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FORMULATION AND IN VITRO EVALUATION OF NIFEDIPINE MUCOADHESIVE BUCCAL TABLETS

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Keywords:

Nifedipine, carbopol 940, ex vivo mucoadhesion, swelling index, in vitro drug release

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ABSTRACT

The aim of the present study is to formulate and evaluate Nifedipine mucoadhesive buccal tablets. Nifedipine is a calcium channel blocker and is used to treat hypertension and stable angina. 12 formulations of mucoadhesive buccal tablets were prepared by direct compression method using carbopol 940 in various proportions with different secondary polymers such as HPMC E15 Lv, PVP K30, Sodium CMC, HEC. Prepared tablets were evaluated for different parameters such as thickness, hardness, weight variation, drug content uniformity, swelling index, surface pH study, in vitro drug release, exvivo mucoadhesion study. Drug release and mucoadhesive strength were found to depend upon polymer type and proportions. The dissolution of all the prepared tablets into phosphate buffer (pH 6.8) was controlled and followed diffusion mechanisms. The optimized formulation (F7) prepared by using carbopol 940 and sodium CMC in 1:2 ratio showed 98.8% drug release and significant bioadhesive property. The result of stability study indicates no significant changes. Nifedipine is having less bioavailability (45-50%). In order to increase the bioavailability to avoid the hepatic metabolism, the mucoadhesive buccal tablets of Nifedipine were prepared.

INTRODUCTION

Mucoadhesion is known to increase the intimacy and duration of contact between drug-containing polymer and a mucous surface. It is believed that the Mucoadhesive nature of the device can increase the residence time of the drug in the body. The bioavailability of the drug is improved because of the combined effects of the direct drug absorption and the decrease in excretion rate. Increased residence time and adhesion may lead to lower API concentrations and lower administration frequency to achieve the desired therapeutic outcome.¹

Before formulating mucoadhesive drug delivery systems, one has to decide whether the intended, action is for rapid release/prolonged release and for local/systemic effect. The selection of suitable drug for the design of buccoadhesive drug delivery systems should be based on pharmacokinetic properties.

The drug should have following characteristics²

- ❖ The conventional single dose of the drug should be small (less than 25mg).
- ❖ The drugs having biological half-life between 2-8 hrs are good candidates for controlled drug delivery.
- T max of the drug shows wider-fluctuations or higher values when given orally.
- ❖ Through oral route drug may exhibit first pass effect or presystemic drug elimination.

The drug absorption should be passive when given orally

ADHESIVE TABLETS

Buccal adhesive tablets are small, flat and oval with a diameter of approximately 5-10 mm and about 4 mm in thickness. In presence of saliva, they adhere to the mucosal surface until dissolution and/or drug release is complete and allows drug permeation across the buccal mucosa. After a short time following application in the mouth, the patient is not aware of its presence, allowing speaking, drinking and eating without any discomfort. Adhesive buccal tablets can be applied to different sites in the oral cavity, including the palate, the mucosa of the cheeks or in any comfortable position between lip and gum in case of patient wearing dentures. ³ They are a feasible dosage form for the transmucosal absorption of systemically acting drugs, which are ineffective when administered by conventional routes. Buccal tablets are designed to erode slowly since the buccal route is generally used in the treatment of chronic disorders when a prolonged release of the active substance is required. In order to prevent drug loss from the top

surface of the dosage form, specialized tablets with two layers have been developed. They contain a drug-loaded bioadhesive layer and an impermeable backing layer to promote unidirectional drug absorption and to minimize drug leakage in the oral cavity. Several investigators have reported on the development of buccal adhesive tablets containing a fast-release and a controlled-release layer. The fast release layer contains poly(vinyl pyrrolidone) (PVP) as the bioadhesive component and is designed to adhere to the buccal mucosa and the controlled release layer consists of a mixture of PVP and poly(acrylic acid). In order to achieve unidirectional release with minimal drug loss, the drug release can be restricted to occurs only from the face of the tablet in contact with the buccal mucosa and other faces are coated with water impermeable hydrophobic substances such as ethyl cellulose, oil etc..⁵

Nifedipine is a calcium channel blocker used to treat hypertension and chronic stable angina. It is incompletely absorbed following oral administration and undergoes extensive first pass metabolism resulting low bioavailability (40-50%). The physicochemical properties of Nifedipine, its low half-life (1.5-2hrs), molecular weight (346.34g/mol) and first pass metabolism make it suitable candidate for administration by buccal route.

MATERIALS AND METHODS

List of ingredients used for the preparation of formulation

Sl.No	INGREDIENTS	SUPPLIER	
1	Nifedipine	Yarrow chem products, Mumbi	
2	Carbopol 940	Chemdyes corporation, Rajkot	
3	Hydroxyl propyl methyl cellulose E15Lv	Chemdyes corporation, Rajkot	
4	Poly vinyl pyrrolidone K30	Yarrow chem products, Mumbi	
5	Sodium carboxy methyl cellulose	Yarrow chem products, Mumbi	
6	Hydroxyl ethyl cellulose	Yarrow chem products, Mumbi	
7	Mannitol	Nice chemicals, Cochin	
8	Magnesium stearate	Nice chemicals, Cochin	
9	Talc	Nice chemicals, Cochin	
10	Saccharine sodium	Nice chemicals, Cochin	

List of equipments/instruments used for the preparation of formulation.

Sl .No.	INSTRUMENT	MANUFACTURER		
1	Electronic balance	Citizen model: CY 104		
2	Rotary tablet punching machine	Riddhi pharma, Andhra		
3	Monsanto hardness tester	Remi equipments, Mumbai		
4	Roche friabilator	Remi equipments ,Mumbai		
5	Vernier caliper	Remi equipments, kochi		
6	Tablet dissolution tester	Electrolab Ltd		
7	UV spectrophotometer	Schimadzu UV 1800		
8	FTIR spectrophotometer	Schimadzu ,japan		
9	Physical balance	K.Roy instruments pvt LTD		
10	Humidity chamber	Chemi, edapalli		
11	pH meter	Microtonics, model M-19		
12	Melting point apparatus	Raas ,Pvt LTD		

FORMULATION OF NIFEDIPINE MUCOADHESIVE BUCCAL TABLETS

Mucoadhesive buccal tablets, each containing 20mg Nifedipine were prepared by directcompression method. Composition of various formulations employing Carbopol 940, HPMC E15 Lv, sodium CMC, PVP K30, HEC are shown in table. All the ingredients of tablets were blended in mortar with a pestle for 15 minute to obtain uniform mixture. The blended powder was then compressed into 200mg tablets (at 5-8 Kg/cm²) on a single stock, 8 station rotary tablet machine, with 10mm round shaped flat punch.

Composition of different batches of Nifedipine mucoadhesive buccal tablets

FORMULATIONS												
INGREDIENTS Mg/tablets	F1	F2	F3	F4	F5	F6	F 7	F8	F9	F10	F11	F12
NIFEDIPINE	20	20	20	20	20	20	20	20	20	20	20	20
CARBOPOL 940	40	60	80	40	60	80	40	60	80	40	60	80
HPMC E15 Lv	80	60	40	350	(C)	15-7-70	S -710	1	S = 7 = 2.	35550		2777
PVP K30			(S 244 8)	80	60	40			(3-1-1)	1999		
SCMC		-	(G##)	200		()	80	60	40	1444	-	8++0
HEC	222		100	222		7222	223		-	80	60	40
MANNITOL	55	55	55	55	55	55	55	55	55	55	55	55
Mg STEARATE	3	3	3	3	3	3	3	3	3	3	3	3
TALC	1	1	1	1	1	1	1	1	1	1	1	1
SACCHARINE SODIUM	1	1	1	1	1	1	1	1	1	1	1	1

RESULTS AND DISCUSSIONS

ORGANOLEPTIC PROPERTIES:

Nifedipine pure drug was found to be yellow crystalline powder, odourless and tasteless.

B. SOLUBILITY:

Solubility of Nifedipine was determined in phosphate buffer pH 6.8, acetone, chloroform, ethanol and water.

Solubility study of Nifedipine

SOLVENT	SOLUBILITY		
Phosphate buffer pH 6.8	Freely soluble		
Acetone and chloroform	Freely soluble		
Ethanol	Sparingly soluble		
Water	Practically insoluble		

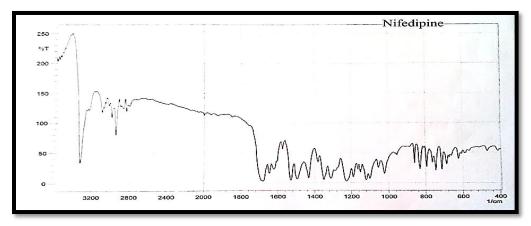
IDENTIFICATION OF PURE DRUG

A.MELTING POINT:

Melting point of Nifedipine was found to be in the range of 172-174^oC, which was in conformity with the reported range.

B.IDENTIFICATION OF PURE DRUG BY FTIR:

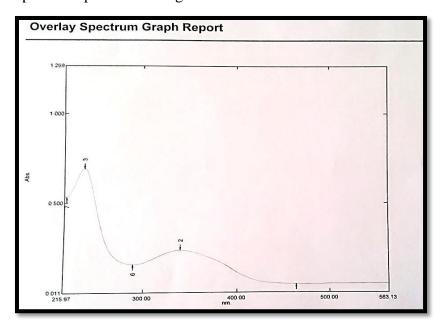
IR spectral analysis of pure drug sample showed characteristic peaks as shown in figure. The IR spectra of pure drug complied with the standard IR spectrum of Nifedipine which revealed identity to drug sample.



FTIR spectrum of Nifedipine pure drug

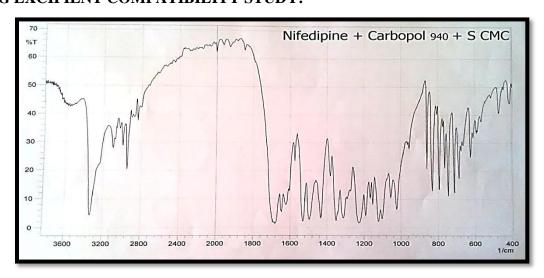
Determination of λ max for Nifedipine

The absorption spectrum of pure drug was scanned between 200-400 nm with $5\mu g/ml$ concentration in phosphate buffer pH 6.8 solutions using UV Spectrophotometer. The maximum peak was obtained at 238 nm and that was taken as the λ max. The UV spectrum of Nifedipine in phosphate buffer pH 6.8 is presented in figure.

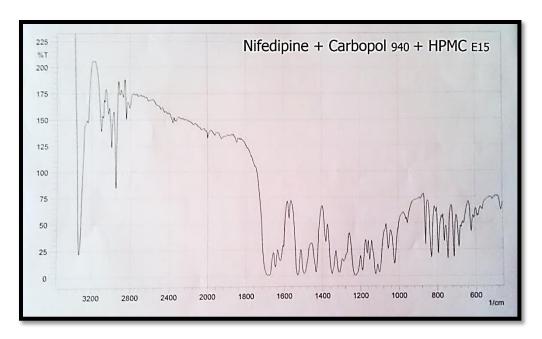


λ max of Nifedipine

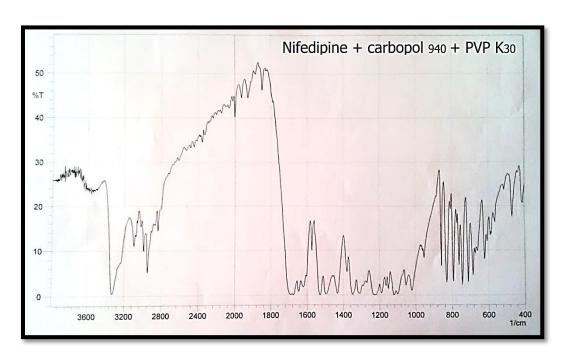
DRUG EXCIPIENT COMPATIBILITY STUDY:



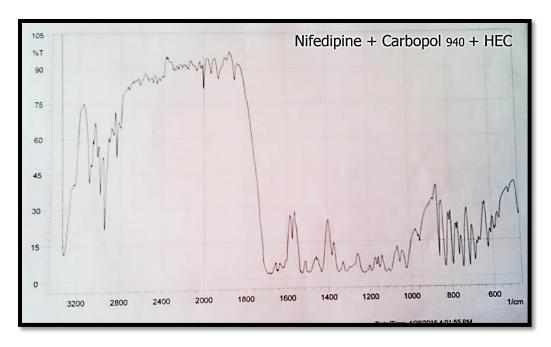
FTIR spectrum of Nifedipine ,carbopol 940 and SCMC



FTIR spectrum of Nifedipine, Carbopol 940 and HPMC E15



FTIR spectrum of Nifedipine , Carbopol 940 and PVP K30



FTIR spectrum of Nifedipine, Carbopol 940 and HEC

EVALUATION PARAMETERS

PRECOMPRESSIONAL PARAMETERS:

Blended drug/excipient mixture of all the formulations were subjected for various precompressional evaluation parameters such as bulk density, tapped density, Compressibility index, Hausner's ratio and angle of repose.

Precompression evaluation of Nifedipine powder blend

	DERIVED PR	OPERTIES	FLO	W PROPERTIES	
F.CODE	Bulk density (gm/cc)	Tapped density (gm/cc)	Angle of repose (degrees)	Carr's index	Hausner's ratio
F1	0.46	0.49	33.23	6.12	1.07
F2	0.47	0.50	32.39	5.45	1.06
F3	0.43	0.47	32.65	9.01	1.10
F4	0.44	0.47	31.60	7.23	1.08
F5	0.44	0.46	29.93	6.08	1.06
F6	0.45	0.48	28.44	5.19	1.05
F7	0.47	0.50	26.57	5.24	1.07
F8	0.45	0.48	30.44	6.87	1.05
F9	0.47	0.49	28.69	8.56	1.09
F10	0.49	0.44	26.7	9.37	1.07
F11	0.45	0.47	25.52	3.39	1.10
F12	0.42	0.48	26.04	7.03	1.04

The bulk density was found to be in the range of 0.42-0.47 gm/cc. The tapped density was found to be in the range of 0.47-0.50 gm/cc. The compressibility index was well below 10% and the Hausners ratio values were found to be between 1.04-1.1. The granules had excellent flow property having angle of repose within 25^{0} - 33^{0} . The overall physical properties of the powder blend of Nifedipine were good and suitable for compression into tablets.

EVALUATION OF NIFEDIPINE BUCCAL TABLETS

The prepared tablets were evaluated for general appearance, content uniformity, hardness, friability, weight variation, thickness, diameter, swelling index, surface pH, ex vivo mucoadhesive strength and in vitro dissolution profile using methods specified in Indian Pharmacopoeia. ⁵

i) GENERAL APPEARANCE:

All the formulated tablets from each batch were found to be flat, yellow incolor, circular in shape and having good physical appearance. There was no change in the color and odour of the tablets from all the batches.

ii) THICKNESS:

Thickness of all prepared formulated tablets was measured by using calibrated vernier callipers. The tablets of all the formulations showed thickness in the range of 3.15mm-3.9 mm.

iii) HARDNESS:

Tablets require certain amount of strength, hardness to withstand mechanical shocks during manufacture, packaging and shipping. The hardness was found to be in the range of 6-8 kg/cm². The obtained results revealed that the tablets were having good mechanical strength and compactness.

iv) FRIABILITY TEST:

Adequate tablet hardness and resistance to friability are necessary to prevent damage to the tablet during manufacture, packing and transport. % Friability of tablets less than 1% was considered acceptable. Percentage friability ranged from 0..251 to 0.35%.

v) WEIGHT VARIATION

The average weight of Nifedipine buccal tablet was 200 mg. The weight variation was found to be in the range of 199.7 mg to 200.2 mg. The obtained results indicated that all tablets of different formulations were within the I.P specifications.

Post compression parameters of formulations

Formulat ion code	Diameter (mm)	Thickness (mm)	Hardness (Kg/cm ²)	Friability (%)	Weight variation (mg)	Content Uniformity (%)
F1	10	3.22	6	0.321	200.1	95.5
F2	10	3.56	7	0.298	200.1	98.3
F3	10	3.44	8	0.275	200	98.5
F4	10	3.15	7	0.281	199.9	101.2
F5	10	3.29	7	0.351	199.7	96.6
F6	10	3.86	8	0.31	199.9	98.7
F7	10	3.9	6	0.301	200.01	99.8
F8	10	3.20	8	0.271	200.23	97.3
F9	10	3.25	7	0.251	200.03	98.2
F10	10	3.81	6	0.287	199.8	99.15
F11	10	3.3	6	0.296	199.9	98.3
F12	10	3.45	7	0.318	200.21	97.47

vi) SURFACE PH ⁶

The surface pH of the mucoadhesive tablets was in the range of 5.9 -6.9. The surface pH of the tablets was close to that of salivary glands thereby decreased the chances of irritation and discomfort at the point of contact with the mucosa. The average pH of all formulations was around neutral pH significantly similar to that of saliva and hence no mucosal irritation was expected thus improving patient compliance.

Surface pH of mucoadhesive buccal tablets of Nifedipine

Formulation	Surface
code	pН
F1	6.3
F2	6.1
F3	6.2
F4	6.5
F5	6.4
F6	6.5
F7	6.9
F8	6.8
F9	67
F10	6.2
F11	6.7
F12	5.9

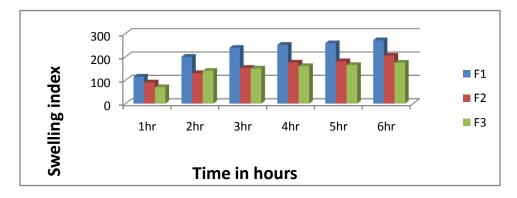
viii) SWELLING STUDY⁷

The swelling index values of various mucoadhesive buccal tablets formulations containing Nifedipine was tabulated in tables and in figures. The swelling of all the tablets was increased as the time proceeds because the polymer gradually absorbs water due to hydrophilicity of the polymer. The outermost hydrophilic polymer layer hydrates/swells first and as the hydrated layer progressively dissolves or disperse, the hydration swelling process will continue towards new exposed surfaces thus maintaining the integrity of dosage form. The swelling index was 115 to 273 for the formulation F1 which contains Carbopol 940 as primary polymer and HPMC E15 Lv as secondary polymer. The swelling index was 72 to 248 for the formulation F6 which contains Carbopol 940 as primary polymer and PVP K30 as secondary polymer. The swelling index was 478.9-1050 for the formulation F7 which contains Carbopol 940 and SCMC as secondary polymer. It was observed that when tablet came in contact with aqueous medium, wetting occurred first at the lower surface of tablet and then progressed to whole. The rate of spreading of water was dependent on the ratio of two polymers used. The swelling was get affected in the formulations containing secondary polymer along with Carbopol as a primary polymer.

The highest swelling was 478.9 to 1050 for formulations F7 which contains Sodium CMC as secondary polymer because SCMC is more water soluble and rapidly gets hydrated.

Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of Carbopol 940 &HPMC E15 Lv.

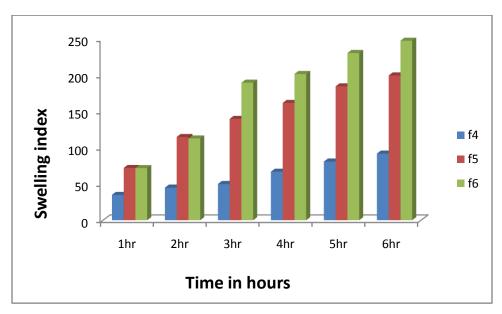
Formula	PERCENTAGE SWELLING INDEX							
tion code	1Hrs	2Hrs	3Hrs	4Hrs	5Hrs	6Hrs		
F1	115	200	238.09	251.2	258	271		
F2	90	130	152.38	175.5	181	205		
F3	70	140	150	160.2	165	175		



Comparison of swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of Carbopol 940 & HPMC E15 Lv.

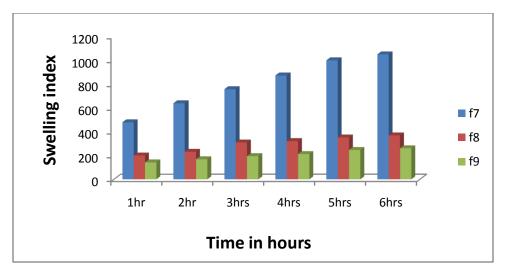
Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of Carbopol 940 &PVP K30

Formula	PERCENTAGE SWELLING INDEX						
tion code	1Hrs	2Hrs	3Hrs	4Hrs	5Hrs	6Hrs	
F4	35	45	50	67	81	92	
F5	72.2	115	140	162	185	200	
F6	72	113	190	202	231	248	



Comparison of Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of Carbopol 940 & PVP K30 Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of Carbopol 940 & SCMC.

Formula tion code	PERCENTAGE SWELLING INDEX						
tion code	1Hrs	2Hrs	3Hrs	4Hrs	5Hrs	6Hrs	
F7	478.9	638.8	757.14	872.5	1000	1050	
F8	200	231.8	309.5	321	352	369	
F9	142.1	168.4	194.7	212	247	261	

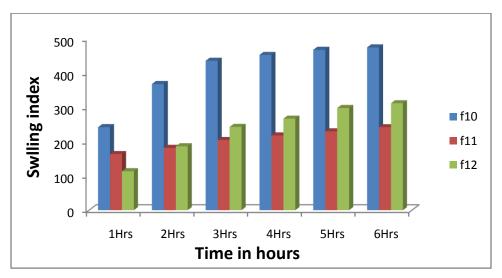


Comparison of Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of Carbopol 940 &SCMC.

Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets

containing different concentrations of Carbopol 940 &HEC.

Formula tion	PERCENTAGE SWELLING INDEX					
code	1Hrs	2Hrs	3Hrs	4Hrs	5Hrs	6Hrs
F10	242.1	368	436	453	468	475
F11	163.6	181.8	204.7	218	230	242
F12	113.6	186.3	242.8	267	298	312



Comparison of Swelling behaviour of different batches of Nifedipine mucoadhesive buccal tablets containing different concentrations of HEC and Carbopol 940

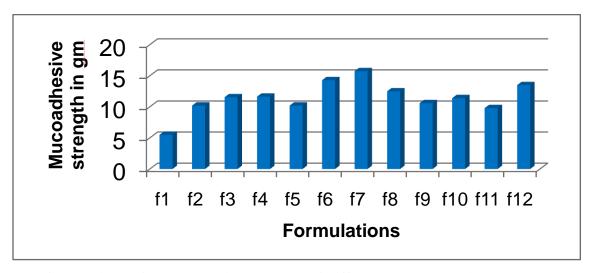
ix) MUCO ADHESION STRENGTH 8

Mucoadhesive strength of mucoadhesive buccal formulations containing Nifedipine was listed in table 21 and in figure 25. The maximum mucoadhesive strength (15.7gm) was found for formulation F7 (Carbopol 940 as primary polymer and sodium CMC as secondary polymer) and low mucoadhesion (5.5gm) was found for formulation F1 (Carbopol 940 as primary polymer and HPMC E15 Lv as secondary polymer). The mucoadhesive strength were influenced by the nature and proportions of the mucoadhesive polymers used in the formulations. In all the formulations, as the mucoadhesive polymer mixture concentration increased, the mucoadhesive strength also increased.



Mucoadhesive strength of Nifedipine mucoadhesive buccal tablets.

Formulation Code	Mucoadhesive strength(gm)	Force of adhesion , N
F1	5.5	0.49
F2	10.2	1
F3	11.5	1.12
F4	11.65	1.14
F5	10.2	1
F6	14.35	1.4
F7	15.7	1.54
F8	12.3	1.22
F9	10.5	1.03
F10	11.4	0.11
F11	9.7	0.961
F12	13.5	1.32



Comparison of mucoadhesive strength of different Mucoadhesive buccal tablets of Nifedipine

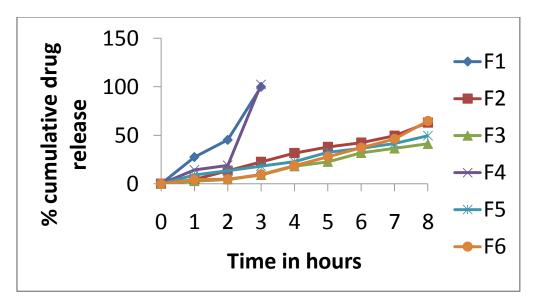
X) IN-VITRO DRUG RELEASE PROFILE9

In vitro drug release studies revealed that the release of Nifedipine from different formulations varied according to the type and ratios of the matrix forming mucoadhesive polymers. The results of *in vitro* drug release of Nifedipine formulations tabulated in table and figures.

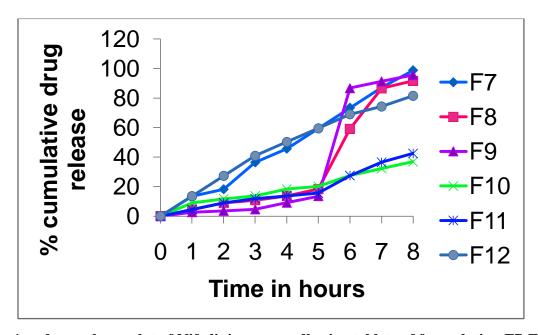
Among these 12 formulations F7 was found to be highest percentage drug release,98.8% at the end of 8 hr. Thus the dissolution study revealed that the formulation F7 showed good controlled release of drug for 8 hr.

In vitro drug release data of Nifedipine mucoadhesive buccal tablets

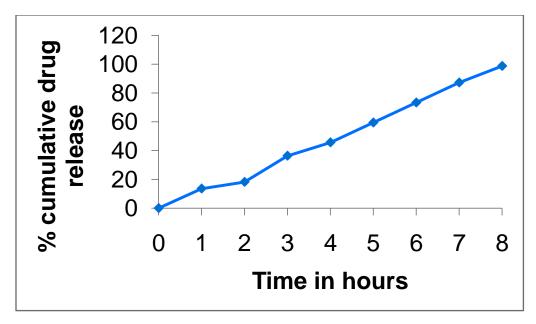
TP\$	Percentage cumulative drug release											
Time	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1hr	27.5	4.5	2.7	14.3	9.07	4.52	13.62	4.53	2.72	9.07	4.5	13.6
2hr	45.2	13.5	4.5	18.9	13.65	4.55	18.22	9.08	3.64	11.84	9.08	27.2
3hr	100	22.5	9.04	103.5	18.2	9.5	36.4	10.9	4.57	13.7	11.8	40.9
4hr		31.6	18		22.8	18.6	45.67	13.7	9.12	18.31	13.7	50.2
5hr		37.9	22.6		32.05	27.8	59.5	18.3	13.6	20.2	15.6	59.5
6hr		42.4	31.8		36.75	37	73.4	59.1	86.1	27.5	27.4	68.9
7hr		49.6	36.4		41.4	46.2	87.3	86.6	91.3	32.2	36.6	74.3
8hr		63	41.1		49.5	64.6	98.8	91.6	95.6	36.9	42.5	81.5



in vitro drug release plot of Nifedipine mucoadhesive buccal tablets of formulation F1- F6.



in vitro drug release plot of Nifedipine mucoadhesive tablets of formulation F7-F12



in vitro drug release plot of optimized formulation ,F7

XI) KINETIC DATA ANALYSIS¹⁰

The result obtained from *in vitro* release studies were plotted in different kinetic models. Regression coefficient (R²) values of different kinetic models are shown in figure. Kinetic data analysis is given in table. The correlation coefficient (R²) value of each formulation for zero order kinetics, first order kinetics, Higuchi, Hixoncrowel and value of release exponent from KorsmeyerPeppas shown in table. The criterion for selecting the most appropriate model was on the basis of goodness of best fit.

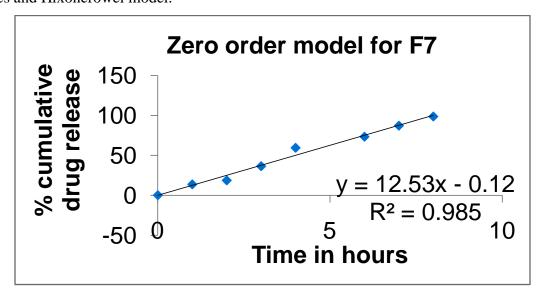
Kinetics data analysis of mucoadhesive buccal tablet formulation F7

Time	Log Time	Square root of time ,√T	% CDR	Log % CDR	Cumulative % drug remaining	Log cumulative % drug remaining	Cube root of cumulative % drug remaining
0	0	0	0	100	2	0	33.3
1	0	1	13.6	86.4	1.93	1.13	28.8
2	0.301	1.41	18.2	81.8	1.91	1.26	27.6
3	0.477	1.73	36.4	63.6	1.80	1.56	21.2
4	0.602	2	45.67	54.33	1.73	1.65	18.11
5	0.698	2.23	59.5	40.5	1.60	1.77	13.5
6	0.778	2.44	73.4	26.6	1.42	1.86	8.86
7	0.895	2.64	87.3	12.7	1.10	1.94	4.23
8	0.903	2.82	98.8	1.2	0.079	1.99	0.4

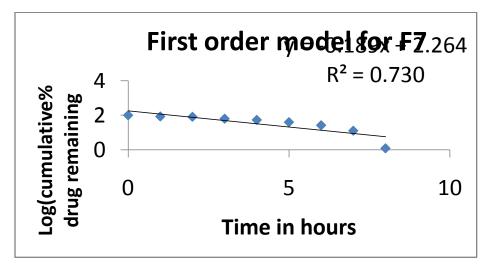
Correlation coefficient values and exponent value of formulation F7

	R ² Value			n value
Zero order	First order	Higuchi	Hixoncrowel	Korsmeyer peppas
0.9853	0.7305	0.8899	0.9935	1.554

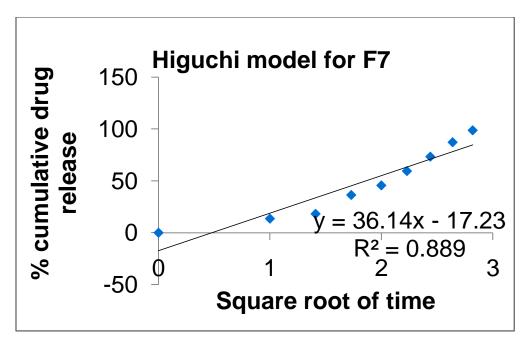
The release kinetics indicates that the release of drug from F7 best fit to zero order release kinetics and Hixoncrowel model.



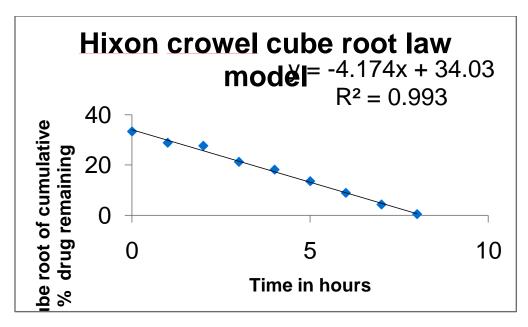
Zero order model for F7



First order model for F7

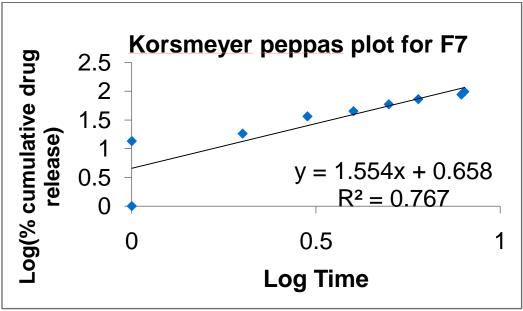


Higuchi model for F7



Hixoncrowel cube root model for F7





Korsmeyerpeppas plot for F7

The value of diffusion exponent, (n) for F8 was found to be 1.554. The 'n' value of the formulation was found to be more than 0.89 indicating that the drug release followed Super case II transport type of release mechanism due to the erosion of the polymer.

XII) STABILITY STUDY

The stability of this optimized formulation was known by performing stability studies for three months at accelerated conditions of 40^0 C± 2^0 C / 75 %±5%RH on optimized formulation. The formulation was found to be stable, with no significant change in the weight variation, thickness, friability, hardness, swelling index, surface pH, mucoadhesive strength, drug content and in vitro drug release pattern.

Evaluation parameters after stability study of formulation F7

PARAMETERS	ZERO DAYS	INITIAL MONTH	THIRD MONTH	
Thickness (mm)	3.9	3.9	3.9	
Hardness (Kg/cm ²)	6	6	6	
Friability (%)	0.301	0.301	0.301	
Weight variation (mg)	200.1	200	200	

Drug content (%)	100.8	100.8	100.8
Swelling index (%) in 5 th hour	1000	1000	1000
Surface pH	6.5	6.5	6.5
Mucoadhesive strength (mg)	15.7	15.5	15.6
In vitro drug release (%)	98	98.9	98.8

CONCLUSION

In this work an attempt was made to formulate and evaluate Nifedipine mucoadhesive buccal tablets. The main objective of formulating mucoadhesive buccal tablets of Nifedipine was to enhance bioavailability of drug, avoid first pass metabolism, to prolong the drug release and to improve patient compliance.

Before the formulations were made, the preformulation parameters like solubility study, determination of melting point were evaluated. The compatibility of drug with the polymers was determined by performing FTIR studies. 12 formulations were prepared using Carbopol 940 as primary polymer and different secondary polymers.

Precompression parameters such as angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio, were evaluated and results showed that granules have good flow property and good packing ability. The Precompression parameters of all formulations were within the required limit that was suitable for the formulation of the tablet.

From the evaluation parameters such as , swelling index, *ex vivo* mucoadhesive strength, *in vitro* release study, it was concluded that F7 showed the best overall performance and acceptability. Using the best formulation F7 kinetic study was done and best fits to zero order kinetics. And the stability study of F7 in 3 month shows good stability.

From the results of all the above mentioned studies, it was concluded that formulation F7 fullfilled all the requirements needed for a mucoadhesive buccal delivery of Nifedipine.

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