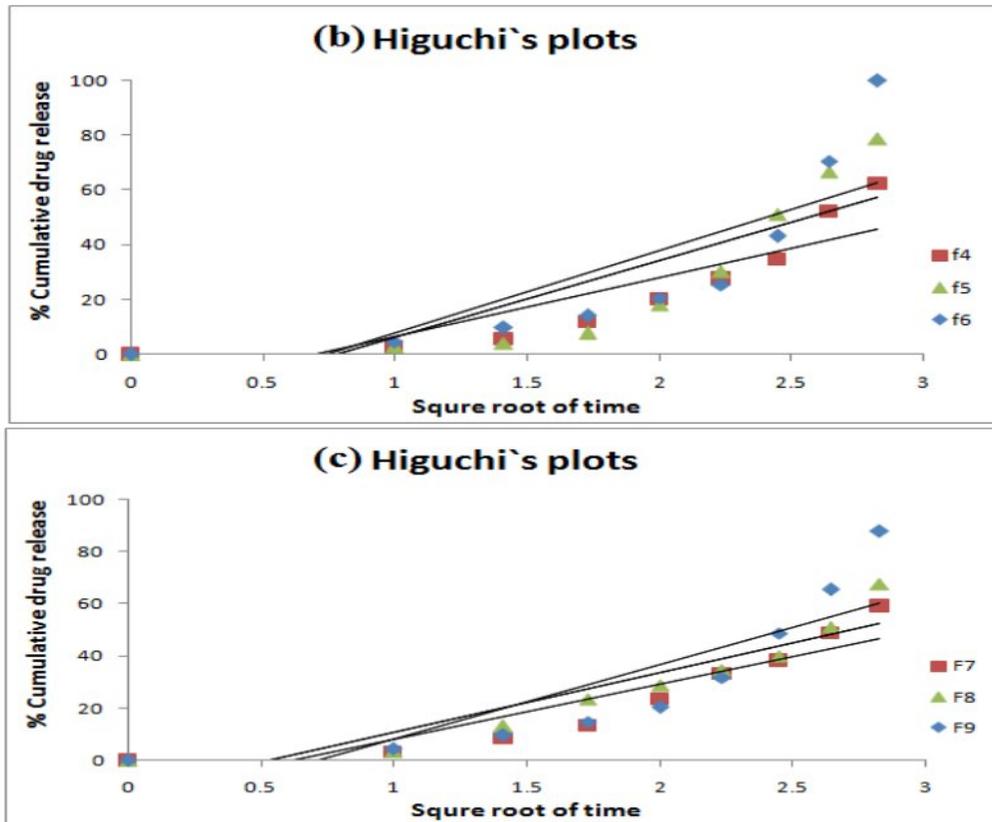
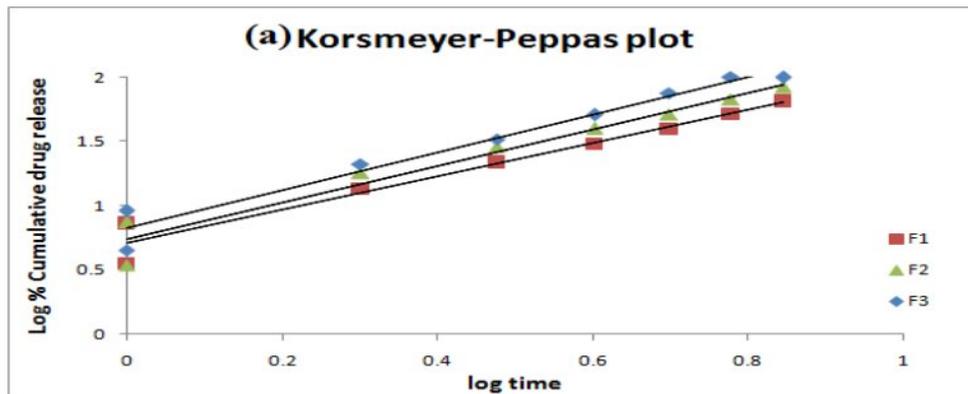


Fig 10: Higuchi plots of Ofloxacin Buccoadhesive tablets (a) F1 to F3, (b) F4 to F6, (c) F7 to F9



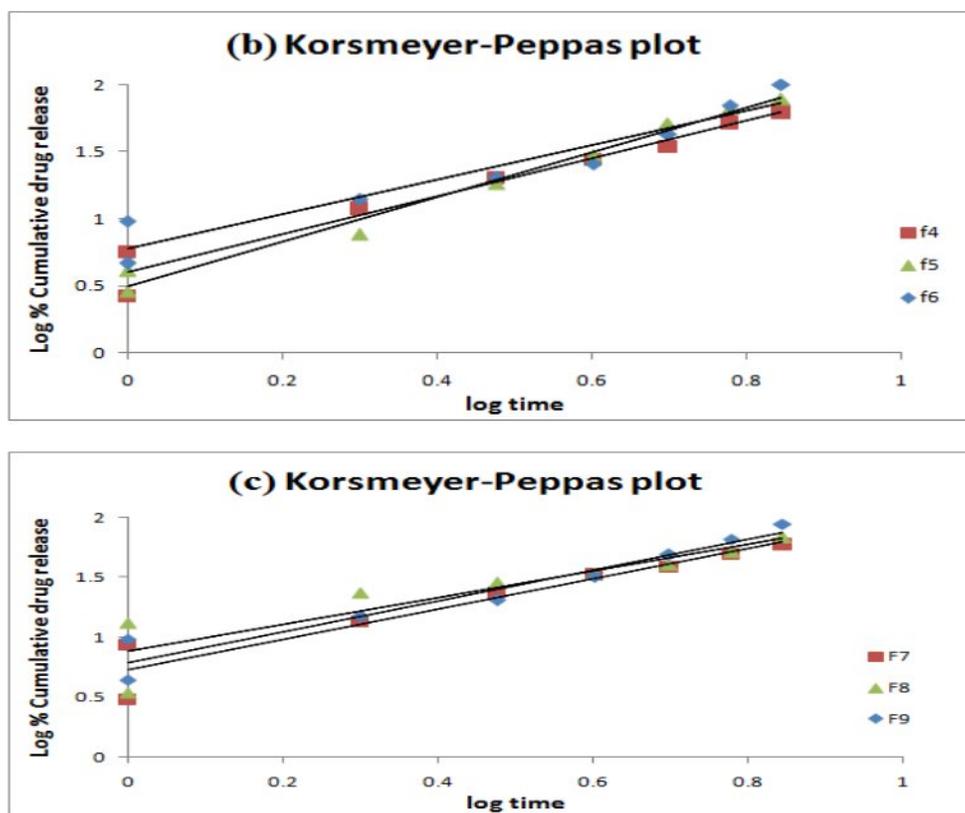


Fig11: Korsmeyer-Peppas plots of Ofloxacin Buccoadhesive tablets (a) F1 to F3, (b) F4 to F6, (c) F7 to F9

DISCUSSION:

Ofloxacin bucco adhesive tablets were prepared by direct compression method. Formulation with varying concentration of primary polymer chitosan and secondary polymers guar gum (F1-F3), sodium alginate (F4-F6), HPMC K15M (F7-F9) in ratios of 3:1, 1:1 and 1:3 were prepared. The compatibility of the drug was found out by ATR studies indicating that there is no interaction between ofloxacin and other formulation excipients. The prepared buccoadhesive tablets were evaluated for post compression evaluation and results indicated that all the prepared tablets were in acceptable range of weight variation, hardness, thickness, friability and drug content as per the pharmacopoeial specifications.

The surface pH of all formulations is well within the limit of acceptable salivary pH range; hence they may not produce any local irritation to the mucosal surface. Chitosan is cationic polyelectrolyte, undergoes electrostatic interactions with the negatively charged mucin chains thereby exhibiting mucoadhesive property. The buccoadhesive strength was influenced by the nature and proportions of buccoadhesive polymers used in the formulations. The order of buccoadhesive strength of bioadhesive polymer used in the formulation can be given as

sodium alginate > HPMC K15M > guar gum. The buccal tablets showed good swelling up to 8 h in phosphate buffer pH 6.8 maintaining the integrity of formulation which is required for bioadhesion. Among all formulations highest swelling was seen with the formulation containing Chitosan and guar gum, this may be due to quick hydration of polymers.

The drug release from Ofloxacin buccoadhesive tablets was governed by amount of matrix forming polymers. The most important factor affecting the rate of release from buccal tablets is the drug and polymer ratio. With increase in the polymer concentration, viscosity of the gel as well as the formation of gel layer increases with longer diffusional path. This could cause a decrease in the effective diffusion coefficient of drug and therefore reduction in drug release rate. Further, the increase in rate of drug release could be explained by the ability of the hydrophilic polymers to absorb water, thereby promoting the dissolution. Moreover, the hydrophilic polymers would leach out and hence, create more pores and channels for the drug to diffuse out of the device.

Chitosan has excellent mucoadhesive, gelling properties and also helps in sustaining effect. Burst release was observed in formulations with gaur gum.

The buccal tablets containing sodium alginate showed >90% of prolonged release up to 8 hrs due to fact that sodium alginate get rapidly swelled and form complex with chitosan as it is an anionic polymer. The formulations containing HPMC have less drug release because HPMC K15M forms a hydrophilic matrix which retarded the drug release. Among all formulations F6 containing chitosan: Sodium alginate in ratio of 1:3 exhibited desired drug release of 99.755% for 8hrs with good buccoadhesive strength, Surface pH and hence selected as best formulation. The *in-vitro* drug release of the selected best formulation followed zero order kinetics with non-fickian mechanism.

Hence, the buccoadhesive tablets of ofloxacin may be a good choice for treatment of periodontal diseases with an improvement in the bioavailability of ofloxacin through buccal mucosa. The study conducted so far reveals a promising result suggesting scope for pharmacodynamic and pharmacokinetic evaluations.

CONCLUSION:

Buccoadhesive tablets of ofloxacin can be successfully prepared by direct compression method using gaur gum, sodium alginate and HPMC K15M along with chitosan as mucoadhesive polymers in different ratios. The results reveal that with increase in the polymer concentration in tablets swelling index, mucoadhesive strength increased and controlled drug release. Formulation F6 containing drug and polymer (chitosan & sodium alginate) showed significant mucoadhesive strength (13.5g) with optimum drug release profile (99.755 % in 8 hours) and could be a successful approach for buccal administration of ofloxacin to treat periodontitis.

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